

CURRICULUM VITAE

Name Samir N. Khleif, M.D.

Citizenship: USA

Education:

1986 M.B., B.S., University of Jordan, School of Medicine, Amman, Jordan

Training:

1990 - 1994 Fellow in Medical Oncology, National Cancer Institute (NCI), Bethesda, Maryland

1988 - 1990 Resident in Internal Medicine, Medical College of Ohio, Toledo, Ohio

1987 - 1988 Intern in Internal Medicine, St. Luke's Hospital, Case Western Reserve University, Cleveland, Ohio

1986 - 1987 Post-doctoral Research Fellow, Hematology-Oncology Section, Michigan State University, E. Lansing, Michigan

General Statement on Leadership:

Dr. Khleif has developed diverse and vast experience in academic, health-care, and research administration and leadership. He has a proven record in visionary transformational leadership, and in leading the development of clinical and basic research, strategic and programmatic national and institutional programs. His experience includes leading the development of national strategies and strategic programs and complex trans- and inter-disciplinary educational, academic, research, and clinical health care systems at institutions in the US and internationally. He assembled and lead highly talented teams designed with the purpose to meet specific institutional and national strategies. He also has significant experience in leading institutional transformations to meet new goals and higher performance levels, directing institutional fundraising, and engaging local and state-wide alumni and community stakeholders. Throughout his career, he led the development of highly impactful research and clinical institutions and programs including:

A pioneering Cancer Vaccine Program at NCI/NIH; the King Hussein Cancer Center, Amman Jordan; The Critical Path for Oncology, FDA; The King Hussein Cancer and Biotechnology Institute; The Kingdom of Jordan Cancer Control Plan; The Georgia Cancer Center, Augusta University. Currently, Dr. Khleif started a new leadership position in leading a global cancer care and research project of developing more than 40 cancer centers in the developing world.

He is also a recognized national pioneer and leader in basic and translational science in immune-oncology and immunotherapy with more than 25 years of experience.

Research Interest and Expertise:

Dr. Khleif's is a pioneer and a leading researcher and Key Opinion Leader in the field of immunotherapy.

He has a long track record and vast experience in both clinical and basic research in immuno-oncology has made him a leader in this field for more than 20 years. During his tenure at the National Cancer Institute, he established one of the first immune therapy and cancer vaccine program in the field, under which he pioneered the clinical trials of neoantigens-directed cancer vaccines, particularly targeting antigenic oncoproteins such as mutant ras, p53, VHL and HPV, utilizing single or in immune combinatorial approaches. These clinical trials included some of the seminal early-phase peptide vaccine dose-escalation trials, which in turn, provided the FDA with enough base data to recommend the elimination of peptide vaccine dose escalation in early phase clinical trials. Furthermore, this program initiated some of the earliest trials in immunotherapy; utilizing checkpoint inhibitors and introducing the concept of combination immunotherapy that are currently being used in cancer immune therapy trials to-date. During his tenure as the Director of the Georgia Cancer Center of Augusta University, he has established a comprehensive Immuno-Oncology Program which connects basic research discovery to clinical trials with highly integrated translational elements, all of which have led to the development of many innovative first-in-human clinical trials. Currently, he was recruited to Georgetown University to lead the development of a new innovative and high impact immune-oncology laboratory to continue his scientific contribution and translate many of his discoveries into high-impact clinical trials

The group's research program focuses on understanding the molecular mechanisms of interaction between the tumor and the immune system. Specifically, defining the mechanisms of cancer-induced immune suppression and utilizing this knowledge for the development of novel **immune therapeutics** against cancer. Currently, Dr. Khleif's group research is focused on the following areas of interests: 1) Understanding the mechanism of immunotherapy failure and developing strategies to overcome resistance; 2) understanding the mechanism of small molecules in modulating T-cell and the immune microenvironment and utilizing targeted small molecules in combination immune therapy; 3) Developing rational approaches to immunotherapy combination and understanding the mechanism of failure of such combinations; and 4) innovative strategies to target immune suppressive mechanisms of the T regulatory cells.

Dr. Khleif has designed and served as a Principal Investigator of more than 30 immuno-oncology clinical trials testing novel I-O as single agents or in combination approaches (e.g. vaccines, CPI or IDO inhibitors). He has led the development of these trials from conception through approval by NCI and FDA. Furthermore, he trained in his group more than 50 students, fellows and post doctorate trainees.

Regulatory experience, Dr. Khleif has served as a Special Assistant to the FDA Commissioner for more than 3 years and developed many INDs and driven many protocol through the FDA regulatory approval process

Currently serves in the following capacity:

- a. Elected Board Member of the Society of Immune Therapy of Cancer
- b. Chair of the US national NRG cooperative Group Immune Therapy Committee
- c. Chair of the NCI Immunotherapy-Radiation Oncology Working Group
- d. Member of the Immunotherapy Biomarker Steering Committee
- e. Chair of the Institute of Medicine, National Cancer Policy Forum Immune Therapy Workshop
- f. Member of corporate boards and Scientific Advisory Boards of many Immunology pharmaceutical and bio Pharma Companies
- g. Chair and invited speaker of many national and international scientific conferences in immune-oncology

Finally, Dr. Khleif is a highly-funded investigator. He was able to obtain more than \$9.0 millions of direct funding for his own basic research and more than \$8.0 millions of total contractual value for clinical research and has an approved funding of \$6.0 million awaiting execution in the next 3-6 months

Brief Chronology of Employment and Professional Positions:

2017 – present Director, The Loop Immuno-Oncology Research Laboratory,
Lombardi Cancer Center, Georgetown University, Washington DC

2017 – present CEO, Evercare Global Cancer Centers
Director, Global Cancer Research and Impact Institute

Responsibilities: *Leads and oversees the buildup of a full organization that would be responsible on the development operation of western-style 40 cancer centers for the world's underserved population (family income \$5-10/day). These cancer centers will be developed in India, Pakistan and countries in sub-Saharan Africa with the intention of 1) providing services to population with no or suboptimal access to cancer care, 2) conduct population research to understand the biology and therapeutic intervention of the population's cancers, and 3) conduct outreach program to decrease the incidence and the staging of cancer. The fund supporting the project is collaborative amongst many large institutions including The Gates Foundations, International Monetary Fund, The World Bank, Medtronic, Philips, Merck, Novartis and others*

2017 **Research Sabbatical year to lead the development of two projects:**

1. Lead the development of the strategy and implementation plan for a global program to develop cancer services, research and centers for low and low middle income countries. The project

funded by the *Gates Foundations, International Monetary Fund, The World Bank, Medtronic, Philips, Merck, Novartis and others*

2. launch a spinout biotechnology startups company out of intellectual property developed by our laboratory. The company licensed 12 patents and provisional patent applications. The company contain two platforms a. T-regulatory cell regulation with medications that enhance and suppress Tregs for autoimmune disease and cancer, respectively. The second technology is based on the development of antibody for a novel T cell epitope that we discovered in the lab.

Georgiamune, LLC, Delaware, RI

2012 –2016

**Director, Georgia Cancer Center
Director, Immuno-Oncology & Immune Therapeutic Program
Augusta University, Augusta, GA**

Responsibilities: for 5 years *led the development and transformation of the Georgia Cancer Center at Augusta University (Medical College of Georgia), the only State/public Cancer Center in Georgia; established and managed the development of the Cancer Service Line in a novel model within the health care system that integrates cancer clinical services across the different cancer disciplines into a cohesive integrated across-discipline system. Oversaw the growth and development of existing and new clinical, translational, and basic science research programs. Oversaw and supervised all basic and clinical cancer faculty members. Direct report to the President of the University.*

Institutional Service:

Member, President's Cabinet

Member, Provost Cabinet

Chairman, Cancer Center Executive Committee

Chairman, Cancer Center Clinical Council

Chairman, Cancer Center Clinical Leadership Committee

Member, the Medical College of Georgia Executive Committee

Member, AU Health Quality and Safety Steering Committee

Accomplishments:

Research and Education:

- *Established the administrative and financial structures of the **Cancer Center**. This included all CC offices needed for the building process towards NCI designation requirements*
- *Restructured and established an integrated clinical trials operation and process in accordance with CCSG NCI guidelines, including PRMC and processes and a Cancer IRB. Increased and transformed clinical trial types from less than 1% PI-initiated into 33%. This led to the conduct of many first-in-the-nation first-in-human PI initiated clinical trials*
- *Developed an 8-year strategic plan for NCI designation and organized needed core facilities—currently exceeded the milestones and EAB believe that application can be put in in 2 years. Initiated the process for the CCSG application.*
- *Established four scientific programs, including Molecular Oncology, Cancer Immunology Inflation and Tolerance, Molecular Signaling, and Cancer Vascular Biology, Developmental Therapeutic, and Population Science Programs.*
- *Supervised, with direct reporting, Cancer Center basic and translational science and clinical faculty.*
- *Recruited 37 new clinical faculty and funded investigators, in addition to 12 senior office directors.*
- ***increase total cancer funding by 73% and NCI funding by 40% over the past 3 years***
- ***increase the Cancer Center's share of the total university research funding from 10% to 38%***
- ***established more than 25 collaborative agreements with pharmaceutical and biotechnology companies encompassing both preclinical and clinical research***
- ***lead the development of new underserved/minority- based community program network cCARE***
- ***lead the establishment of minority based clinical trial program leading to be awarded one of 11 Minority Based NCI Community Oncology Based Program (MB-NCORP)***
- *Established a combined Biochemistry and Cancer Biology PhD program in collaboration with, and administered by, both the Cancer Center and the Department of Biochemistry*
- *Developed integrated community outreach and education programs with emphasis on disparity cancer health care. Developed a statewide network of cancer services, clinical trials, and public education resources, and created an efficient and economic process that will lead to doubling clinical revenues and tripling research direct funding in five years.*

- *Led a clinical and research team to oversee the design of a new 70k sq ft translational cancer center facility*

Clinical Services:

- *Established a fully integrated **Cancer Service Line** by transforming cancer care within the AU Health System from a silo-based care into a fully structured Service Line, where all cancer care faculty reside functionally in multi-disciplinary teams.*
- *Established, implemented, and oversaw the operational, quality management, administrative, and financial structures of the cancer service line.*
- *Supervised, with direct reporting, all cancer faculty including medical, surgical, radiation, pediatrics, gynecologic, head and neck, urologic, and orthopedic oncology.*
- *Established new cancer support services and integrated them within the multi-disciplinary service line teams.*
- ***Increased patient referrals 27% over 3 years, chemotherapy charges by 120%, radiation oncology charges by 200% and surgical Oncology by 100%***

2004 – 2012 **Chief, Cancer Vaccine Section, National Cancer Institute, National Institutes of Health, Bethesda, Maryland**

2007 – 2009 **Director General / Chief Executive Officer, and Member of the Board of Trustees and the Executive Board, King Hussein Cancer and Biotechnology Institute (KHIBC), Amman, Jordan**

Appointed by the Secretary of the Department of Health and Human Services (DHHS) through an agreement between the US DHHS and the Kingdom of Jordan.

The Institute is a 1.2 million sq ft, 260 bed cancer center, and biotechnology and life science research facility that is intended to function as a regional cancer center for the Middle East and a nucleus for research-of-excellence in biomedical sciences.

Responsibilities: *Planned, developed, and managed the full project budget.*

Led the process for the overall strategic and operational development of the institute that included:

Oversaw the development of the design of the 1.2 million sq ft facility-including a 260 bed inpatient hospital, a comprehensive outpatients facility, a research building and an educational and conference center; led the development and implementation of the strategic, organizational, operational, financial and human resource plans; developing administrative, clinical and research operation organizational structure; hired the leadership team

including the directors of the operational and clinical planning departments; led the negotiations and establishing strategic partnerships and alliances with multiple multi-national pharmaceutical and biotechnology industries and partnership agreements with international academic institutions; overseeing the development and implementation of institutional bylaws, rules and regulations, and operational policies, procedures and guidelines; developing; and overseeing the development and implementation of marketing, public relation and fund raising plans including presentations to major donors.

Led the development of the National Cancer Control Plan for the country of Jordan, in collaboration with the World Health Organization (WHO). The plan was adopted by the WHO as a prototype to be implemented for countries in the Middle East.

Led the development of a national biotechnology strategy for Jordan including market gap analysis for pharmaceutical and biotechnology investments in the Middle East.

2006 – 2009 **Special Assistant to the FDA Commissioner, Food and Drug Administration, Maryland**

Led the FDA oncology efforts for the Critical Path Initiative. This is a national effort to restructure the drug discovery and development system into a more efficient, innovative, and less expensive system by setting a process that facilitates: developing more efficient alternative clinical trial design, enhancing the ability of sponsors and developers in improving biomarker development, and integrating biomarkers into clinical design and the drug discovery process. This effort resulted in the launching of a major national initiative involving more than 200 government, academia, and industry experts and advocacy groups.

Led and co-chair national initiatives including the American Association of Cancer Research-FDA-NCI Cancer Biomarkers Collaborative, the American Society of Clinical Oncology-FDA Alternative Clinical Trials Design Task Force, and The International Society of Biologic Therapy of Cancer-FDA Immunotherapy Biomarkers Task Force.

2002 – 2006 **Director General / Chief Executive Officer, King Hussein Cancer Center (KHCC), Amman, Jordan**

Appointed by the NCI through an agreement between NIH/NCI and the Kingdom of Jordan. An NIH/NCI initiative to reform and restructure the failing 160-bed free-standing cancer center.

Positions held:

Chief Executive Officer/Director General

Chairman, Executive Committee

Chairman, Medical Board
Chairman, Quality Management Council
Chairman, Accreditation Steering Committee

Planned and led a turn-around comprehensive strategy in administrative, financial and programmatic restructuring for the cancer center; successfully recruited more than 250 physicians and health care professional leaders (many US trained and American Board holders); directed the expansion of clinical services and accomplished a 350 % growth by developing more than 16 multidisciplinary services/clinics and programs of excellence, developing and implementing aggressive community outreach and marketing programs, expanding the referral base to a reaching market of 7 other countries in the Middle East; managed the operating budget of the center leading to an enhanced performance of 16% profit margin.

The efforts led to the development of the only comprehensive cancer center in the Middle East; including the first multi-disciplinary care, national bone marrow transplant and psycho-oncology programs. Developed the 6 accredited fellowship and residency programs in oncology disciplines; an overarching quality management program; and presided over the KHCC becoming the first institution in the Middle East to obtain Joint Commission Accreditation (JCIA) Built the first hospice and palliative care program in Jordan; this program became the leading model for the Jordanian National Committee for Hospice and Palliative Care.

The model in health care transformation of KHCC was written by the Duke Business School as a case study entitled "Transformational leadership, transnational culture and political competence in globalizing health care services: a case study of Jordan's King Hussein Cancer Center" published in Globalization and Health in November, 2007.

- 2001 – 2012 **Principal Investigator, National Cancer Institute, National Institutes of Health, Bethesda, Maryland**
- 1994 - 2012 **Oncology Consultant, National Naval Hospital, Bethesda, Maryland**
- 1994 – 2012 **Senior Staff Fellow, National Institutes of Health Clinical Center, Bethesda, Maryland**

Academic Positions:

2017 – present	Biomedical Scholar and Professor, Lombardi Cancer Center, Georgetown University Medical School, Georgetown University, Washington D.C.
2012 – present	Professor of Medicine, Medical College of Georgia, Georgia Regents University, Augusta, Georgia
2012 – 2017	Professor of Biochemistry and Molecular Biology, Medical College of Georgia, Georgia Regents University, Augusta, Georgia
2012 – 2017	Professor of Graduate Studies, Georgia Regents University, Augusta, Georgia
2008 – 2012	Professor, Department of Medicine, The Uniformed Services University of the Health Sciences, Bethesda, Maryland
2001 – 2008	Associate Professor, Department of Medicine, The Uniformed Services University of the Health Sciences, Bethesda, Maryland
1997 – 2001	Assistant Professor, Department of Medicine, The Uniformed Services University of the Health Sciences, Bethesda, Maryland
1995 – 1997	Instructor of Medicine, Department of Medicine, The Uniformed Services University of the Health Sciences, Bethesda, Maryland

Uniformed Services:

1996 - 2001 Lieutenant Commander, Public Health Service, US Department of Health and Human Services. Separated from the Commission Corps in 2001

Board Certification:

Diplomat, Internal Medicine, American Board of Internal Medicine 1991
Diplomat, Medical Oncology, American Board of Internal Medicine 1997

Honors and Other Special Scientific Recognition:

College of Medicine Distinguished Alumnus Award, University of Toledo, 2017
Elected, Member of the National Board for the Society of Immunotherapy of Cancer 2015
Augusta Economic Development Authority, Proclamation of Excellence, Augusta, GA, 2015 *“In recognition of his and the Cancer Center’s contributions in the areas of education, outreach, economic impact and the fostering of private, industry and legislative partnerships in the Greater Augusta area and throughout the region”*.
Medical Trailblazer Award Augusta City Classic, Augusta, Georgia, 2014
Member, National Cancer Policy Forum, Institute of Medicine, National Academies of Sciences, Washington DC, 2014
The Naji Sahyoun Lecture in Basic Science of Excellence, American University of Beirut, Beirut Lebanon, 2014
Georgia Research Alliance Distinguished Scientist and Clinician, 2012 - 2016
Federal Technology Transfer Award, 2012
Federal Technology Transfer Award, 2011
Dietary Supplement Research Award, Office of Dietary Supplements, NIH, 2010
Federal Technology Transfer Award, 2010

Federal Technology Transfer Award, 2009
Elected Member, American Society for Clinical Investigation (ASCI), inducted 2009
Distinguished Oncologist Leadership Award and Lecture, Arab American Medical Association against Cancer, 2009,
Recognizes one individual once every two years who made a major contribution to cancer care in the Arab World
The National Institutes of Health Award for Merit, 2008, *Recognizes individuals whose achievements warrant special recognition*
Lifetime Achievement Award, Jordan Medical Association/General Union of Physician in the Arab World 50th Anniversary Celebration. Amman, Jordan, April 2008
Honoring the 10 physicians who contributed the most for advancing the health care system in Jordan.
The National Institutes of Health, Clinical Center Bench to Bedside Award 2007.
The Jordan Medical Association Honorary Accomplishment Award, Amman, Jordan, April 2006
Awarded for providing exemplary leadership in building a regional cancer center of excellence for Jordan
The Jordan Minister of Health Honorary Award, Amman Jordan, March 2006.
NCI Directors' Gold Star Award, National Cancer Institute, February 2004
Outstanding Unit Citation, US Public Health Service, June, 1999, presented for "*superior and exceptional service toward achieving the goals and objectives of the U.S. Public Health Service on national or international levels*",
Career Development Award, American Society of Clinical Oncology, 1995-1998
NCI Representative, NIH Fellows Committee of the NIH Clinical Board, 1992-1994
Alpha Omega Alpha, inducted 1990
Department of Medicine Meritorious Service Award, Medical College of Ohio, Toledo, Ohio, 1990

Patents and Patent Applications:

1. **Khleif S, Qian J**, inventor; DHHS, assignee.
IMMUNOGENIC PEPTIDES FROM HUMAN PAPILLOMAVIRUS TYPE 16E2
US Patent: 7,691,579. Issued April 6, 2010 [Patent]
European Patent EP1877087
Australian Patent: 2006236905 issued September 16, 2010
Canada Patent Application 2604909
Licensed to: PDS Biotechnology Corporation
2. **Khleif S, Berzofsky J**, inventor; DHHS, assignee.
HUMAN PAPILLOMA VIRUS IMMUNOREACTIVE PEPTIDES.
US Patent: 7,507,538. Issued 24 Mar 2009 [Patent]
Australian patent 2002258614, Issued March 22, 2002
European Patent EP1425039
Canada Patent Application 2441947
Licensed to: PDS Biotechnology Corporation

3. **Khleif S**, Berzofsky J, inventor; DHHS, assignee.
HUMAN PAPILOMA VIRUS IMMUNOGENIC PEPTIDES.
AU-GRU 2015-015; US Patent: 7,189,513. Issued 13 Mar 2007 [Patent]
11/685,632
Licensed to: PDS Biotechnology Corporation
4. Qian, Jiahua, Berzofsky, Jay A., **Khleif, Samir, inventor.**
METHODS AND COMPOSITIONS FOR PRODUCING AN ENHANCED
IMMUNE RESPONSE TO A HUMAN PAPILOMAVIRUS
IMMUNOGEN.
UA-GRU 2015-016; US Patent 7,691,579 issued April 6, 2010 11/918,557
US Patent Application 20090068214, filed March 12 2009
5. **Khleif S**, Berzofsky J, inventor; DHHS, assignee.
METHODS AND COMPOSITION FOR CO-STIMULATION OF
IMMUNOLOGICAL RESPONSES TO PEPTIDE ANTIGENS.
US Patent Application No. 09/810,310,
European Patent EP1877087
6. **Khleif SN** and Dong Y. inventor; DHHS, assignee
IDENTIFICATION OF H2-DB AND HLA-A2 SPECIFIC CD8 EPITOPES
FROM HUMAN KDR/VEGFR-2 THAT INHIBIT ANGIOGENESIS BY
VACCINATION.
US Patent 8,378,071 issued 11 Feb, 2013
US, Application No. 60/671,867 filed 15 Apr 2005
US, Application No. 12/402,401 filed 11 Mar 2009
7. **Khleif S**, Mkrtychyan M, Inventors, AU/GRU, assignee
METHODS OF MODULATING IMMUNE RESPONSES BY MODIFYING
AKT3 BIOACTIVITY
AU/GRU 2014-020; 14/689,517; U.S.S.N. 61/980,795 Non-Provisional
Application
8. **Khleif S**, Mkrtychyan M, Inventors, AU/GRU, assignee
METHODS FOR SELECTING TREATMENT FOR CANCER
GRU 2014-019; 14/689,314; U.S.S.N. 61/980,790 Non-Provisional
Application
9. **Khleif S**, Ahmad S, Mkrtychyan M, Inventors, AU/GRU, assignee
COMPOSITIONS AND METHODS FOR SELECTIVELY MODULATING
TREGS
GRU 2014-030; 14/832,915, U.S.S.N. 61/ Non-Provisional Application
10. **Khleif S**, Abu Eid R, Mkrtychyan M, AU/GRU, assignee
COMPOSITIONS AND METHODS FOR IMMUNE THERAPY
GRU2015-004; PCT/US2015/068061 [PCT]

11. **Khleif, S**, Inventor, GRU
METHODS FOR ENHANCING THE EFFICACY OF A TUMOR-DIRECTED IMMUNE RESPONSE
U.S.S.N. 61/974,781 Provisional Application
EFS ID: 18667167
US Filing Date: April 3, 2014
12. Mkrtychyan M, **Khleif SN**, Johnson K, Jacobson E, Bedu-Addo F- Inventors
CATIONIC LIPID VACCINE COMPOSITIONS AND METHODS OF USE
US Patent Application 61/660,172 Filed 15 June 2012
13. **Khleif SN**, Berzofsky JA, Chen Z, Petit R- Inventors
METHODS AND COMPOSITIONS FOR INCREASING A T-CELL EFFECTOR CELL TO REGULATORY T CELL RATIO
US Patent Application 61/948,453
US filing Date Mar 5, 2014
14. **Khleif SN**- Inventor
METHODS FOR ENHANCING THE EFFICACY OF TUMOR-DIRECTED IMMUNE RESPONSE
US Patent Application 61/974,781 [Provisional]
US filing Date April, 2015
15. **Khleif S**, Mkrtychyan M, Inventors, GRU, assignee
METHOD OF ENHANCING THE ANTI-TUMOR EFFICACY OF LISTERIA-BASED IMMUNE THERAPY BY COMBINING IT WITH OX40 AGONIST
AU-GRU 2015-032; US Patent Application PCT/US2013/531954
US filing Date Apr 14, 2015
16. **Khleif S**, Mkrtychyan M, Inventors, GRU, assignee
Combination of Listeria-based vaccine with Anti-OX40 or Anti-GITR Antibodies
AU-GRU2015-032; US Patent Application 62/147,463
US filing Date
17. Gazdar A, Johnson B, Kaye F, **Khleif SN**, Mina J, Oie H, Pass H (submitted: 2007) Establishment Of Cell Lines From Human Tumors. E-112-2007/0-EIR-00
License awarded to:
Abbott Laboratory, INC; AstraZeneca Pharmaceuticals L.P; Charles River Laboratories; Eli Lilly and Company; Genzyme Corporation; BioNumerik Pharmaceuticals; Janssen Pharmaceutica, N.V.; Kao Corporation; Nichirei Bioscience, INC; Pfizer, INC; Sanofi-Avantis R&D; Ventana Medical

System, INC. Genomics Institute; Cell Genesys, Inc; ARIAD Pharmaceuticals; Amgen, Inc.; Genentech Inc.; Novartis

18. **Khleif, SN; Mkrtychyan, M**
SPECIFIC AKT ISOFORM INHIBITOR AND USES THEREOF
AU-GRU 2016-016; US Patent Application 62/279,248 [Provisional]
US filing Date Jan 15, 2016
19. **Khleif, SN; Mkrtychyan, M; Iryna, N**
METHODS AND COMPOSITIONS FOR INHIBITING AKT ISOFORM
AU-GRU 2016-017; US Patent Application 62/279,150 [Provisional]
US filing Date Jan 15, 2016
20. **Khleif, SN; Mkrtychyan, M**
METHODS AND COMPOSITIONS FOR ENHANCING T-CELL
AU-GRU 2016-018; US Patent Application 62/290,227 [Provisional]
US filing Date Feb 2, 2016
21. **Khleif, SN; Mkrtychyan, M; Iryna, N**
COMPOSITIONS FOR MODULATING PD-1 SIGNAL TRANSDUCTION
AU-GRU 2017-010; Application No. 62/429,126 [Provisional]. Filed
22. **Khleif, SN; Verma, V**
INDUCED STEM MEMORY T CELLS AND METHODS OF USE
THEREOF
AU-GRU 2017-075; Application No. 62577819 [Provisional]. Filed

Grants and Awards Active:

- | | |
|---|---|
| 1. Sponsored Clinical Research Agreement
(PI: Khleif) <u>PI-Initiated Clinical Trials</u>
AstraZeneca | 07/29/2018 – 03/02/2022

\$496,031.00 |
| <i>A Phase II Study of the Combination of Trastuzumab and MEDI4736 Monoclonal Antibody in Adults With HER-2 Positive Breast Cancer</i> | |
| 2. Sponsored Clinical Research Agreement
(PI: Khleif) <u>PI-Initiated Clinical Trials</u>
AstraZeneca | 07/29/2018 – 08/30/2022

\$1,448,000.00 |
| <i>“A Phase I/II Trial of Stereotactic Body Radiation Therapy (SBRT), MEDI4736 and Tremelimumab in Patients with Locally Advanced and Metastatic Pancreatic Cancer”</i> , | |
| 12. Sponsored Non-Clinical Research Agreement (Khleif, PI)
Syndax | 01/05/18 – 01/05/20
\$200K <u>Direct cost per annum</u> |
| Understanding the role of HDAC inhibitors in immunotherapy of cancer | |

13. Sponsored Non-Clinical Research Agreement (Khleif, PI) 01/05/18 – 01/05/20
I-O Biotech **\$200K Direct cost per annum**
Development of IDO based Vaccine in combination Immune Therapy and identification of
Immune Therapy Biomarkers

14. Sponsored Non-Clinical Research Agreement (Khleif, PI) 01/05/18 – 01/05/20
Bioline Therapeutics **\$200K Direct cost per annum**
Development TLR agonist immuothrapeutic approaches

16. Sponsored Non-Clinical Research Agreement (Khleif, PI) 01/05/18 – 01/05/20
Lycera **\$200K Direct cost per annum**
Understanding the role of RORgt in the therapeutic approaches to cancer and the
development of RORgt against in combinational approaches in immunethrapy of cancer

20. Sponsored Non-Clinical Research Agreement (PI: Khleif) 01/05/18 – 01/05/20
AstraZeneca UK **\$300K Direct cost per annum**
Combination of small molecule and immune therapy.

Sponsored Clinical Research Agreements (Completed)
Institutional Clinical Trials

1. Sponsored Clinical Research Agreement 1/02/14 – 11/30/16
(PI: Khleif)
EMR 100070-001 (EMDSER00007)
Merck Serono **\$891,688**
A Phase 1, Open-Label, Multiple-Ascending Dose Trial to Investigate the Safety,
Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0010718C in
Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected
Indications
2. Sponsored Clinical Research Agreement 5/5/14 – 5/4/17
(PI: Khleif)
NLG-9191 (NEWLNK00008)
Newlink Genetics **\$765,294**
A Phase I Study of NLG-919 for Adult Patients with Recurrent Advanced Solid Tumors
3. Sponsored Clinical Research Agreement 8/8/12 – 6/15/17
(PI: Khleif)
11-C-0100CT-011 (CURET00001)
Cure Tech **\$57,925**
A Pilot Study to Test the Feasibility of the Combination of Gemcitabine and Anti-PD1
Monoclonal Antibody (CT-011) in the Treatment of Resected Pancreatic Cancer; A Pilot
Study to Test the Feasibility and Immunologic Impact of Sipuleucel-T (Provenge)
Administered with or without anti-PD-1 mAB (CT-011) and Low dose
Cyclophosphamide in Men with Advanced Castrate-resistant Prostate Cancer

4. Sponsored Clinical Research Agreement 8/22/12 – 8/21/17
 (PI: Khleif)
 MEDI4736-1108 (MEDIM00018)
 Medimmune **\$977,502**
 A Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of
 MED14736 in Subjects with Advanced Solid Tumors
5. Sponsored Clinical Research Agreement 12/18/13 – 12/31/16
 (PI: Khleif)
 D4880C00003 (MEDIM00021)
 Medimmune **\$412,852**
 A Phase 2, Randomized, Double-Blind Study Comparing Tremelimumab to Placebo
 Second- or Third-Line Treatment of Subjects with Unresectable Pleural or Peritoneal
 Malignant Mesothelioma
6. Sponsored Clinical Research Agreement 10/21/2014 – 10/20/2017
 (PI: Khleif)
 D4191C00011 (ASTRA 00029)
 Astrazeneca **\$481,957**
 A Phase IIa, Open-Label, Multi-Center, Multi-Cohort, Immune-Modulated Study of
 Selected Small Molecules (Gefitinib, AZD9291, or Selumetinib + Docetaxel) or a 1st
 Immune-Mediated Therapy (IMT; Tremelimumab) with a Sequential Switch to a 2nd IMT
 (MEDI4736) in Patients with Locally Advanced or Metastatic Non-Small-Cell Lung
 Cancer (Stage IIIB-IV)
7. Sponsored Clinical Research Agreement 09/23/2014 – 09/22/2017
 (PI: Khleif)
 C28001 (MILLP00003)
 Millennium **\$173,857**
 An Open-Label, Phase 1, Dose Escalation Study of MLN2480 in Patients With Relapsed
 or Refractory Solid Tumors Followed by a Dose Expansion Phase in Patients With
 Metastatic Melanoma
8. Sponsored Clinical Research Agreement 07/23/2014-02/03/2019
 (PI: Khleif)
 (ADVAX00004)
 Advaxis **\$551,250**
 Nurse Practitioner Services under Master Clinical Trial Agreement
9. Sponsored Clinical Research Agreement 05/01/2014 – 04/30/2017
 (PI: Khleif)
 NLG-2103 (NEWLINK00009)
 Newlink Genetics **\$112,443**
 A Phase 1 / 2 Study of the Concomitant Administration of Indoximod plus Ipilimumab for
 Adult Patients with Metastatic Melanoma
10. Sponsored Clinical Research Agreement 02/27/14 – 12/31/16
 (PI: Khleif)
 AGS-003 (AGS-003-007)
 Argos Therapeutics **\$169,004**

An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT)

11. Sponsored Clinical Research Agreement 04/21/2015-04/20/2018
(PI: Khleif)
D4193C00001 (ASTRA00031)
AstraZeneca Pharmaceuticals **\$703,851**
A Phase II, Multi-center, Single-Arm, Global Study of MEDI4736 Monotherapy in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN) (HAWK)
12. Sponsored Clinical Research Agreement 05/04/2015-05/03/2018
(PI: Khleif)
D4193C00003 (ASTRA00032)
AstraZeneca Pharmaceuticals **\$379,762**
A Phase II, Randomized, Open-label, Multi-center, Global Study of MEDI4736 Monotherapy, Tremelimumab monotherapy, and MEDI4736 in Combination with Tremelimumab in Patients with Recurrent Squamous Cell Carcinoma of the Head and Neck (SCCHN)
13. Sponsored Clinical Research Agreement 10/02/2015-10/01/2018
(PI: Khleif)
Protocol #0761-012 (KHKP00002)
Kyowa Hakko Kirin Pharma, Inc. **\$485,937**
Phase 1 Study of Mogamulizumab (KW-0761) in Combination with MEDI4736 and Mogamulizumab in Combination with Tremelimumab in Subjects with Advanced Solid Tumors

Non-Clinical Research Agreement (Completed):

1. Community Research Fund 12/20/14 – 12/20/17
BMS Foundation (Khleif, PI)
\$576,732 Direct cost per annum
Reducing the Burden of Lung Cancer in the Central Savannah River Area through the cancer-Community Awareness Research and Education (c-CARE) Program
2. 1 U24 CA 180921 (Crowley, PI) 9/25/2013 – 7/31/2018
left at Georgia Cancer Center
NIH/NCI
(Subcontract, institutional PI: Khleif) **\$66,400 Direct cost per annum**
Advanced Development of TIES - Enhancing Access to Tissue for Cancer Research
The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.
3. NCI-UG1CA189851 (Khleif, Co-PI.) 9/1/2014 – 8/31/2019
left at Georgia Cancer Center
NIH/NCI **\$654,813 Direct cost per annum**
NCORP Minority/Underserved Community Site: Georgia CaRes

The NCORP grant will be used to expand patient and provider access to, and enrollment/participation in, cancer prevention, control, imaging, treatment and screening/post-surveillance clinical trials and cancer care delivery research throughout Georgia, particularly for minority and underserved populations in urban and rural settings.

4. Distinguished Cancer Clinician Scientist Award (Khleif) 7/1/12 – 12/31/17
Georgia Cancer Coalition **\$123,580 Direct cost per annum**
5. Sponsored Clinical Research Agreement 07/10/2016 – 07/20/2019
(PI: Khleif) **PI-Initiated Clinical Trials**
Merck **\$997,641.00**
“A phase I trial of pembrolizumab (MK3475/Ketruda) and poly ICLC in patients with colon cancer”
6. Sponsored Clinical Research Agreement 07/26/2012 – 07/25/2017
(PI: Khleif) **PI-Initiated Clinical Trials**
11-C-0231 Provenge (DEND00001)
Dendreon **\$825,327**
“A Pilot Study to Test the Feasibility and Immunologic Impact of Sipuleucel-T (Provenge TM) Administered With or Without Anti-PD-mAb(CT-011)and Low Dose Cyclophosphamide in Men with Advanced Castrate-Resistant Prostate Cancer”
7. Sponsored Non-Clinical Research Agreement (Khleif, PI) 01/01/17 – 01/01/19
Genentech **\$200,000 Direct cost per annum**
Understanding the role of HDAC inhibitors in immunotherapy of cancer
8. Sponsored Non-Clinical Research Agreement (Khleif, PI) 01/01/17 – 01/01/19
Syndax **\$200K Direct cost per annum**
Understanding the role of HDAC inhibitors in immunotherapy of cancer
9. Sponsored Non-Clinical Research Agreement (Khleif, PI) 4/7/16 – 4/6/18
I-O Biotech **\$200K Direct cost per annum**
Development of IDO based Vaccine in combination Immune Therapy and identification of Immune Therapy Biomarkers
10. Sponsored Non-Clinical Research Agreement (Khleif, PI) 8/20/16 – 8/20/18
Bioline Therapeutics **\$200K Direct cost per annum**
Development TLR agonist immuothrapeutic approaches
11. Sponsored Non-Clinical Research Agreement (Khleif, PI) 5/7/16 – 5/6/18
Gilead **\$210K Direct cost per annum**
Development of IDO based Vaccine in combination Immune Therapy and identification of Immune Therapy Biomarkers
12. Sponsored Non-Clinical Research Agreement (Khleif, PI) 7/30/16 – 7/30/18
Lycera **\$200K Direct cost per annum**
Understanding the role of RORgt in the therapeutic approaches to cancer and the development of RORgt against in combinational approaches in immunethrapy of cancer

13. Sponsored Non-Clinical Research Agreement (Khleif, PI) 12/7/12 – 12/6/16
 MedImmune **\$200K Direct cost per annum**
 Development of Combination Immune Therapy and identification of Immune Therapy Biomarkers
14. Sponsored Non-Clinical Research Agreement (PI: Khleif) 3/5/12 – 2/28/17
 Advaxis **\$150K Direct cost per annum**
 Development of Listeria Based Vaccines, Understanding their Mechanism of Action and Enhancing their Effect with Immune Therapy Combinations
15. Sponsored Non-Clinical Research Agreement (PI: Khleif) 3/5/14 – 2/28/17
 Advaxis **\$150K Directper annum**
 Development of Listeria Based Vaccines Combination Strategies
16. Sponsored Non-Clinical Research Agreement (PI: Khleif) 1/14/15 – 1/13/17
 AstraZeneca UK **\$300K Direct cost per annum**
 Combination of small molecule and immune therapy.
17. Sponsored Non-Clinical Research Agreement (PI: Khleif) 09/14/2015-09/13/2017
 PDS Biotechnology **\$200K Direct cost per annum**
 Develop Novel and Effective Vaccines against Various Cancers Utilizing Combinations of Lipids Adjuvants, Cytokines and Cancer Antigens Using Versamune Immune Activating Nanoparticles
18. Sponsored Non-Clinical Research Agreement (PI: Khleif) 10/12/2015-08/31/2017
 Medivation, Inc. **\$252,500 Direct cost per annum**
 Medivation Pre-Clinical Research Collaboration for MDV9300P015
19. Sponsored Clinical Research Agreement 8/24/12 – 8/23/2015
 (PI: Khleif)
 POP6792 (SANOFIA00011)
 Sanofi-Aventis **\$239,704**
 Phase 1 Safety and Pharmacokinetic Study XRP6258 (Cabazitaxel) in Advanced Solid Tumor Patients with Varying Degree of Liver Impairment
20. Sponsored Non-Clinical Research Agreement (PI: Khleif) 2/6/14 – 12/31/15
 NewLink Genetics **\$150K Direct cost per annum**
 Development of IDO inhibitors as immunotherapeutic agents for cancer and defining their mechanism of action alone or in combination with other immune therapy.
21. Sponsored Clinical Research Agreement 10/22/12 – 10/21/15
 (PI: Khleif)
 MEDI-565CP216 (MEDIM00019)
 Medimmune **\$129,127**
 A Phase 1 Open-label Study to Evaluate the Safety, Tolerability, and Antitumor Activity of MEDI-565 in Adults with Gastrointestinal Adenocarcinomas

22. CureTech **\$80K per annum**
Development of Anti PD1 CT011 in Immunotherapy of Cancer And Defining Its Immune Mechanism in the Microenvironment Combination Immune Therapy and Identification of Immune Therapy Biomarkers 2012 – 2014
23. AmplImmune Inc, Rockville, Maryland, Active Cooperative Research and Development Agreement with Industry (CRADA), 2012-2014, **\$150K/y for 3 years**
24. CureTech, Yavne, Israel, Inactive Cooperative Research and Development Agreement with Industry (CRADA), 2010 – 2012, **\$125K/y for 3 years**
25. AmplImmune Inc, Rockville, Maryland, Inactive Cooperative Research and Development Agreement with Industry (CRADA), 2010 – 2012, **\$150K/y for 3 years**
26. Advaxis Inc, North Brunswick, NJ, Inactive Cooperative Research and Development Agreement with Industry (CRADA), 2010 – 2012, **\$150K/y for 3 years**
27. PDS Biotechnology Corp., Inactive Cooperative Research and Development Agreement with Industry (CRADA), Lawrenceburg, 2010 – 2013
28. Astra Zeneca, Inactive Cooperative Research and Development Agreement with Industry (CRADA), 2011 – 2012
29. Merck, MK2206 immune effect CRADA/CTEP 2011
30. Dietary Supplement Research Award, Office of Dietary Supplements, NIH, 2010

Pharmaceutical and BioPharma Boards and Advisory Boards Memberships:

KAHR Biopharmaceutical, Member, Scientific Advisory Board
Tessa Biotechnology, Member, Scientific Advisory Board
Advaxis Immunotherapeutics, Member, Corporate Board of Directors
Northwaest Bio, Member, Scientific Advisory Board
Merus B.V, Member, Scientific Advisory Board
CytomX, Member of Scientific Advisory Board
UbiVac LLC, Member, Scientific Advisory Board
Syndax Pharmaceuticals, Member, Scientific Advisory Board
PDS Biotechnology, Member, Scientific Advisory Board
Bullet Biotechnology Inc, Member, Scientific Advisory Board
NewLink Genetics, Member, Scientific Advisory Board
IO Biotechnology, Member, Scientific Advisory Board
CanImGuideTherapeutics AB, Member, Scientific Advisory Board
Bioline Therapeutics, Member, Scientific Advisory Board
Lycera Corporation, Member, Scientific Advisory Board

Janssen, Advisor

Kyowa Immuno-Oncology Adhoc Advisory Board
Pfizer Alliance/ESM Serrano Adhoc Advisory Board
Nektar Therapeutics, Member, Adhoc Scientific Advisory Board
Astrazeneca, Member, Adhoc Scientific Advisory Board
Jefferies Global Investment Banking Firm- Adhoc Advisor
Medivation, Adhoc Advisor
MedImmune, Member, Adhoc Scientific Advisory Board

Awards of Graduate Students

Mason Webb, PhD Award with distinction, 2016

Awards for Research Fellows

Award of Excellence in Research, GRU, 2015 (Zuzana Berrong, Graduate student)
Fellows Award for Research Excellence, 2012 (Dr. Stephanie Zdanov)
Dietary Supplement Research Award, Office of Dietary Supplements, NIH, 2010 (Dr. Estella Raulfs)
Fellows Award for Research Excellence, 2011 (Dr. Raed Samara)
American Society for Clinical Oncology Foundation Merit Award, American Society of Clinical Oncology, (Dr. Moujahed Achar), 2007
American Society for Clinical Oncology Merit Travel Award, American Society of Clinical Oncology, (Dr. Robert Behrens), 2003
American Society for Clinical Oncology Merit Travel Award, American Society of Clinical Oncology, (Dr. Robert Behrens), 2002
Senior Fellowship Training Award Selection Committee for the National Cancer Institute, NIH (Dr. Malgerzata Wojtowicz), 2001
American Association for Cancer Research/ American Society for Clinical Oncology Workshop: Methods in Clinical Cancer Research, Vail, Colorado, (Competitive, Dr. Malgerzata Wojtowicz), 2000
American Society for Clinical Oncology Merit Travel Award. American Society of Clinical Oncology, (Dr. Malgerzata Wojtowicz), 2000
Fellows' Travel Award for the Tenth Annual Mayo Clinic Jacksonville Hematology/Oncology Reviews. Amelia Island Plantation, Florida, (Competitive, Dr. Malgerzata Wojtowicz), 2000

International Health Policy and Health Institutional Development Reports:

Restructuring the Qatari Biomedical Research Institution SIDRA, SIDRA Scientific Advisory Council, 2017

Restructuring the National Institute of Health Malaysia, US NIH mission to develop a plan for restructuring national research in Malaysia, 2015

National Biotechnology Strategy for the Kingdom of Jordan, 2009

Cancer Control Plan for the Kingdom of Jordan, 2009

National Higher Education and Innovation 10-Year Plan, The National Agenda for the Kingdom of Jordan, 2007

National Health Care 10-Year Plan, The National Agenda for the Kingdom of Jordan, 2007

Restructuring the Academic and Development Relationship of the Saint Jude Cancer Center of Lebanon and the American University of Beirut. A project commissioned by Saint Jude Children Research Hospital in Memphis TN

National and International Professional Committees Membership

2018	Co-Chair, National Cancer Policy Forum, National Academy of Medicine, Combination Immunotherapy Working Group
2017- present	Member, Biden Cancer Initiative Advisory Board
2017	Member, Data Standardization and Data Sharing Working Group, The Biden Cancer Initiative
2017	Member, French NCI (INCA) Committee for the review and designation of national French cancer center SIRIC, Paris, France, November 2017
2017	Member, Scientific Advisory Council, Sidra Medical Research Hospital, Doha, Qatar
2017	Member, American Association for Cancer Research (AACR) 2017 Annual Meeting Organizing Committee, April 2017
2016 – present	Member, Scientific Advisory Board, Parker Institute for Immunotherapy of Cancer
2016 – present	Member, NCI-Cervical Cancer Strategic Working Group
2016 – present	Chair, Policy Committee, Society of Immunotherapy of Cancer (SITC)
2015 – present	Chair, NCI Radiation Therapy and Immune Modulation Working Group
2015 – 2018	Elected, Member of the Board, Society of Immunotherapy of Cancer (SITC)
2015	Member, French NCI (INCA) Committee for the review and designation of national French cancer center SIRIC, Paris, France, December 2015
2015 – present	Chair, National Cancer Policy Forum Immunotherapy for Cancer Care Working Group
2015 – present	Member, National Cancer Policy Forum (NCPF) Lung Cancer Screening Policy Working Group
2015 – 2017	Member, Cancer Drug Development Forum, Regulatory Working Group, Innsbruck, Austria
2014 – present	Member, National Cancer Policy Forum (NCPF), Institute of Medicine, The National Academy of Sciences
2014 – 2016	Member, National Cancer Policy Forum (NCPF) Low Resource Cancer Care Working Group
2014 – 2017	Member, Association of Cancer Immune Therapy, Regulatory Research Group, CIMT RRG
2014 – present	Member, Steering Committee, Society of Immune Therapy of Cancer Biomarker Task Force
2014	Member, Program Committee, American Society of Clinical Oncology (ASCO) Annual Meeting

2014 – present	Chair, Immunotherapy and Immune-Modulation Committee, NRG Cooperative Group
2012 - 2013	Member, World Oncology Forum
2012 - present	Member, World Immunotherapy Council
2012	Member, French NCI (INCA) Committee for the review and designation of national French cancer center SIRIC 2012, Paris, France, May 2012
2010 - present	Member, Community Research Forum Steering Committee, American Society of Clinical Oncology (ASCO)
2009 - present	Member, C-Change Research Forum
2009 – 2012	Chair, American Society of Clinical Oncology (ASCO) Committee on Clinical Trial Design for Rare Cancers
2009 – 2012	Cancer Research Committee Clinical Trial Accrual Strategic Planning group, American Society of Clinical Oncology (ASCO)
2009 – 2011	American Society of Clinical Oncology (ASCO) Pre-phase III Working Group
2008 – 2012	NCI Principal Investigator, Gynecologic Oncology Group (GOG)
2008 – 2011	Member, Cancer Research Committee, American Society of Clinical Oncology (ASCO)
2008 - present	Member, Developmental Therapeutic Committee, Gynecologic Oncology Group (GOG)
2007 - 2011	Member, American Association for Cancer Research (AACR) Translational Medicine Think Tank
2007 – 2011	Co-chair, iSBTc-FDA Immunotherapy Biomarkers Task Force.
2007 – 2011	Co-chair, American Society of Clinical Oncology-FDA Alternative Trial Design Working Group (ADWG)
2006 – 2011	Deputy FDA Representative Member, National Cancer Policy Forum (NCPF), Institute of Medicine, National Academy of Sciences
2006 – 2011	Co-chair, AACR/FDA/NCI Cancer Biomarkers Collaborative: <i>a national effort between the American Association for Cancer Research/government agencies and the pharmaceutical industry to coordinate and advance in cancer research</i>
2006 - 2009	Member, Oversight Committee, Oncology Biomarkers Qualification Initiative (OBQI); <i>a Federal Government initiative between FDA, NCI and CMS to advance biomarker utilization in cancer care.</i>
2006 – 2009	Member, Steering Committee, Interagency Oncology Task Force (IOTF); <i>a federal government initiative between the National Cancer Institute and the Food and Drug Administration for coordinating oncology efforts and driving progress in cancer research</i>
2005 - 2007	European Science Foundation Biomedicine Technology Panel, European Young Investigator Award EURYI, 2006
2006 – 2007	UICC (International Union against Cancer) Human Papillomavirus Taskforce
2005 – 2008	Member, International Affair Committee Advisory Group, American Society of Clinical Oncology
2005 - 2006	Member, Biomedicine Panel, European Young Investigator Award,

2004 - 2012	Member, International Affairs Committee, American Association for Cancer Research (AACR)
2002 - 2003	Member, Program Committee, Clinical Immunology Subcommittee, Annual Meeting of the American Association for Cancer Research (AACR)
2001 – 2003	Member, Technology Assessment Working Group, American Society of Clinical Oncology (ASCO)
2001 – 2002	Member, Membership Committee, American Association for Cancer Research (AACR)
2001 – 2002	Member, Expert Panel, Chemo-predictive/Resistance Assays Working Group, American Society of Clinical Oncology
2000 – 2001	Member, Annual Meeting Program Committee, American Society of Clinical Oncology, New Orleans, Louisiana
2000 – 2003	Member, Health Services Research Committee, American Society of Clinical Oncology (ASCO)
1999 – 2001	Member, Program Committee, Vaccine and Immunobiology Subcommittee, Annual Meeting of the American Society of Clinical Oncology (ASCO)
1999 – 2012	Chair, Immunotherapy Subcommittee and predecessor as Cancer Vaccines Subcommittee, Gynecologic Oncology Group (GOG)
1998 - present	Member, Experimental Medicine Committee, Gynecologic Oncology Group (GOG)
1999	Member, Special Emphasis Panel for RFA Application Review, National Cancer Institute, Washington, District of Columbia
1998	Member, Scientific Committee, FDA/NCI workshop on Tumor Vaccines, Washington, District of Columbia
1998 - 2005	Member, Cervix Committee, Gynecologic Oncology Group (GOG)
1998 - 2005	Member, Developmental Therapeutic Committee, Gynecologic Oncology Group (GOG)
1997 - present	Chief Adviser, International Committee for Establishment and Development of Oncology Centers (ICEDOC), Medina, Texas
1996 - 2000	Chair, Ramahi Medical Award Committee, Washington, District of Columbia

International Governmental/Institutional Advisory Committees Membership

2017	Member, SIDRA Scientific Advisory Board, Biomedical Research Agency of the State of Qatar, Doha, Qatar
2015 – present	Member, French NCI (INCA) Committee for the review and designation of national French cancer center SIRIC, Paris, France, November 2017
2015 – present	Member, Advisory Board for Apollo Hospitals, India
2015 – present	Member, Advisory Board for the National Institute of Health, Malaysia
2014 – present	Member, Advisory Board for the SIDRA Medical Research Center, Doha, Qatar

2003 – 2006 Chair, National Strategy Planning Coalition on Iraq
A cooperative effort of Department of Health and Human Services, the National Cancer Institute, Iraqi Ministry of Health, and the Kingdom of Jordan to provided strategic planning to rebuild health care infrastructure for pediatric oncology in Iraq.

National Health Care Leadership Activities in Jordan (NIH/NCI sponsored activities) (2002-2009)

Activities conducted as part of the agreement between the US Government and the Kingdom of Jordan

2008 – 2009 Member, Higher Commission on Biotechnology Strategic Development

2008 – 2009 Chair, National Cancer Control Plan Committee

2004 – 2009 Chairman, National Task Force for the Development of Life Sciences Research and Biotechnology Promotion initiative in Jordan:

Task force formed to conduct research on the infrastructure status and the preparedness of the Kingdom and the Middle East region for research and development operation and multinational investment in the field. The initiative has published two white papers so far:

- “The regulatory and legal infrastructure for research development and innovation in Jordan”
- “Life Sciences Research and Biotechnology Status in Jordan”

2005 – 2006 Member, the National Planning Committee “Committee on National Agenda” on Higher Education and Scientific Innovation
Member, the National Planning Committee for Health Care Strategy Development.

National committee that is part of the “National Agenda” charged by the King of Jordan to develop and publish a 10-year national strategy plan. The report was finalized and published in March 2006

2005 – 2006 Member, Higher National Cancer Guidelines Committee:
An ad hoc committee appointed by the Minister of Health to address cancer treatment standards and guidelines in the Kingdom.

2003 – 2009 Chairman, National Task Force on Palliative Care in Jordan.
The committee planned, directed and coordinated the development of a national palliative care program that is the first national palliative program in the Middle East and was adopted as a model program by the World Health Organization.

2003 – 2006 Member, National Committee on Hospital Accreditation and Quality Management in Jordan.
The Committee charged with developing accreditation and quality assurance standards for health care institutions in Jordan.

National Institutes of Health and National Naval Medical Command Institutional Committees

2009 – 2012 Member, Clinical Trial Scientific Review Committee, Medicine Branch and Affiliates, NCI

2008 – 2012 NCI Principal Investigator, Gynecologic Oncology Group (GOG)

- 2001 – 2005 Co-Chair and Member, Steering Committee, National Cancer Institute Gynecologic Oncology Faculty, Bethesda, Maryland
- 1998 - 2012 Member, Steering Committee, National Cancer Institute Cancer Vaccine Working Group, Bethesda, Maryland
- 1998 – 2001 Chair, Cancer Vaccine Group, Medicine Branch, National Cancer Institute, Bethesda, Maryland
- 1997 - 2002 Member, National Cancer Institute Certificate of Confidentiality Subcommittee, Bethesda, Maryland
- 1997 - 1998 Co-Chair, Clinical Guidelines Committee for Biologics, Naval Hospital Bethesda, Bethesda, Maryland
- 1997 - 1998 Member, Clinical Guideline Steering Committee, Naval Hospital Bethesda, Bethesda, Maryland
- 1995 - 1999 Member, Institutional Review Board (IRB), National Cancer Institute, National Human Genome Research Institute, National Institutes of Health, Bethesda Maryland
- 1989 - 1990 Member, Quality Assurance Committee, Medical College of Ohio, Toledo, Ohio
- 1988 - 1990 Member, Residency Program Acceptance Committee, Medical College of Ohio, Toledo, Ohio

Chair, Discussant or Panelist in National and International Scientific Conferences

- Chair, TIMO XIV Conference, Halle, Germany, May 24-26, 2018
- Chair, 5th Immunotherapy of Cancer Conference (ITOC5) SITC-ITOC4, Prague, Czech Republic, March 19-21, 2018
- Chair, American Society of Clinical Oncology Annual Meeting (ASCO), Immunotherapy of Gynecologic Malignancies, Educational Session, Chicago, IL, June 2-6, 2017
- Chair, TIMO XIII Conference, Halle, Germany, May 4-6, 2017
- Chair, 4th Immunotherapy of Cancer Conference (ITOC4) SITC-ITOC4, Prague, Czech Republic, March 19-23, 2017
- Member, Organizing Committee, 3rd Immune Therapy of Cancer Conference (ITOC3), Munich, Germany, March 19-23, 2017
- Chair, Society of Gynecologic Oncology Annual Meeting, Immunotherapy for cancer, Washington Harbor, Maryland, March 12, 2-17
- Chair, “Community outreach for Underserved Population”, Cancer Moon Shot Program, The White House, Washington DC, January 10th, 2017
- Discussant, United States Vice President’s Cancer Moonshot Summit, Washington, DC, June 29, 2016
- Chair, “Hypo-fractionated Radiation Therapy, Immune-modulation and Immunotherapy” *A joint session supported by The Radiosurgery Society, Society for Immunotherapy of Cancer, Radiation Research Society and National Cancer Institute (NCI), Symposium on - Bridging the Gap: Advancing Research and Education.* SRS/SBRT Scientific Annual Meeting June 2016, Orlando, Florida
- Chair, Aganox T Cell Based Immunotherapy: A Deeper Dive. June 10-12, Maui, Hawaii
- Chair, American Association for Cancer Research (AACR) Annual Meeting, “Immune Modulation of Cancer”, New Orleans, LA, April 16, 2016
- Panelist, Jefferies 2016 I-O Summit, Boston, MA, April 8, 2016

Chair, SITC Immunotherapy Biomarker 2016 Meeting, Bethesda, MD, April 1, 2016

Chair, NCI-SITC Radiation-Immunotherapy Leadership Summit, Rockville, MD, March 31, 2016

Member, Organizing Committee, 3rd Immune Therapy of Cancer Conference (ITOC3), Munich, Germany, March 21-23, 2016

Chair, Institute of Medicine (IOM) Immunotherapy Workshop, Washington DC, February 29-March 1, 2016

Member, Nektar Advisory Board, Napa, CA, January 29, 2016

Chair, NRG Scientific Symposium, NRG Semiannual Meeting, Atlanta, GA, January 21, 2016

Panelist, Institut National du Cancer (INCa) SIRIC Midterm Evaluations, Boulogne-Billancourt, France, December 9-10, 2015

Co-Chair, SITC's 30th Anniversary Annual Meeting & Associated Programs, "Tumor Vaccine and Cell Therapy Working Group (TVACT)", National Harbor, MD, November 4-8, 2015

Chair, Institute of Medicine (IOM) Immunotherapy Workshop, Washington DC, October 26-27, 2015

Panelist, Jefferies Immuno-Oncology Summit, "Checkpoint Inhibitor/Vaccines Panel", Boston, MA, April 15, 2015

Panelist, Apollo Oncology Advisory Board, Washington DC, September 23, 2015

Chair, World Vaccine Congress, Washington DC, April 8-9, 2015

Member, Organizing Committee, 2nd Immune Therapy of Cancer Conference (ITOC2), Munich, Germany, March 25-27, 2015

Member, Organizing Committee, National Cancer Policy Forum Workshop: Policy Issues in the Development and Adoption of Molecularly Targeted Therapies for Cancer, Washington DC, November, 2014

Chair, Challenges in developing clinical biomarker tests session, NCPF Workshop on Policy Issues in the Development and Adoption of Molecularly Targeted Therapies for Cancer, Washington DC, November, 2014

Member, Organizing Committee, Biotherapy Development Association, How to Improve Access to Innovative Therapies in Oncology, Innsbruck Germany, October 29-31, 2014

Co-Chair, Society for Immunotherapy of Cancer (SITC) 27TH Annual Meeting "SITC Workshop- Focus on the Target: The Tumor Microenvironment, and Critical Issues in Immunotherapy Clinical Trials," North Bethesda, MD, October, 2012

Expert, World Oncology Forum, "Are we winning the war on cancer?," Lugano, Switzerland, October, 2012

Chair, 6th Annual GHSU Cancer Center Symposium, Savannah, Georgia, September 2012

Chair, Tumor Vaccine Cell Therapy of Tumors XVIII Annual Meeting, Chicago, IL, April, 2012

Chair, World Immunology Forum, Curacao, The Dutch Isles, February, 2012

Chair, American Society for Clinical Oncology Panel on Trial Design in Small Populations, Alexandria, VA, December, 2010

Chair of Conference, "The 2nd American Association for Cancer Research (AACR)'s Dead Sea Conference" International Conference on Advances in Cancer Research: From the Laboratory to the Clinic in Jordan," Dead Sea, Jordan, March, 2010

Chair, "Selecting and Integrating the Optimal Combination Therapy Strategy into Your Oncology Clinical Development Program," Active Immunotherapy Forum, Barcelona, Spain, June, 2009

Moderator, Panel Discussion, Exploring the Development of Two or More Unlicensed Technologies in Development as Combination Therapy," Active Immunotherapy Forum, Barcelona, Spain, June, 2009

Chair, "New Science Architecture for the Middle East," World Economic Forum, Dead Sea, Jordan, May, 2009

Chair, Speaker, "The AACR-FDA-NCI Cancer Biomarker Collaborative, Update and Recommendations," American Cancer Association Annual Meeting, Denver, CO, 2009

Chair "Biomarkers in Biologic Therapy Development," Biotherapy Development Association Fourth Alpine Meeting, Innsbruck, Austria, October 15-17, 2008

Chair of Conference, "American Association for Cancer Research (AACR)'s International Conference on Advances in Cancer Research: From the Laboratory to the Clinic in Jordan," Dead Sea, Jordan, March, 2008

Co-Chair, Special Session on the AACR-FDA-NCI Cancer Biomarkers Collaborative, 98th Annual Meeting, San Diego, CA, April, 2008

Chairman, "Serum Proteomics and Biomarkers in Cancer," Educational Session, American Association for Cancer Research (AACR) 98th Annual Meeting, San Diego, CA, April, 2008

Chair, NCI-KHCBI-Duke University Middle East and North Africa Cancer Research Conference, September, 2007

Co-Chair, SCO-FDA Alternative Clinical Trial Design Workshop, Washington DC, April, 2007

Co-Chair, AACR/FDA/NCI Think Tank on Biomarkers, Philadelphia, PA, November, 2006

Chairman, International NCI-KHCC Women's Cancer Conference, Amman, Jordan, September, 2005

Chairman, "Cervical Cancer: The Role of Human Papillomavirus Vaccines in Prevention," American Society for Clinical Oncology (ASCO) Annual Meeting, Orlando, FL, May, 2005

Chairman, "New Therapeutic Approaches in Cervical Cancer Session," International Society of Gynecologic Cancers, Edinburgh, Scotland, October, 2004

Chairman, "Postgraduate Course on Immune Therapy for Gynecologic Malignancies," Gynecologic Oncology Society Annual Meeting, San Diego, CA, January, 2004

Chairman, "Clinical Specimen Procurement, Processing and Preservation," National Workshop National Cancer Institute, Bethesda, MD, July, 2002

Invited Discussant, International Workshop on Human Papillomavirus Immunology, National Cancer Institute, Rockville, MD, June, 2002

Chairman, "Tumor Vaccine Oral Presentation Session," American Association for Cancer Research (AACR) 93rd Annual Meeting, San Francisco, CA, April, 2002

Invited Discussant, International Workshop on Immune Monitoring for Cancer Immunotherapy, Society of Biologic Therapy, NCI/CTEP, FDA, Bethesda, MD, November, 2001

Invited Discussant, CTEP Vaccine Working Group Workshop: “Consensus on Immune Monitoring for Cancer Vaccine Trials,” Rockville, MD, August, 2001
Chairman, Gynecologic Oncology Group (GOG) Biannual Meeting Scientific Session, “Vaccines for Gynecologic Malignancies”, Cincinnati, OH, July, 2001
Chairman, “Immune Biology Oral Presentation Session,” American Society for Clinical Oncology (ASCO) 37th Annual Meeting, San Francisco, CA, May, 2001
Invited Panelist, Vaccine Development against HPV, The Fifth International AIDS Malignancy Conference (IAMC), National Institutes of Health, Bethesda, MD, April, 2001
Chairman, American Association for Cancer Research (AACR) Educational Session and Method Workshop, “Molecular Targeted Therapy,” AACR Annual Meeting, New Orleans, LA, March, 2001
Chairman, “Molecular Targeted Therapy Session,” the Fourth UAE International Cancer Conference, Abu-Dhabi, United Arab Emirates, January, 2001
Chairman, “Tumor Vaccine Oral Presentation Session,” American Society for Clinical Oncology (ASCO) 36th Annual Meeting, New Orleans, LA, May, 2000
Invited Discussant, “Tumor Vaccine Oral Presentation Session,” American Society for Clinical Oncology (ASCO) 36th Annual Meeting, New Orleans, LA, May, 2000
Organizer, Member of the Scientific Committee, Chairman of the Poster Session, FDA/NCI Workshop on Tumor Vaccines, Washington DC, December, 1998
Invited Panelist, “Vaccine and Immunological Monitoring,” FDA/NCI Workshop on Tumor Vaccines, Washington DC, December, 1998
Organizer, Second Arab–International Oncology Conference, Amman, Jordan, June, 1999

Invited Scientific Speaker and Professorship:

2018

Speaker, TIMO XIII Conference, Rational Approaches to Combination Immunotherapy, Halle, Germany, May 24-26, 2018
Speaker, 4th Immunotherapy of Cancer Conference (ITOC5) SITC-ITOC5, Current Understanding of Resistance to Immunotherapy, Berlin, Germany, March 19-21, 2018

2017

Speaker, Discussant, High Impact Clinical Trials, Are we on the right path?, SITC Annual Meeting, Washington DC, November 10th, 2017
Speaker, “Rational Combination Immunotherapy; it is Science Not Logic”, Lombardi Comprehensive Cancer Center Grand Round, October 10th, 2017
Speaker, College of Medicine Grand Round, “Resurrection of Cancer Immunotherapy; Hopes and Trepidation” University of Toledo, Toledo Ohio, October 6th, 2017
Speaker, NRG Scientific Meeting “Mucosal Melanoma”, NRG Semiannual Meeting, Philadelphia, Pennsylvania, July 13-15
Speaker, 4th Newcastle Therapeutic Tolerance Workshop, “Rational Design of Immunotherapy”, Newcastle, Scotland, June 27-29, 2017

Speaker, American Society of Clinical Oncology Annual Meeting (ASCO), Immunotherapy of Gynecologic Malignancies, “Immunotherapy of Ovarian Cancer”, Chicago, IL, June 2-6, 2017

Speaker, The International Symposium of Immunotherapy, “Role of Vaccine in Rational Design of Immunotherapy”, The Royal Society, London, May 12-13, 2017

Speaker, TIMO XIII Conference, Natural products, a smart Ration-al approach to combination immune therapy, Halle, Germany, May 4-6, 2017

Speaker, 4th ImmunoTherapy of Cancer Conference (ITOC4) SITC-ITOC4, Targeting PI3K for Immunotherapy, Prague, Czech Republic, March 19-23, 2017

Speaker, Society of Gynecologic Oncology Annual Meeting, Immunotherapy for cancer, Washington Harbor, Maryland, March 12, 2-17

Speaker, Panelist, Cowen 37th Annual Health Care Conference, Boston, Massachusetts, March 8th, 2017

Speaker, “Rational approaches to combination immunotherapy, Strategies vs. Science”, New Jersey Cancer Institute, Rutgers University, New Brunswick, NJ February 28, 2017

Speaker, “targeting PI3K pathway, a New Immune Modulatory Approach”, Fred Hutchinson Cancer Institute, Seattle Washington, February 1st, 2017

Speaker, “Rational Design for Combination Immunotherapy”, University of Iowa Cancer Center, University of Iowa, Iowa City, Iowa, January 30th, 2017

Speaker, “Clinical Trials design in Immunology”, Precisions Medicine World Conference 2017, Silicon Valley, California, January 25th, 2017

Moderator, “Community outreach for Underserved Population”, Cancer Moon Shot Program, The White House, Washington DC, January 10th, 2017

2016

Speaker, “Rational Design for Combination Immunotherapy, when Science and Logic Collide!!” Karolinska Institute Tumor Immunology and Immune Therapy of Cancer Course, Stockholm, Sweden, December 1, 2016

Speaker, “Immune modulatory effects of methylselenocysteine enhances the therapeutic potential of tumor vaccine” Melanoma Bridge 2016, Naples, Italy,

Speaker, Novel Cancer Therapeutic Summit 2016, November 7-9, 2016, San Francisco, CA

Speaker, AstraZeneca Immuno-Oncology Externally Sponsored Research Symposium taking place November 3-4, 2016, in Gaithersburg, Maryland.

Speaker, “The Challenges of Biomarker Development”, Cancer Drug Development Forum (CDDF) 9th Alpine Conference on ‘current and future challenges of innovative oncology drug development’, Innsbruck, Austria, 19 to 21 October 2016

Speaker, MD Anderson Cancer Center Grand Rounds, “Cancer Prevention and Control in Low Resource Settings: Rural Georgia vs. Jordan”, Houston, TX, August 26, 2016

Speaker, NRG Oncology Conference, “Recommendations from the SITC Radiotherapy Immunotherapy Workshop 2016”, Dallas, TX, July 16, 2016

Speaker, “Hypo-fractionated Radiation Therapy, Immune-modulation and Immunotherapy” *A joint session supported by The Radiosurgery Society, Society for Immunotherapy of Cancer, Radiation Research Society and National Cancer Institute (NCI), Symposium on - Bridging the Gap: Advancing Research and*

Education. SRS/SBRT Scientific Annual Meeting June 2016, Orlando, Florida
Speaker, Aganox T Cell Based Immunotherapy: A Deeper Dive. June 10-12, Maui, Hawaii
Speaker, Internal Medicine Grand Round, University of Toledo, “Cancer Immunotherapy: The Latest Revolution in Medicine.” Toledo, OH, May 19, 2016
Speaker, American Association for Cancer Research (AACR) Annual Meeting, “Combination Radiation Therapy and Immunotherapy of Cancer”, New Orleans, LA, April 16, 2016
Speaker/Chair, American Association for Cancer Research (AACR) Annual Meeting, “Immune Modulation of Cancer”, New Orleans, LA, April 16, 2016
Speaker, Jefferies 2016 I-O Summit, Boston, MA, April 8, 2016
Speaker, SITC Immunotherapy Biomarker 2016 Meeting, “Tumor Microenvironment at a Genetic Level”, Bethesda, MD, April 1, 2016
Speaker, NCI-SITC Radiation-Immunotherapy Leadership Summit, “Framing the Question”, Rockville, MD, March 31, 2016
Speaker and Session Chair, 3rd Immune Therapy of Cancer Conference (ITOC3), Munich, Germany, March 21-23, 2016
Speaker, AstraZeneca Scientific Review meeting on “Overview of Critical Issues Related to Combination Immune Therapy and Radiation from the Cooperative Group Perspective”, Scottsdale, AZ, February 20, 2016
Speaker, EMA & CDDF Joint meeting on “challenges for the approval of anti-cancer immunotherapeutic drugs”, “How do we sequence or combine immunotherapies with targeted therapies: US perspective, Canary Wharf London E14 5EU, United Kingdom, February 2-7, 2016
Speaker, Independent Global Scientific Workshop on Combination Cancer Immunotherapy (CCIT), “Translational endpoints for Immunotherapy”, Vancouver, CAN, January 24-28, 2016
Chair, NRG Oncology Semiannual Meeting, Winter Symposium- "Immunotherapy for Cancer, Current Status and Future Prospects", Atlanta, GA, January 20-23, 2016
Speaker, Grand Rounds Fairfax Inova, “Cancer Immunotherapy: The Latest Revolution in Medicine”, Falls Church, VA 22042, January 16-19, 2015

2015

Speaker, Melanoma Bridge 2015, Naples, Italy, December 6, 2015
Speaker, Vaccines R&D-2015, “Vaccines in Combination Immune Therapy for Cancer” Baltimore, MD, November 2, 2015
Speaker, IOM National Cancer Policy Forum, Workshop on Prevention and Early Detection of Cancer in Low Resource Countries, Washington DC, October 26-27, 2015
Speaker, NSABP investigators Meeting, “Overview of Immunotherapy in 2015, and future directions”, Chicago, IL, October 16, 2015
Speaker, Gilead Sciences, “Combination Immune Therapy: Informed Strategies” Foster City, CA, October 12, 2015
Speaker, Radiation Research Society (61st) meeting, “Combination immunotherapy and Immune Biomarkers”, Weston, Florida, September, 22, 2015
Speaker, Society of

Immunotherapy of Cancer Augusta, “Basic Principles of Tumor Immunotherapy”, GA, September 18, 2015

Speaker, Cancer Immunology Department, “Combination Immune Therapy: Strategies & Designs”, San Francisco, CA, August 4, 2015

Speaker, 2nd Annual Summit on Harnessing the Immune System in Cancer, “Immune Combination Strategies and Design”, Palm Beach, FL, July 25, 2015

Speaker, NRG Oncology Semiannual Meeting, “Immune Combination Therapy, Strategies and Design”, Denver, CO, July 16, 2015

Speaker, Rotary Club of Augusta Speaking Engagement, “Cancer in Georgia: Answering the Call”, Augusta, GA, June 15, 2015

Speaker, Tumor Immunology, “Strategies and design for combination immunotherapies”, Halle, Germany, May 21, 2015

Speaker, International Symposium on Immunotherapy, “Navigating Geopolitics of Tumor Microenvironments Strategies for Combination Immune Therapy”, London, May 15-16, 2015

Speaker, American Association for Cancer Research (AACR) Annual Meeting, “Therapeutic Cancer Vaccines”, Philadelphia, PA, April 18, 2015

Panelist, Jefferies Immuno-Oncology Summit, “Checkpoint Inhibitor/Vaccines Panel”, Boston, MA, April 15, 2015

Speaker, Society of Immune Therapy of Cancer: Breast Cancer Conference in Doha, “Combination Immunotherapy, Strategies and Designs”, Doha, Qatar, April 11-13, 2015 Doha Qatar

Keynote Speaker, Louisiana Cancer Research Consortium Scientific Retreat (2015), “Combination Immune Therapy: Informed and Intelligent Strategies”, New Orleans, LA, April 10, 2015

Chair and Panelist, World Vaccine Congress, Washington, DC, April 8-9, 2015

Keynote Speaker, Combination Immunotherapy, 1st Immune Therapy of Cancer Conference ITOC3, Munich, Germany, March 12-14, 2015

Keynote Speaker, International Anal Neoplasia Society Scientific Meeting 2015, “Immunotherapy of HPV-Related Cancer”, Atlanta, GA, March 13, 2015

Keynote Speaker, CDDF 8th Alpine Conference, “Immuno-Oncology, a New Mainstay in Cancer Treatment”, Innsbruck, Austria, March 2-4, 2015

Chair and Speaker, NRG Oncology Meeting, “Immune Therapy and Immune Modulation”, San Diego, CA, February 5-6, 2015

Speaker, Analyst and Investors Day, Advaxis “Immunotherapies, Immunotherapy Technology”, New York, NY, February 3, 2015

Speaker, Tri-Center Cancer Immunology Research Retreat, “Georgia Regents University Program Overview”, Tides Folly Beach, SC, January 22-24, 2015 Chair and

2014

Speaker, Melanoma Bridge 2014, Naples, Italy, December 6, 2014

Speaker, Society for Immunotherapy of Cancer (SITC), Advances in Cancer Immunotherapy, Tampa FL, December 5, 2014

Speaker, International Conference On Radiation Biology 2014 (ICRB 2014), Nov 11-13, 2014, New Delhi, India

Speaker, Biotherapy Development Association, How to Improve Access to Innovative Therapies in Oncology, Innsbruck Germany, October 29-31, 2014

Speaker, Third International Conference and Exhibition on Clinical & Cellular Immunology, Immunology Summit 2014, Baltimore, MD, October 1, 2014

Speaker, 3rd International Conference on Clinical and Cellular Immunology; Baltimore, MD, September 29 – October 1st, 2014

Speaker, 4th International Conference on Vaccine and Vaccination, Valencia, Spain, September 24-26, 2014

Speaker, Ninth Annual ImVacS, The Immunotherapies and Vaccines Summit, “Immune Corrective Strategies” Boston, Massachusetts, August 11-13, 2014

Speaker, First Annual Summit on Practical Applications of Immune and Oncolytic Therapies in Oncology, “Immune Combination Strategies and Design”, Palm Beach, FL, July 18-20, 2014

Speaker, NRT Oncology, “Hurdles in the Development of Combination Immune Therapy of Cancer”, Chicago, IL, July 9, 2014

Keynote Speaker, Combination Immune Therapy, 8th Miltenyi Cordeliers Meeting on Immunochemotherapy, Paris, France July, 2014

Keynote Speaker, The Naji Sahyoun Basic Science of Excellence Lecture, Middle East Medical Association Conference (MEMA), American University of Beirut, Beirut Lebanon, April 25, 2014

Speaker, Plenary Session, Regulatory Considerations for Targeted Immunotherapies, Regulatory Science and Policy Session, American Association for Cancer Research, 2014 Annual Meeting, San Diego, CA, April 4-8, 2014

Keynote Speaker, Combination Immunotherapy, 1st Immune Therapy of Cancer Conference ITOC, Munich, Germany, March 12-14, 2014

Speaker, NRG Immune Therapy Working Group, Combination Immune Therapy, San Diego, CA, February 6-9, 2014

Keynote Speaker, Society for the Immune Therapy of Cancer (SITC), Sidra conference, Doha, Qatar January 22-24, 2014

2013

Speaker, European Society for Medical Oncology (ESMO), “MEDI4736, an anti-PD-L1 antibody with modified Fc domain: preclinical evaluation and early clinical results from a phase 1 study in patients with advanced solid tumors”, Amsterdam, Netherlands, September 27-Oct. 1, 2013

Expert, L-BL925 START Ancillary Review Committee Meeting, Jamaica, NY, August 23-24, 2013

Speaker, Gynecologic Oncology Group (GOG), “Harvesting the Immune System for Therapeutic Purposes”, San Antonio, TX, July 18, 2013

Speaker, Nanjing 8.1 Hospital, Nanjing, China, June 27, 2013

Speaker, Beijing Kery, “Cancer Immunology Studies in the United States”, Beijing, China, June 24, 2013

Speaker, Tumor Vaccine and Cell Therapy Working Group (TVACT), Honolulu, HI, May 3, 2013

Speaker, Cancer Immunotherapy Consortium (CIC), “B7-DC-Ig: A Different Kind of PD1 Targeting Agent”, Washington DC, April 24, 2013

Chair and Speaker, Society for Immunotherapy of Cancer (SITC), “Do We Need Phase I Design for Vaccine Development and When?”, Bethesda, MD, April 3, 2013
Speaker, First Annual Expert Forum on Immuno-Oncology, “Clinical Development of Immune Checkpoint Inhibitors: Pidilizumab”, Miami, FL, March 8, 2013
Seminar Speaker, University of Georgia, Center for Drug Discovery, Athens, GA, February 18, 2013
Speaker, Georgia Baptist Ministers Conference, “Cancer Disparities in Georgia”, Augusta, GA, February 12, 2013
Keynote Speaker, First International Meeting on Personalized Medicine and Targeted Therapies in Cancer (PMTTC 2013), “Cancer Immunotherapy and Vaccines- Simple and Complex Pictures”, Sharjah, United Arab Emirates, January 31, 2013
Keynote Speaker, BDA Immuno-Oncology Workshop, “Immuno-Oncology, Where Are We Today?”, Frankfurt, Germany, January 28, 2013

2012

Visiting Professor, International Agency for Research on Cancer (IARC), Paris, France, November, 2012.
Speaker, Morehouse School of Medicine, “Immune Corrective Therapy, Modulating the Tumor-Immune Microenvironment,” November, 2012
Visiting Professor, M2Gen/Moffitt Cancer Center, Tampa, Florida, November, 2012
Panelist, World Oncology Forum (WOF), Lugana, Italy, October, 2012
Speaker, SITC 27th Annual 2012 Meeting, “Microenvironment Immunogenetics Biomarkers in Combination Therapy,” North Bethesda, Maryland, October, 2012
Speaker, Marie Curie Institute, “Modulating the Tumor-Immune Network,” Paris, France, Sept 2012
ASCO Quality Assessment, Sept 2012
Speaker, Georgia Society of Clinical Oncology (GASCO), “The Expanding Role of Patient Navigation from a Local and National Perspective,” Atlanta, GA, September 2012
Speaker, STaR Conference 2012 – Cancer Therapy: Making It Personal, “Cancer and the Immune System,” Augusta, GA, Sept 2012
American Cancer Society 4th Annual Cancer Center Directors’ Retreat, September, 2012.
Speaker, 10th Annual Meeting on Cancer Immunotherapy (CIMT), “Vaccines targeting mutations in known antigens,” Mainz, Germany, May, 2012
Speaker, American Association for Cancer Research (AACR), “Scientific and Regulatory Challenges in Co-development of Predictive *in vitro* Diagnostics,” Chicago, IL, April 2012
Speaker, Immunotherapy in combination, TVACT, Chicago, IL, April 2012
Speaker, “Combination Immunotherapy Strategies”, World Immunology Council Summit, Curacao, The Dutch Isles, February, 2012

2011

Speaker, Immunotherapeutics & Vaccines Summit, “Clinical Development of Therapeutic Vaccines”, Boston, MA, August 16-18, 2011
Speaker, Grand Round, Institut Gustav Roussi, Paris, France June 23rd, 2011
Speaker, 8th Annual Meeting on Cancer Immunotherapy, Mainz, Germany, May 26-28, 2011

Speaker, 3rd Annual Active Immuno-therapeutics Forum, Barcelona, Spain, May 11-13, 2011

Speaker, 4th annual Middle East Medical Assembly (MEMA), May 5-8, 2011

Speaker, 11th Arab Medical Association against Cancer Meeting, Casa Blanca, Morocco, April 27-30, 2011

Keynote Speaker, Translational Approaches in Cancer Therapeutics Conference, University of California at Irvine, Irvine, CA

Speaker, monthly seminars “Meet the Oncology Expert”, Institut Jules Bordet, Brussels, Belgium, February 25, 2011

Speaker, The Ramanbhai Foundation 5th International Symposium - Advances in Translational Research and Medicine, Zydus Research Centre, Ahmedabad, India, February 1-4, 2011

Speaker, Strategic Considerations for Executives in Translational Medicine, Washington DC, January, 2011

2010

Keynote Speaker, 2nd Annual SEHA Research Conference, Abu Dhabi, UAE, December 12-13, 2010

Speaker, NCI-ASCO Overcoming Barriers to International Clinical Trials for Rare Cancers, Rockville, MD, December 10, 2010

Chair/Speaker, American Society for Clinical Oncology Panel on Trial Design in Small Populations, Alexandria, VA, December 9, 2010

Speaker, Internal Medicine Grand Rounds, University of Oklahoma Medical School, “Tumors and the Immune System, the Love-Hate Relationship”, Oklahoma City, OK, December 1, 2010

Speaker, 2nd International Workshop on Cancer Pharmacogenomics in Bethesda, MD, October 28, 2010

Speaker, Symposium on Immuno-Oncology Biomarkers, 2010 and Beyond, International Society for Biologic Therapy Annual Meeting, Biomarker, Bethesda, MD, September 30, 2010

Speaker, NCI's Immunity, Inflammation & Cancer Conference, Bethesda, MD, September 23-24, 2010

Visiting Professor, University of Chicago, Experimental Therapeutics & Imaging, Cancer Control and Population Science, and Biopharmaceutical Sciences programs, Chicago, IL, September, 2010

Guest Lecturer, Wayne State University School of Medicine and the Detroit Medical Center, September, 2010

Speaker, Ludwig Maximilian University of Munich, Division of Clinical Pharmacology, Munich, Germany, September, 2010

Speaker, 10th International Meeting “Biological Therapy of Cancer”, Munich, Germany, September 8-12, 2010

Speaker, 2nd Annual Active Immunotherapeutics Forum, Barcelona, Spain, June 21-23, 2010

Speaker, 8th Annual Meeting on Cancer Immunotherapy, Mainz, Germany, May 26-28, 2010

Speaker, 10th Pan Arab Cancer Congress, Algiers, Algeria, April 30-May 2, 2010

Speaker, 5th International APOCP Congress/Bridging Continents for Cancer Control, Istanbul, Turkey, April 3-7, 2010

Speaker, 7th Annual Symposium on Ovarian Cancer and Other Gynecologic Malignancies, NY, March 26-27, 2010

Speaker, Panelist, President's Cancer Panel Meeting, Miami, FL, February 2, 2010

2009

Speaker, Recent Progress in Cancer Therapeutics, Cairo, Egypt, December 14-16, 2009

Speaker, Radiologic Society of North America RSNA-coordinated Imaging Biomarkers Roundtable, Chicago, Illinois, November 2nd, 2009

Speaker, "Development of Breast Cancer Research Programs in Countries with Limited Resources", The 15th Annual Multidisciplinary Symposium on Breast Disease & The First International Breast Health Educational Program, Cairo, Egypt October 2009

Speaker, "Revamping the Biomarker Development Process for Oncology Drug Development," Oncology Biomarkers Conference, Philadelphia, September 2009

Speaker, "Biomarkers and Personalized Medicine Challenges and Solutions," The Move toward Personalized Medicine in Cancer, CBI's 3rd Annual Oncology Clinical Trial Summit, Bethesda, Maryland, September 2009

Speaker, Medical Grand Rounds, "Tumor Immune Escape...We Shall Overcome," University of Toledo Department of Medicine, Toledo, Ohio, August, 2009

Speaker, "Tumor-Immune Escape, Understanding and Strategies," 3rd Tegernsee Conference of Immunotherapy of Cancer, Lake Starnberg, Germany, July, 2009

Keynote, "Cancer Biomarkers, the Critical Path and Immunotherapeutics - Where Do We Stand?" Active Immunotherapy Forum, Barcelona, Spain, June 2009

Speaker, "Tumor Immune Escape, We Shall Overcome," MD Anderson Immunology Translational Research Seminar, Houston, Texas, May 2009

Speaker, "New Science Architecture for the Middle East," World Economic Forum, Dead Sea, Jordan, May 2009

Speaker, "Middle East Healthcare, Ready for Growth," World Economic Forum, Dead Sea, Jordan, May 2009

Keynote, "Scientific Research Made Easy in Developing Countries," Arab Medical Association Against Cancer Annual Conference, Cairo, Egypt, May, 2009

Speaker, "The AACR-FDA-NCI Cancer Biomarker Collaborative, Update and Recommendations," American Cancer Association Annual Meeting, Denver, Colorado, 2009

Speaker, 7th Annual Partnering with Central Labs, ECG, and Imaging Labs, "Working Together to Develop Biomarkers for Safety Monitoring and Surrogate Endpoints," Las Vegas, Nevada, February, 2009

2008

Speaker, American Association for Cancer Research (AACR) Translational Cancer Medicine Conference in Jerusalem, "Regulating T regulatory cells and enhancing activated T cells", November 3-6, 2008

Speaker, International Society for Biologic Therapy (iSBTc), October 30th- November 2nd, San Diego, California, 2008

Speaker, Biologic Therapy of Cancer, The Biotherapy Development Association, Enosburg, Germany, October 14-16 2008

Speaker, Angiogenesis Foundation 6th International Symposium *Antiangiogenesis: New Frontiers in Therapeutic Development*, Cambridge, Massachusetts. October 13-14, 2008

Keynote Speaker, CBI's 2nd Annual Oncology Clinical Trial Summit, Hilton Alexandria Old Town, Alexandria, Virginia, September, 2008

Speaker, American Society of Clinical Oncology (ASCO) 2008 Breast Cancer Symposium, Washington, DC. September 5 – 7, 2008

Speaker, Karolinska Institute, "'Tumor Evasion, Mechanisms and Strategies... We Shall Overcome,'" Stockholm, Sweden, June 2008

Speaker, The International Society for Biological and Environmental Repositories (ISBER) 2008 Annual Meeting, Bethesda, Maryland, May 18 - 21, 2008

Keynote Panelist, Biomarker Workshop, Next Generation Pharmaceutical Summit, , Laguna Beach, California, May 2008

Chair/Speaker, "Incorporating Serum Proteomics as Biomarkers in Clinical Trials," Innovation in Drug Development and Clinical Trials Session, 99th Annual Meeting of the American Association for Cancer Research (AACR), San Diego, California, April 2008

Chair/Speaker, "The Critical Path" at the AACR-FDA-NCI Cancer Biomarkers Collaborative Special Session, 99th Annual Meeting of the American Association for Cancer Research (AACR), San Diego, California, April 2008

Chair/Speaker, "Cancer Vaccine: Reality or Hype," the International Society of Hyperthermia Annual Meeting, Munich, Germany, April 2008

Panel/Speaker, "Biomarkers, are we there yet?" Nineteenth Annual Cancer Progress Conference, New York, NY, March 11, 2008

Speaker/Session Chair, Biologic Therapy of Cancer, The Biotherapy Development Association/European Society of Medical Oncology/NCI, Munich, Germany, March 2008

Speaker, "Cultural Ironing in Cancer Institution Development" American Association for Cancer Research (AACR) 's International Conference on Advances in Cancer Research: From the Laboratory to the Clinic in Jordan, Dead Sea, Jordan, March 2008

Speaker, "Regulating the regulators, an immunologic approach to cancer" "American Association for Cancer Research's International Conference on Advances in Cancer Research: From the Laboratory to the Clinic in Jordan," Dead Sea, Jordan, March 2008

Speaker/Panelist, "Preclinical Development and Validation of Molecular Biomarkers," Oncology Biologics Development Primer; International Society of Biologic Therapy, Gaithersburg, February 28-29, 2008

2007

Visiting Professor, the Earl Chiles Research Institute, Oregon, November 29, 2007

Speaker, EORTC-NCI-ASCO Meeting on Molecular Markers in Cancer, Brussels, Belgium, 15 17 November 2007

Speaker, The European Commission Workshop on "Molecular Targets for Cancer - Turning Knowledge on Therapeutics, Prevention and Biomarkers into Applications," Luxembourg, 28-29 September 2007

Panelist, the Second Annual American Association for Cancer Research (AACR) International Conference on Molecular Diagnostics in Cancer Therapeutic Development "Maximizing Opportunities for Personalized Treatment," Atlanta, Georgia. September 17-20, 2007

Speaker, "Cervical Cancer Vaccines" Christophe Merieux Conference: Trends in Virology, Veyrier-du-lac, France June 2007

Meet the Professor, "Cancer Vaccines, Is It Ready for Primetime?," American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, IL, June, 2007

Speaker, "Targeting Human Papillomavirus in the Treatment of Invasive Cancer" HPV Vaccines, Educational Session, American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, IL, June, 2007

Speaker, "Translational Correlates to Immunotherapy Trials in Gynecologic Neoplasms," NY Cancer Consortium Developmental Therapeutics Conference, New York, New York, May 11, 2007

Keynote Speaker, "The Future of Cancer Therapeutics," Novartis Middle East Summit, Paris, France, May 2007

Speaker, "Translational Correlates to Immunotherapy Trials in Gynecologic Neoplasms," New York Cancer Consortium Conference, New York, New York, May, 2007

Speaker, "Incorporating Biomarkers in Clinical Trials," Innovation in Drug Development and Clinical Trials Session, 98th Annual Meeting of the American Association for Cancer Research (AACR), Los Angeles, California, April 2007

Speaker, "Culture and Relationships," Starting and Managing Collaborations in an Increasingly Global Cancer Research Community Session, 98th Annual Meeting of the American Association for Cancer Research (AACR), Los Angeles, California, April 2007

Distinguished Guest Lecturer, "Vaccines For Cervical Cancer from Prophylactic to Therapy," University of Miami Sylvester Cancer Center, March, 2007

Speaker, "Developing Westernized Medical Services in Emerging Economies," the 17th Annual National Interdisciplinary Breast Conference. Las Vegas, Nevada, February 26th 2007

Guest Speaker, American Association for Cancer Research (AACR) Industry Round Table, Phoenix, Arizona, February 21, 2007

Keynote Speaker, "Developing Westernized Medicine in the Middle East," The Annual Gala Dinner for Arab American Medical Association DC Chapter, Washington DC, February, 2007

Keynote Address, American Association Cancer Research Oncogenomics 2007 Conference, Biomarkers, Development and Regulatory Issues. Phoenix, Arizona, January 31, 2007

Highlights of San Antonio 2006, Review of breast cancer vaccines presentation, Ryadh, Saudi Arabia, January 2007

Speaker, Ovarian Cancer Vaccines, Ovarian Cancer Update Symposium, Gynecologic Oncology Group Semiannual Meeting, San Diego, CA, January, 2007

Speaker, "Novel Vaccine Targets for Cervical Cancer," Therapeutic HPV Vaccines Symposium, Gynecologic Oncology Group Semiannual Meeting, San Diego, CA, January, 2007

2006

Keynote Address, Ein Shams International Oncology Conference, Cairo, Egypt, December 2006

Speaker, "Biomarkers and the Critical Path," AACR/FDA/NCI Think Tank on Biomarkers, Philadelphia, PA, November, 2006

Speaker, "Cancer Vaccine, an Overview of the NIH Program," Middle East Cancer Consortium Scientific Conference, Istanbul, Turkey, November, 2006.

Panelist, Future of Clinical Trials, Clinical Trial Summit X, Baltimore, Maryland, November 2006

Keynote Address, Comparing current US, European and Japanese regulatory requirements for proving the safety and efficacy of novel oncology therapies," Phacilitate Oncology Leaders' Forum, the Hilton La Jolla Terrey Pines, San Diego, CA, October, 2006

Speaker, "Navigating the Critical Pathway: integrating biomarkers into cancer drug development," Drug Development Strategies in Oncology Conference, Cancer Therapy and Research Center, San Antonio, TX, October, 2006

Speaker, "HPV Vaccines," Women's Health Conference, Inova Health Care System, Fairfax, VA, September 2006

Main Scientific Speaker, Expert Panelist, North Carolina Cancer Advisory Board, HPV Vaccine Development, Chappell Hill, NC, July 2006
Keynote address, "Globalization of Medicine, Building Western-Standard Health Care in Emerging Economies," The Fifth International Conference for the Jordan Oncology Society, Amman, Jordan, April, 2006

Speaker, "The Future for Cancer Vaccines," Research Triangle Institute Fellows Symposium, "Frontiers in Science: Implications for Research and Policy." Research Triangle Institute (RTI), Chapel Hill, NC, April 2006

Speaker, Massachusetts General Hospital, Harvard Medical School. "Development of Health Care Institutions in Developing Economies," Boston, Massachusetts, April, 2006

Panelist, Duke University, Health Sector Advisory Council. "Globalizing Health Care." Duke University, Chapel Hill, North Carolina, March 2006

2005

Speaker, "Cancer Vaccines, New Trends for Biotechnology Development," 2005 WHTS' 3rd Annual Congress of International Drug Discovery Science and Technology, Shanghai, China, October 2005

Scientific Grand Rounds, Cancer Vaccines; the Way to the Future, National Cancer Institute, Cairo, Egypt, October 2005

Panelist, Prophylactic Cervical Cancer Vaccines, Kentucky Congressional Committee on Cervical Cancer, September 2005

Keynote Lecture, "Can Cervical Cancer be irradiated," Lebanese Obstetrics and Gynecology International Conference, September 2005

Postgraduate Course, "Cancer from the esophagus through the colon: Prevention to treatment," Turkey Mediterranean School of Oncology, Malatya, Turkey, August, 2005

Speaker, "Cancer Vaccine: Taking a Shot at Cancer," 2nd Tegernsee Conference of Immunotherapy of Solid Cancers, Tegernsee, Germany, July, 2005

Keynote Lecture, Italian Inter-Universities Consortium for Oncology (CINBO), Cancer Vaccines, the Way to the Future, UNICH, Chieti, Italy, June, 2005

Speaker, Development of cell-mediated vaccine for prevention of HPV infection, Educational Session, American Society for Clinical Oncology (ASCO) Annual Meeting, Orlando, FL, May, 2005

Speaker, "Cancer Vaccines," The First International Jordanian Conference of the Jordanian Society of Allergy and Immunology, Amman, Jordan, May, 2005

Speaker, "Emerging Technologies: Vaccines for Cervical Cancer," 2nd Annual Gynecologic Malignancies Conference, New York, NY, April 2005,

Speaker, "Prophylactic Vaccines for Cervical Cancer," 2005 Global Cancer Conference, Dublin, Ireland, March, 2005

Keynote Lecture, Roche 3rd Middle East Oncology Conference, Dead Sea, Amman, Jordan, February, 2005

Prior to 2004

Speaker, "Cancer Immunology and Immunotherapy," Advances in Cancer Therapeutic Targeting and Genetics Session. The First National Cancer Institute/King Hussein Cancer Center International Oncology Conference, April, 2004

Speaker, Cervical Cancer Educational Session, "HPV Vaccine for Cervical Cancer," American Society for Clinical Oncology (ASCO) 38th Annual Meeting, Orlando, Florida, May, 2004

Post-graduate Course on Immune Therapy against Cervical Cancer, Society of Gynecologic Oncology Annual Meeting, San Diego, California, February, 2004

Speaker, "Immune Therapy against Ovarian Cancer," Ovarian National Coalition, San Diego, California, February, 2004

Speaker, "Frontiers in Medicine Conference," National Academy of Sciences, Istanbul, Turkey, September, 2003

Grand Rounds, "Vaccines for Gynecologic Malignancies," Wayne State University Medical Center, Detroit, MI, June, 2003

Medical Grand Rounds, "Cancer Vaccine Development for Solid Tumors," Medical College of Ohio, Toledo, OH, May, 2003

Post-graduate Course on Vaccine Development against Gynecologic Malignancies, Society of Gynecologic Oncology Annual Meeting, New Orleans, Louisiana, February, 2003

Speaker, "Immune Therapy against Ovarian Cancer," Ovarian National Coalition, New Orleans, Louisiana, February, 2003

Speaker, "Oncogene-based Cancer Vaccine Development," University of Illinois Pharmacy College, Chicago, Illinois, October, 2002

Speaker, "Peptide-based Vaccines in Breast Cancers," International Breast Cancer Congress, Paradise Island, Bahamas, August, 2002

Speaker, "Proteomics Application for Cancer Vaccine Development," Gynecologic Oncology Group Biannual Meeting Scientific Session, Vancouver, Ohio, July, 2002

Speaker, "Immunotherapy of Solid Cancer," Tegerensee Immunology Conference, Tegerensee, Germany, July, 2002

Speaker, "HPV Vaccine for Cervical Cancer," Cervical Cancer Educational Session, American Society for Clinical Oncology (ASCO) 38th Annual Meeting, Orlando, Florida, May, 2002

Keynote Lecture, "Updates on the Development of Immune Therapy for Cancer," Middle East Medical Association Biannual Conference, Beirut, Lebanon, May, 2002

Grand Rounds in Internal Medicine, University of Mississippi, November, 2001

Cellular Immunotherapy of Cancer Symposium, The Norwegian Radium Hospital, Oslo, Norway, October, 2001

The Third Jordanian International Oncology Conference, Amman, Jordan, September, 2001

Grand Rounds, Department of Obstetrics and Gynecology, "Human Papillomavirus Vaccine and its Implications," Temple University, West Pennsylvania Hospital, Pittsburgh, Pennsylvania, August, 2001

Lecture, "HPV Vaccines for Cervical Malignancies," Gynecologic Oncology Group Biannual Meeting Scientific Session, Cincinnati, Ohio, July, 2001

Visiting Professor for a Course on Vaccinology, "Cancer Vaccine," Center for Vaccine Development, University of Maryland, Baltimore, Maryland, May, 2001

Grand Rounds in Internal Medicine, "Vaccine: (taking a shot) at Cancer," Naval Hospital Bethesda, Bethesda, Maryland, April, 2001

Lecture, "Immunotherapy of Cancer," University of Paris, 4^{emes} rencontres Franco-Américains en endocrinologie au Center Hospitalier at Universitaire de Bobigny, February, 2001

Plenary Session, "Cervical Cancer: HPV and New Therapies," The Fourth UAE International Cancer Conference, Abu-Dhabi, United Arab Emirates, January, 2001

Grand Rounds, Mayo Clinic Oncologic Society Monthly Lecture Series, Mayo Clinic, Rochester Minnesota, November, 2000

Lecture, "Novel Therapies," Ovarian Cancer National Alliance Third Annual Advocacy Conference, Washington, District of Columbia, September, 2000

Medical Grand Rounds, University of Rochester, Rochester, New York, May, 2000

Special Lecture, Third Pan-Arab Cancer Conference, Beirut, Lebanon, April, 2000

Visiting Professor, "Tumor Immunology and Therapeutic Development," Department of Immunology and Molecular Biology, University of Texas at Galveston, Galveston, Texas, March, 2000

Qatar Cancer Society International Meeting, Doha, Qatar, November, 1999

Cancer Center Grand Rounds, "Oncogene-Directed Cancer Vaccines," Northwestern University, Chicago, Illinois, October, 1999

Grand Rounds, "Cancer Vaccines, a Targeted Therapy against Oncogenes," Roswell Park Cancer Institute, Buffalo, New York, July, 1999

Cancer Center Inaugural Grand Rounds: "Oncogene-Derived Vaccines: Integrating Cancer Genetics and Immunology," University of Indiana, Indianapolis, Indiana, July, 1999

Symposium in honor of Dr. Gianni Bonadonna, "Cancer Genetics and Therapeutic Application," Salem Cancer Institute, Rome, Italy, June, 1999

Grand Rounds in the Department of Obstetrics and Gynecology, "Immunotherapy in Gynecologic Malignancies, HPV and Others," University of Texas at Galveston, Galveston, Texas, May, 1999

Grand Rounds in Medical Oncology, "Cancer Vaccine Development," University of Texas at Galveston, Galveston, Texas, May, 1999

Lecture, "Promising Avenues of Cancer Research: From Bench to Bedside," Society of Gynecologic Oncology Annual Meeting, San Francisco, California, March, 1999

Lecture, "Oncogenes: Targets for Vaccine Development," Massachusetts General Hospital Cancer Center, Harvard Medical School, Boston, Massachusetts, January, 1999

Lecture, "Vaccines, a targeted approach to cancer therapy," First International Cancer Conference on the Biology of Cancer Therapy, United Arab Emirates, November, 1998

Lecture, "Identifying New HPV Immunogenic Antigens," Strategy-Planning Meeting on Cervical Cancer and HPV Vaccine, organized by CTEP, Baltimore, Maryland, September, 1998

Organizer and invited speaker, Second Arab-International Oncology Conference, Amman, Jordan, June, 1998

Lecture, "Cervical Cancer Vaccines, New Therapy under Development," Gynecologic Oncology Department Seminar, Walter Reed Medical Center, Washington, District of Columbia, September, 1997

Grand Rounds, Al-Amal Cancer Center, "New Strategies in Cancer Management," Amman, Jordan, July, 1997

Lecture, "Immunotherapy of Cancer," American Cancer Convention, Damascus, Syria, June, 1997

Lombardi Cancer Center Grand Rounds, "Cancer Vaccine Development," Georgetown University Medical School, Washington, DC, May, 1997

Grand Rounds, "Oncogene-Derived Cancer Vaccines," University of Maryland, Center for Vaccine Development, Baltimore, Maryland, April, 1997

Grand Rounds in Medicine/Surgery, "The Genetics of Immune System," Berkshire Medical Center University of Massachusetts, Pittsfield, Massachusetts, April, 1997

Medical Grand Rounds, Medical College of Ohio, Toledo, Ohio, October, 1996

Professional Societies

American Society of Clinical Investigation
American Association of Immunology
Society for Immunotherapy of Cancer
American Society of Clinical Oncology
American Association for Cancer Research
American Association for the Advancement of Science
International Society of Human Papillomavirus

Editorial Boards

Journal of Translational Medicine
Molecular Cancer Therapeutics

Journal of Immunotherapy of Cancer (JITC)
Journal of Immune Research
Journal of Cancer and Cure
Gavin Journal of Oncology Research and Therapy
Journal of Immunization
Journal of Cancer Studies and Therapy
International Journal of Virology studies and Research

Selected Journal Reviewer

Archives of Dermatology, Blood, Cancer, Cancer Research, Cancer Immunology Research, Cancer Immunology and Immunotherapy, Clinical Cancer Research, Clinical Immunology, Cytotherapy Gynecologic Oncology, Journal of Clinical Investigation, Journal of Immunotherapy, Journal of Immunotherapy of Cancer, Journal of Immunology and Immunotherapy, Journal of the National Cancer Institute, Journal of Virology, Nature, Nature Medicine, Molecular Cancer Therapeutics, New England Journal of Medicine, Oncoimmunology, Oncotargets, Oncogene, Science Translational Medicine, Veteran Administration Special Grants' Reviewer

Principal Investigator: Clinical Protocols

Active/approved:

Investigator Initiated Clinical Trial:

1. A Phase I Study of NLG-919, a Novel IDO Inhibitor, for Adult Patients with Recurrent Advanced Solid Tumors, PI Initiated, **Principal Investigator**
2. A Pilot Study to Test the Feasibility of the Combination of Gemcitabine and anti-PD1 monoclonal antibody (CT-011) in the Treatment of Resected Pancreatic Cancer, PI Initiated, **Principal Investigator**
3. A Pilot Study to Test the Feasibility and Immunologic Impact of Sipuleucel-T (ProvengeTM) Administered With or Without Anti-PD-1 mAb (CT-011) and Low Dose Cyclophosphamide in Men with Advanced Castrate-Resistant Prostate Cancer, PI Initiated, **Principal Investigator**
4. A Phase I/II Trial of Durvalumab in combination with AZD5363 in patients with solid tumors and extension in advanced NSCLC and cervical cancer. PI Initiated, **Principal Investigator**
5. A Phase I/II Trial of Stereotactic Body Radiation Therapy (SBRT), Durvalumab and Tremelimumab in patients with locally advanced and metastatic pancreatic cancer
6. A Phase I/II Study of the combination of Traztuzumab and Durvalumab in adults with her 2+ breast cancer, PI Initiated, **Principal Investigator**
7. A Phase I Trial of Pembrolizumab and poly ICLC in patients with microsatellite repair proficient colon cancer, PI Initiated, **Principal Investigator**
8. A Phase II Trial of Chemo-radiation in combination with Pembrolizumab in patients with locally advanced cervical cancer, PI Initiated, **Principal Investigator**
9. A Phase IB Trial of Pembrolizumab and Idelalisib in patients with non-small cell lung cancer (NSCLC), PI Initiated, **Principal Investigator**

National Clinical Trial, International PI

10. A Phase I/II Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Durvalumab and Tremelimumab in Combination with Platinum or Taxane Based Standard First Line Chemotherapy in Patients with Advanced Solid Tumors, **International Coordinator**
11. A Phase IIa, Open-Label, Multi-Center, Multi-Cohort, Immune-Modulated Study of Selected Small Molecules (Gefitinib, AZD9291, or Selumetinib + Docetaxel) or a 1st Immune-Mediated Therapy (IMT; Tremelimumab) with a Sequential Switch to a 2nd IMT (MEDI4736) in Patients with Locally Advanced or Metastatic Non-Small-Cell Lung Cancer (Stage IIIB-IV), **International Coordinator**

National Clinical Trial, Institutional PI

12. A Phase 1, Open-Label, Multiple-Ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of MSB0010718C in Subjects with Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications
13. A Phase 1 / 2 Study of the Concomitant Administration of Indoximod plus Ipilimumab for Adult Patients with Metastatic Melanoma

14. A Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of MEDI4736 in Subjects with Advanced Solid Tumors, **Principal Investigator**
15. MediD4880 Mesothelioma Anti-CTLA-4. A Phase 2b Randomized, Double-blind Study Comparing Tremelimumab to Placebo in Second or Third-line Treatment of Subjects with Unresectable Pleural or Peritoneal Malignant Mesothelioma, **Principal Investigator**
16. A Phase 1 / 2 Study of the Concomitant Administration of Indoximod plus Ipilimumab for Adult Patients with Metastatic Melanoma
17. An Open-Label, Phase 1, Dose Escalation Study of MLN2480 in Patients With Relapsed or Refractory Solid Tumors Followed by a Dose Expansion Phase in Patients With Metastatic Melanoma
18. AGS-003-007; An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT) 2/26/2014 – 7/15/2015; closed to accrual
19. D4193C00001; A Phase II, Multi-Center, Single-Arm, Global Study of MEDI4736 Monotherapy in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN) 6/24/2015 – current; open to accrual
20. D4193C00003; A Phase II, Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy, Tremelimumab Monotherapy, and MEDI4736 in Combination with Tremelimumab in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN) 7/8/2015 – current; open to accrual
21. 0761-012; Phase 1 Study of Mogamulizumab (KW-0761) in Combination with MEDI4736 and Mogamulizumab in Combination with Tremelimumab in Subjects with Advanced Solid Tumors pending to be opened
22. GO29779; A Phase Ib, Open-Label, Dose-Escalation Study of the Safety and Pharmacology of GDC-0919 Administered With MPDL3280A in Patients With Locally Advanced or Metastatic Solid Tumors pending to be opened

Completed

1. Adjuvant vaccine therapy and detection of immunologic responses with tumor specific mutated Ras peptides in adult cancer patients with solid tumors (Completed). **Principal Investigator**
2. Vaccine therapy and detection of immunologic responses with Human Papillomavirus 16 E6 and E7 peptides in patients with metastatic or locally advanced cervical cancer and other cancers carrying the HPV (Completed). **Principal Investigator**
3. Vaccine therapy with tumor specific mutated p53 or Ras peptides alone or in combination with cellular immunotherapy with Peptide Activated Lymphocytes (PAL cells) along with subcutaneous IL-2 (Completed). **Principal Investigator**
4. Vaccine therapy with tumor specific mutated Ras peptides and IL-2 or GM-CSF for adult patients with solid tumors (Completed). **Principal Investigator**
5. Vaccine therapy with tumor specific mutated VHL peptides in adult cancer patients with Renal Cell Carcinoma (Completed). **Principal Investigator**
6. Vaccine therapy with tumor specific p53 peptides in adult patients with advanced adenocarcinoma of the Breast. **Principal Investigator**

7. Vaccine therapy with tumor specific p53 peptides in adult patients with low burden adenocarcinoma of the ovary. Gynecologic Oncology Group, Protocol Gynecologic Oncology Group (GOG) 9910 (Completed). **Principal Investigator**
8. A phase II randomized study of vaccination with two different doses of hsp-E7 fusion protein in women with advanced cervical cancer. Gynecologic Oncology Group, Protocol GOG 196 (GOG Approved) **Principal Investigator**
9. A Pilot Trial of a Multivalent VEGFR2 Peptide Vaccine in Adults with Metastatic Renal Cell Carcinoma. (Approved) **Principal Investigator**
10. Targeting HPV16/18 E2 as a vaccine against HPV mediated CIN1 and CIN2. Gynecologic Oncology Group, Protocol GOG-DTM 00817. (GOG Approved) **Principal Investigator**
11. An Open-Label, Phase 1, Dose Escalation Study of MLN2480 in Patients With Relapsed or Refractory Solid Tumors Followed by a Dose Expansion Phase in Patients With Metastatic Melanoma
12. Medi-565 CP216 - A Phase 1 Open-label Study to Evaluate the Safety, Tolerability, and Antitumor Activity of MEDI-565 in Adults with Gastrointestinal Adenocarcinomas, Principal Investigator

Principal Investigator on Translational Protocols

- Serum proteomics profiling in advanced patients with advanced cervical cancer (Gynecologic Oncology Group (GOG) Protocol (GOG 8006)
- Serum proteomics profiling in patients with advanced ovarian cancer, Co-investigator Gynecologic Oncology Group protocol.

BIBLIOGRAPHY

Book Editor

1. Tumor Immunology and Cancer Vaccines. **Samir Khleif** (Ed.), Kluwer Academic Publishers, Boston, USA, 2005.
2. Handbook of Cancer Chemotherapy. **Skeel & Khleif** (Eds.), Eighth Edition, Walter Kluwer/Lippincott Williams & Wilkins, USA, 2011.
3. Skeel's Handbook of Cancer Therapy, **Khleif, Skeel & Rixe** (Eds.), Ninth Edition, Walter Kluwer/Lippincott Williams & Wilkins, USA, 2016.
4. Handbook of Immunotherapy of Cancer, **Khleif, Hodi, Berzofsky** (Eds), First Edition, Wolter Kluwer/Lippincott Williams & Wilkins, USA, *in preparation*
5. Immunotherapy of Gynecologic Oncology, **Khleif, Finn, Koucos, Odunsi and Melief** (Eds), First Edition, Springer, USA, *in preparation*

Publications

1. **Khleif SN**, Myers T, Carter BJ, Trempe JP. Inhibition of cellular transformation by the adeno-associated virus rep gene. *Virology* 181(2): 738-741, 1991.
2. **Khleif SN** and Skeel RT. Carcinoma of the thyroid and adrenal gland. In: Skeel RT (Ed.), Handbook of Chemotherapy (3rd ed.), Boston, Little, Brown and Co., 1991.
3. **Khleif SN** and Curt GA. Animal models in cancer drug discovery and development. In: Holland JF, Frei E, Bast RC, Kufe DW, Morton DL, Wechselbaum RR (Eds). Cancer Medicine (3rd ed.), Philadelphia, Lea and Febiger, pp. 653-666, 1993.
4. Sartor O, Cooper MR, **Khleif SN**, Myers CE. Suramin decreases circulating levels of insulin-like growth factor-I. *American Journal of Medicine*, 90(4): 390, 1994.
5. Otterson GA, **Khleif SN**, Chen W, Coxon AB, Kaye FJ. CDKN2 gene silencing in lung cancer by DNA hypermethylation and kinetics of p16^{INK4} protein induction by 5-aza 2'deoxyctidine. *Oncogene*, 11, 1211-16, 1995.
6. **Khleif SN**, DeGregori J, Yee C, Otterson GA, Kaye FJ, Nevins JR, Howley PM. Inhibition of Cyclin D-CDK4/CDK6 activity is associated with an E2F mediated induction of CKI activity. *Proceedings of the National Academy of Science*, 93(9): 4350-4354, 1996.
7. Kashanchi F, **Khleif SN**, Duvall JF, Sadaie MR, Radonovich MF, Cho M, Martin M, Chen SY, Weinmann R, Brady JN. Interaction of Human Immunodeficiency Virus Type 1 Tat with a unique site of TFIID inhibits negative cofactor Dr1 and stabilizes TFIID/TFIIA complex. *Journal of Virology* 70 (8): 5503-5510, 1996.
8. Bernstein S and **Khleif SN**. Investigational Therapies: Vaccine therapy for patients with metastatic or locally advanced cervical cancer. *Gynecologic Oncology Nursing*, 6 (3); 16-18, 1996.
9. **Khleif SN**. Exploring the Biologic Treatment of Human Cancer, Cover Story, *Internal Medicine*, 17(10), 89-104, 1996.
10. **Khleif SN**. Carcinoma of thyroid and adrenal gland. In: Skeel RT and Lachant N (Eds). Handbook of Chemotherapy (4th ed.), Boston, Little Brown and Co., pp. 335-352, 1996.

11. **Khleif SN** and Curt GA: Animal models in cancer drug discovery and development. In: Holland JF, Frei E, Bast RC, Kufe DW, Morton DL, Weschselbaum RR (Eds.). *Cancer Medicine* (4th ed.), Philadelphia, William and Wilkins, pp. 855-868, 1996.
12. Kaye FJ, Chen W, **Khleif SN**, Otterson GA. Lung Cancer, molecular and cellular abnormalities. In: Bertino JR (Ed.), *Molecular Biology of Cancer*, Academic Press Inc., San Diego, CA, pp. 1004-1014, 1996.
13. Kashanchi F, Araujo J, Doniger J, Muralidhar S, **Khleif SN**, Mendelson E, Thompson J, Azumi N, Brady J, Luppi M, Torelli G, Rosenthal LJ. Human Herpesvirus type 6 (HHV-6) ORF-1 transactivating gene exhibits malignant transforming activity, is detected in human angioimmunoblastic lymphadenopathy, and its protein binds to p53. *Oncogene*, 14: 359-367, 1997.
14. **Khleif SN**. Urologic Implications of Cancer Vaccines. Invited author, *Contemporary Urology*, 9 (4): 53 - 65, 1997.
15. Chen WD, Otterson GA, Lipkowitz S, **Khleif SN**, Coxon AB, Kaye FJ. Apoptosis is associated with cleavage of a 5-kDa fragment from Rb which mimics dephosphorylation and modulates E2F binding. *Oncogene*, 14(10): 1243-8, 1997.
16. Otterson GA, Chen W, Coxon AB, **Khleif SN**, Kay FJ. Incomplete penetrance of familial retinoblastoma linked to germ-line mutations that result in partial loss of Rb function. *Proceedings of the National Academy of Science*, 94 (9): 2888, 1997.
17. Abrams SI, **Khleif SN**, Bergmann-Leitner ES, Cantor J, Chang Y, Hamilton JM, Schlom J. Generation of stable CD4+ and CD8+ T cell lines from patients immunized with mutated Ras oncogene-derived peptides reflecting codon 12 mutations. *Cell Immunology*, 182, 137 - 151, 1997.
18. Chu E, Copur SM, Ju J, Chen T, **Khleif SN**, Voeller DM, Mizunuma N, Patel M, Maley GF, Maley F, Allegra CJ. Thymidylate Synthase Protein and p53 mRNA Form an *in vivo* Ribonucleoprotein Complex. *Molecular Cell Biology* 19(2), 1582-94, 1999.
19. **Khleif SN**, Abrams SI, Hamilton JM, Bergmann-Leitner E, Chen A, Bastian A, Bernstein S, Chung Y, Allegra CJ, Schlom J. A phase I vaccine trial with peptides reflecting *ras* oncogene mutations of solid tumors, *Journal of Immunotherapy* 22(2): 155-65, 1999.
20. **Khleif SN**. Carcinoma of thyroid and adrenal gland. In: Skeel RT (Ed.). *Handbook of Chemotherapy* (5th ed.), Philadelphia, Lippincott, Williams and Wilkins, pp. 335-352, 1999.
21. **Khleif SN** and Curt GA. Animal models in developmental therapeutics. In: Holland JF, Frei E, Bast RC, Kufe DW, Pollock R, Weichselbaum RR (Eds.). *Cancer Medicine* (5th ed.), B.C. Decker Inc. Hamilton, Ontario Canada. pp. 573-584, 2000.
22. Maher EV, Worley SB, Contois D, Smith C, Kelley MJ, Stipanov M, **Khleif SN**, Goletz T, van den Broke L, Mackall C, Helman LJ, Carbone DP, Berzofsky JA. Mutant Oncogene and Tumor Suppressor Gene Products and Fusion Proteins Created by Chromosomal Translocation as Targets for Cancer Vaccines. In *Peptide-based Cancer Vaccines*. Kast WM (Ed.) Landes Bioscience, Austin. Chapter 2, pp. 17-39, 2000.
23. McBride AA and **Khleif SN**. Strategies for the Treatment of Cervical Cancer. *International Antiviral News*, 8: 113-117, 2000.
24. **Khleif SN** and Frederickson H. The Role of Vaccines in Cancer Prevention. In: Bergan R, (Ed.) *Cancer Chemoprevention*. Kluwer Academic Publishers, pp. 283-306, 2001.

25. Simon RM, Steinberg SM, Hamilton M, Hildesheim A, **Khleif SN**, Kwak LW, Mackall CL, Schlom J, Topalian SL, Berzofsky JA. Clinical Trial Designs for the Early Clinical Development of Therapeutic Cancer Vaccines, *Journal of Clinical Oncology* 19(6): 1848 - 54, 2001.
26. Wojtowicz M, Khong H, **Khleif SN**. Cervical Cancer. In Abraham & Allegra (Eds). Handbook of Clinical Oncology. Philadelphia, Lippincott, Williams and Wilkins. pp. 211- 223, 2001.
27. Wojtowicz M, Khong H, **Khleif SN**. Uterine Corpus Cancer. In Abraham & Allegra (Eds). Handbook of Clinical Oncology. Philadelphia, Lippincott, Williams and Wilkins. pp. 225- 230, 2001.
28. Wojtowicz M, Khong H, **Khleif SN**. Vulvar Cancer. In Abraham & Allegra (Eds). Handbook of Clinical Oncology. Philadelphia, Lippincott, Williams and Wilkins. pp. 203- 209, 2001.
29. **Khleif SN** and Takimoto CH. Preclinical drug development. In: Atkinson AJ. Principles of Clinical Pharmacology, Academic Press, pp. 373-387, 2001.
30. **Khleif SN** and Lucci JA. III. Oncogenes as Targets for Cancer Vaccines. In: Rak J (Ed.), Oncogene-Directed Therapies, Humana, 2002.
31. **Khleif SN**. Human Papilloma Virus Vaccine in Cervical Cancer. In American Society for Clinical Oncology (ASCO) Spring Educational Book, 2002.
32. Agrawal M and **Khleif SN**. Neurologic Emergencies. In: Johnston P (Ed.) Oncologic Emergencies, Oxford University Press, 2002.
33. Khleif, S.N., Human papillomavirus therapy for the prevention and treatment of cervical cancer, *Curr Treat Options Oncol*; 4(2)111-9, April 2003
34. Skeel R, **Khleif SN**. Biologic and Pharmacologic Basis of Cancer Chemotherapy. In: Skeel RT, Handbook of Chemotherapy (6th ed.), Philadelphia, Lippincott, Williams and Wilkins, pp. 1-45, 2003.
35. **Khleif SN**. Abu-Labdeh H., Carcinoma of thyroid and adrenal gland. In: Skeel RT, Lachant NA (Eds.). Handbook of Chemotherapy (6th ed.), Philadelphia, Lippincott, Williams and Wilkins, pp. 335-352, 2003.
36. **Khleif SN**. Biologic Therapy for Gynecologic Malignancies. In: Gershinson, DM, McGuire WP, Gore M, Quinn MA, Thomas G (Eds). Gynecologic Cancer: Controversies in Management, pp. 935 – 968. Elsevier Churchill Livingstone, 2004.
37. **Khleif, S.N**. Human Papilloma Virus Vaccines. In American Society for Clinical Oncology (ASCO), Spring Educational Book, 2005.
38. Dong Y, Qian J, Ibrahim R, Berzofsky J, **Khleif SN**. Identification of H-2Db-specific CD8+ T-cell epitopes from mouse VEGFR2 that can inhibit angiogenesis and tumor growth. *J Immunother*. 29(1):32-40, Jan-Feb 2006
39. Ibrahim R, Frederickson H, Parr A, Ward Y, Moncur J, **Khleif SN**. Expression of FasL in squamous cell carcinomas of the cervix and cervical intraepithelial neoplasia and its role in tumor escape mechanism. *Cancer*, 106(5):1065-77, March 2006
40. Qian J, Dong Y, Pang YY, Ibrahim R, Berzofsky JA, Schiller JT, **Khleif SN**. Combined prophylactic and therapeutic cancer vaccine: Enhancing CTL responses to HPV16 E2 using a chimeric VLP in HLA-A2 mice. *Int J cancer*, 118(12):3022-3029, June 2006
41. Stjernsward J, Ferris FD, **Khleif SN**, Jamous W, Treish IM, Milhem M, Bushnaq M, Al-Khateib A, Al-Shtiat MN, Wheeler MS, and Alwan A. Jordan Palliative Care

Initiative: A WHO Demonstration Project, *The Journal of Pain and Symptom Control*, May 2007

42. Toubaji A, Hill S, Terabe M, Qian J, Floyd T, Simpson M, Berzofsky JA, **Khleif SN**. The combination of GM-CSF and IL-2 as local adjuvant shows synergy in enhancing peptide vaccines and provides long term tumor protection, *Vaccine*, 1;25(31):5882-91, August, 2007.
43. Skeel R, **Khleif SN**. Biologic and Pharmacologic Basis of Cancer Chemotherapy. In: Skeel RT, (Eds.). *Handbook of Chemotherapy (7th ed.)*, Philadelphia, Lippincott, Williams and Wilkins, 2007.
44. **Khleif SN**. Abu-Labdeh H., Carcinoma of thyroid and adrenal gland. In: Skeel RT, (Ed.). *Handbook of Chemotherapy (7th ed.)*, Philadelphia, Lippincott, Williams and Wilkins. 2007
45. Samara R, **Khleif SN**. Targeting Human Papillomavirus Vaccines in the Treatment of Invasive Cancer, American Society for Clinical Oncology (ASCO) Educational Book 2007 Annual Meeting.
46. **Khleif, SN**, Q & A: Samir Khleif, *Nature Med*, 14(4):362, Apr 2008
47. Toubaji A, Ahtar MS, Provenzano M, Herrin VE, Behren R, Hamilton M, Bernstein S, Venzon D, Gause B, Marincola F, **Khleif SN**. Pilot Study of mutant ras peptide-based vaccine as an adjuvant treatment in pancreatic and colorectal cancers, *Cancer Immunology Immunotherapy*, Feb 23, 2008
48. Boyle P, Anderson BO, Andersson LC, Ariyaratne Y, Auleley GR, Barbacid M, Bartelink H, Baselga J, Behbehani K, Belardelli F, Berns A, Bishop J, Brawley O, Burns H, Clanton M, Cox B, Currow D, Dangou JM, de Valeriola D, Dinshaw K, Eggermont A, Fitzpatrick J, Forstman M, Garaci E, Gavin AT, Kakizoe T, Kasler M, Keita N, Kerr D, Khayat D, **Khleif SN**, Khuhaprema T, Knezevic T, Kubinova R, Mallath M, Martin-Moreno J, McCance D, McVie JG, Merriman A, Ngoma T, Nowacki M, Orgelbrand J, Park JG, Pierotti M, Ashton LP, Puska P, Escobar CV, Rajan B, Rajkumar T, Ringborg U, Robertson C, Rodger A, Roovali L, Santini LA, Sarhan M, Seffrin J, Semiglazov V, Shrestha BM, Soo KC, Stamenic V, Tamblyn C, Thomas R, Tuncer M, Tursz T, Vaitkiene R, Vallejos C, Veronesi U, Wojtyla A, Yach D, Yoo KY, Zatonski W, Zaridze D, Zeng YX, Zhao P, Zheng T. Need for global action for cancer control. *Ann Oncol*. 2008 Sep; 19(9):1519-21.
49. Butterfield LH*, Disis ML*, Fox BA*, Lee PP*, **Khleif SN***, Thurin M*, Trinchieri G*, Wang E*, Wigginton J*, Chaussabel D, Coukos G, Dhodapkar M, Hakansson L, Janetzki S, Kleen TO, Kirkwood J, Maccalli C, Maecker H, Maio M, Malyguine A, Masucci G, Palucka AK, Potter DM, Ribas A, Rivoltini L, Schendel D, Seliger B, Selvan S, Slingluff CL Jr, Stroncek DF, Streicher H, Wu X, Zeskind B, Zhao Y, Zocca MB, Zwierzina H, Marincola FM. A systematic approach to biomarker discovery; Preamble to "the iSBTc-FDA taskforce on Immunotherapy Biomarkers". *J Transl Med*. 2008 Dec 23;6(1):81. (***Writing Committee in alphabetical order**)
50. **Khleif SN**. Update of FDA's Critical Path Initiative. *Clin Adv Hematol Oncol*. 2009 Mar; 7(3):173-4.
51. Tahara H*, Sato M*, Thurin M*, Wang E*, Butterfield LH*, Disis ML*, Fox BA*, Lee PP*, **Khleif SN***, Wigginton JM, Ambs S, Akutsu Y, Chaussabel D, Doki Y, Eremin O, Fridman WH, Hirohashi Y, Imai K, Jacobson J, Jinushi M, Kanamoto A, Kashani-Sabet M, Kato K, Kawakami Y, Kirkwood JM, Kleen TO, Lehmann PV,

Liotta L, Lotze MT, Maio M, Malyguine A, Masucci G, Matsubara H, Mayrand-Chung S, Nakamura K, Nishikawa H, Palucka AK, Petricoin EF, Pos Z, Ribas A, Rivoltini L, Sato N, Shiku H, Slingluff CA, Streicher H, Stroncek DF, Takeuchi H, Toyota M, Wada H, Wu X, Wulfkuhle J, Yaguchi T, Zeskind B, Zhao Y, Zocca MB, Marincola FM. Emerging concepts in biomarker discovery; The US-Japan workshop on immunological molecular markers in oncology. *J Transl Med.* 2009 Jun 17; 7(1):45. (***Writing Committee**)

52. Qian J, Floyd T, Jiang Y, Ohali A, Samara R, Yang H, **Khleif SN**, Cancer Immune Escape, Manfred Schwab (ed.) *Cancer Encyclopedia*, 2nd Ed., Springer, 2009
53. Samara RN, and **Khleif SN**. HPV as a model for Development of Prophylactic and Therapeutic Cancer Vaccines. *Current Molecular Medicine*, 2009 Aug;9(6):766-73
54. Rahma O, Ashtar E, Ibrahim RA, Toubaji A, Gause B, Herrin VE, Linehan WM, Steinberg SM, Grollman F, Grimes G, Bernstein SA, Berzofsky JA, & **Khleif SN**, A pilot clinical trial testing mutant von Hippel-Lindau peptide as a novel immune therapy in metastatic renal cell carcinoma. *J Transl Med.* 2010 Jan 28;8(1):8
55. **Khleif SN**, Doroshow JH, Hait WN. AACR-FDA-NCI Cancer Biomarkers Collaborative consensus report: advancing the use of biomarkers in cancer drug development. *Clin Cancer Res.* 2010 Jul 1;16 (13):3299-318.
56. Rahma O, **Khleif SN**. Molecular Targeted Therapy. Skeel RT, Khleif SA (Eds.). *Handbook of Chemotherapy* (8th ed.), Philadelphia, Lippincott, Williams and Wilkins, 2011.
57. Lisa H. Butterfield, Mary L. Disis, **Samir N. Khleif**, Francesco Marincola: Immunology Biomarkers 2010 and Beyond: Perspectives from the iSBTc/SITC Biomarker Task Force, *J Transl Med.* 2010 Dec 7;8:130
58. Meyskens FL Jr, Curt GA, Brenner DE, Gordon G, Herberman RB, Finn O, Kelloff GJ, **Khleif SN**, Sigman CC, Szabo E; Regulatory approval of cancer risk-reducing (chemopreventive) drugs: moving what we have learned into the clinic. *Cancer Prev Res (Phila).* 2011 Mar; 4(3):311-23.
59. Butterfield LH, Palucka AK, Britten CM, Dhodapkar MV, Håkansson L, Janetzki S, Kawakami Y, Kleen TO, Lee PP, Maccalli C, Maecker HT, Maino VC, Maio M, Malyguine A, Masucci G, Pawelec G, Potter DM, Rivoltini L, Salazar LG, Schendel DJ, Slingluff CL Jr, Song W, Stroncek DF, Tahara H, Thurin M, Trinchieri G, van Der Burg SH, Whiteside TL, Wigginton JM, Marincola F, **Khleif S**, Fox BA, Disis ML. Recommendations from the iSBTc-SITC/FDA/NCI Workshop on Immunotherapy Biomarkers. *Clin Cancer Res.* 2011 May 15;17(10):3064-76
60. Mikayel Mkrtychyan, Yana G Najjar, Estella C Raulfs, Maher Y Abdalla, Raed Samara, Rinat Rotem-Yehudar, Michael Schickler, Larry Cook, **Samir N Khleif**. Anti-PD1 synergizes with vaccine and cyclophosphamide to induce potent anti-tumor effects by a novel mechanism of action. *Eur J Immunol*, 2011 [Epub ahead of print]
61. Rahma OE, **Khleif SN**. Therapeutic Vaccines for Gastrointestinal Cancers. *Gastroenterology and Hepatology.* 2011 Aug; 7 (8).
62. Fox BA, Schendel DJ, Butterfield LH, Aamdal S, Allison JP, Ascierto PA, Atkins MB, Bartunkova J, Bergmann L, Berinstein N, Bonorino CC, Borden E, Bramson JL, Britten CM, Cao X, Carson WE, Chang AE, Characiejus D, Choudhury AR, Coukos G, de Gruijl T, Dillman RO, Dolstra H, Dranoff G, Durrant LG, Finke JH, Galon J, Gollob JA, Gouttefangeas C, Grizzi F, Guida M, Håkansson L, Hege K, Herberman RB, Hodi

- FS, Hoos A, Huber C, Hwu P, Imai K, Jaffee EM, Janetzki S, June CH, Kalinski P, Kaufman HL, Kawakami K, Kawakami Y, Keilholtz U, **Khleif SN**, Kiessling R, Kotlan B, Kroemer G, Lapointe R, Levitsky HI, Lotze MT, Maccalli C, Maio M, Marschner JP, Mastrangelo MJ, Masucci G, Melero I, Melief C, Murphy WJ, Nelson B, Nicolini A, Nishimura MI, Odunsi K, Ohashi PS, O'Donnell-Tormey J, Old LJ, Ottensmeier C, Papamichail M, Parmiani G, Pawelec G, Proietti E, Qin S, Rees R, Ribas A, Ridolfi R, Ritter G, Rivoltini L, Romero PJ, Salem ML, Scheper RJ, Seliger B, Sharma P, Shiku H, Singh-Jasuja H, Song W, Straten PT, Tahara H, Tian Z, van Der Burg SH, von Hoegen P, Wang E, Welters MJ, Winter H, Withington T, Wolchok JD, Xiao W, Zitvogel L, Zwierzina H, Marincola FM, Gajewski TF, Wigginton JM, Disis ML. Defining the critical hurdles in cancer immunotherapy. *J Transl Med*. 2011 Dec 14;9(1):214.
63. Rahma OE, Ashtar E, Wieckowski E, Czystowska M, Szajnik ME, Bernstein, Herrin VE, Steinberg SM, Shams MA, Merino M, Steinberg SM, Gooding W, Visus C, Deleo AB, Wolf JK, Bell JG, Berzofsky JA, Whiteside TL, **Khleif SN**. A Gynecologic Oncology Group Phase II Trial Comparing p53 Peptide Subcutaneous Injection and Intravenous Pulsed Dendritic Cells in High-Risk Ovarian Cancer Patients, *Cancer Immunology and Immunotherapy*, *Cancer Immunol Immunother*. 2011 Sep 17. [Epub ahead of print]. 2012 Mar;61(3):373-84
64. Emens LA, Silverstein SC, **Khleif S**, Marincola FM, Galon J. Toward integrative cancer immunotherapy: targeting the tumor microenvironment. *J Transl Med*. 2012 Apr 10;10:70.
65. Galon J, Pagès F, Marincola FM, Angell HK, Thurin M, Lugli A, Zlobec I, Berger A, Bifulco C, Botti G, Tatangelo F, Britten CM, Kreiter S, Chouchane L, Delrio P, Arndt H, Asslaber M, Maio M, Masucci GV, Mihm M, Vidal-Vanaclocha F, Allison JP, Gnjatic S, Hakansson L, Huber C, Singh-Jasuja H, Ottensmeier C, Zwierzina H, Laghi L, Grizzi F, Ohashi PS, Shaw PA, Clarke BA, Wouters BG, Kawakami Y, Hazama S, Okuno K, Wang E, O'Donnell-Tormey J, Lagorce C, Pawelec G, Nishimura MI, Hawkins R, Lapointe R, Lundqvist A, **Khleif SN**, Ogino S, Gibbs P, Waring P, Sato N, Torigoe T, Itoh K, Patel PS, Shukla SN, Palmqvist R, Nagtegaal ID, Wang Y, D'Arrigo C, Kopetz S, Sinicrope FA, Trinchieri G, Gajewski TF, Ascierto PA, Fox BA. Cancer classification using the Immunoscore: a worldwide task force. *J Transl Med*. 2012 Oct 3;10:205. doi: 10.1186/1479-5876-10-205. Review.
66. Mkrtychyan M, Najjar YG, Raulfs EC, Liu L, Langerman S, Guittard G, Ozbun L, **Khleif SN**. B7-DC-Ig enhances vaccine effect by a novel mechanism dependent on PD-1 expression level on T cell subsets. *J Immunol*. 2012 Sep 1;189(5):2338-47. doi: 10.4049/jimmunol.1103085. Epub 2012 Jul 25.
67. David F Stroncek, Cornelis JM Melief, Luciano Castiello, Alessandra Cesano, Martin A Cheever, Sara Civini, Begonya Comin-Anduix, Thomas F Gajewski, Philip D Greenberg, Pawel Kalinski, Howard L Kaufman, Michael H Kershaw, **Samir N Khleif**, Francesco Marincola, William Merritt, David H Munn, Daniel J Powell, Nicholas P Restifo, Steven A Rosenberg, Raj K Puri, Howard Streicher, Aladar A Szalay, Cassian Yee, Laurence Zitvogel, Antoni Ribas. Highlights of the society for immunotherapy of cancer (SITC) 27th annual meeting. *Journal for ImmunoTherapy of Cancer* 2013, **1**:4
68. Melek Sunay, Francesco Marincola, **Samir N Khleif**, Samuel C Silverstein, Bernard A Fox, Jerome Galon, Leisha A Emens. Focus on the target: the tumor

- microenvironment, Society for Immunotherapy of Cancer Annual Meeting Workshop, October 24th-25th 2012. *Journal for Immunotherapy of Cancer* 2013, 1:9
69. Britten CM, Singh-Jasuja H, Flamion B, Hoos A, Huber C, Kallen KJ, **Khleif SN**, Kreiter S, Nielsen M, Rammensee HG, Sahin U, Hinz T, Kalinke U. The regulatory landscape for actively personalized cancer immunotherapies. *Nat Biotechnol.* 2013 Oct;31(10):880-2.
 70. Mkrtychyan M, Chong N, Abu Eid R, Wallecha A, Singh R, Rothman J and **Khleif SN** Anti-PD-1 antibody significantly increases therapeutic efficacy of Listeria monocytogenes (Lm)-LLO immunotherapy *Journal for Immunotherapy of Cancer* 2013, 1:15
 71. Yang AX, Chong N, Jiang Y, Catalano J, Puri RK, **Khleif SN**. Molecular characterization of antigen-Peptide pulsed dendritic cells: immature dendritic cells develop a distinct molecular profile when pulsed with antigen Peptide. *PLoS One.* 2014 Jan 27;9(1):e86306. doi: 10.1371/journal.pone.0086306. eCollection 2014.
 72. Osama E. Rahma, J. Michael Hamilton, Malgorzata Wojtowicz, Omar Dakheel, Sarah Bernstein, David J. Liewehr, Seth M. Steinberg and **Samir N. Khleif**. The Immunological and Clinical Effects of Mutated Ras Peptide Vaccine in Combination with IL-2, GM-CSF, or Both in Patients with Solid Tumors. *Journal of Translational Medicine* 2014
 73. Yousef Zakharia, Osama Rahma, **Samir N Khleif**. Ovarian Cancer from an Immune Perspective, *Radiat Res.* 2014 Jul 18.
 74. Zhisong Chen, Laurent Ozbun, Chong Namju, Anu Wallecha, Jay A. Berzofsky, and **Samir N. Khleif**. Episomal expression of a truncated listeriolysin O in LmddA-LLO-E7 vaccine enhances anti-tumor efficacy by preferentially inducing CD4⁺FoxP3⁺ T cell and CD8⁺ T cell expansion. *Cancer Immunol Res.* 2014 May 28. pii: canimm.0197.2013.
 75. Osama E. Rahma, J. Emily Gammoh, Richard Simon and **Samir N. Khleif**. Is the "3+3" dose escalation phase 1 clinical trial design suitable for therapeutic cancer vaccine development? A recommendation for alternative design. *Clin Cancer Res.* 2014 Jul 18. pii: clincanres.2671.2013
 76. Abu-Eid R, Samara RN, Ozbun L, Abdalla MY, Berzofsky JA, Friedman KM, Mkrtychyan M, **Khleif SN**. Selective inhibition of regulatory T cells by targeting PI3K-Akt pathway. *Cancer Immunol Res.* 2014 Jul 30. pii: canimm.0095.2014
 77. Coleman CN, Formenti SC, Williams TR, Petereit DG, Soo KC, Wong J, Chao N, Shulman LN, Grover S, Magrath I, Hahn S, Liu FF, DeWeese T, **Khleif SN**, Steinberg M, Roth L, Pistenmaa DA, Love RR, Mohiuddin M, Vikram B. The International Cancer Expert Corps: A Unique Approach for Sustainable Cancer Care in Low and Lower-Middle Income Countries. *Front Oncol.* 2014 Nov 19;4:333. 2014.
 78. Osama E. Rahma, Vincent E. Herrin, Rami A. Ibrahim, Anton Toubaji, Sarah Bernstein, Omar Dakheel, Seth M. Steinberg, Rasha Abu Eid, Mikayel Mkrtychyan, Jay A. Berzofsky and **Samir N. Khleif**. Pre-Immature Dendritic Cells (PIDC) Pulsed with HPV16 E6 or E7 Peptide are Capable of Eliciting Specific Immune Response in Patients with Advanced Cervical Cancer. *J Transl Med.* 2014 Dec 16;12(1):353.
 79. Zuzana Berrong, Shamim Ahmad, Rasha Abu Eid, Abdeljabar El Andaloussi, Tanusree Sen, Ross Stewart, Scott A Hammond, Rajeev Shrimali, Mikayel Mkrtychyan, and Samir N Khleif. Immune combinational therapy targeting OX40 andIDO

- synergistically enhances efficacy of a cancer vaccine. *J Immunother Cancer*. 2014; 2(Suppl 3): P226
80. Butterfield L, Disis M, Fox B, **Khleif SN**, Francesco, M. Preamble to the 2015 SITC Immunotherapy Biomarkers Taskforce. *Journal for ImmunoTherapy of Cancer (in press, JITC-D-15-00008)* 2015 March
 81. Rasha Abu Eid, Kevin M Friedman, Mikayel Mkrtychyan, Andrea Walens, William King, John Janik and **Samir N Khleif**. Akt 1 and 2 Inhibition Diminishes Terminal Differentiation and Enhances Central Memory CD8 T Cell Proliferation and Survival. *Oncoimmunology*. 2015 Feb 3;4(5):e1005448.
 82. Shrimali RK, Janik JE, Abu-Eid R, Mkrtychyan M, **Khleif SN**. Programmed death-1 & its ligands: promising targets for cancer immunotherapy. *Immunotherapy*. 2015 Jul;7(7):777-92. doi: 10.2217/imt.15.49. Epub 2015 Aug 7. PMID: 26250412
 83. Finn OJ, **Khleif SN**, Herberman RB. The FDA Guidance on therapeutic cancer vaccines: the need for revision to include preventive cancer vaccines or for a new guidance dedicated to them. *Cancer Prev Res*. 2015 Sep 9. pii: canprevres.0234.2015.
 84. Ascierto PA, Atkins M, Bifulco C, Botti G, Cochran A, Davies M, Demaria S, Dummer R, Ferrone S, Formenti S, Gajewski TF, Garbe C, **Khleif S**, Kiessling R, Lo R, Lorigan P, Arthur GM, Masucci G, Melero I, Mihm M, Palmieri G, Parmiani G, Puzanov I, Romero P, Schilling B, Seliger B, Stroncek D, Taube J, Tomei S, Zarour HM, Testori A, Wang E, Galon J, Ciliberto G, Mozzillo N, Marincola FM, Thurin M. Future perspectives in melanoma research: meeting report from the "Melanoma Bridge": Napoli, December 3rd-6th 2014. *J Transl Med*. 2015 Nov 30;13:374. doi: 10.1186/s12967-015-0736-1.
 85. Jiahua Qian, Tamara Floyd, Yufei Jiang, Anat Ohali, Raed Samar, Hong Yang and Samir N. Khleif, Immune Escape. *Encyclopedia of Cancer*. Manfred Schwab: Editor Springer-Verlag Berlin Heidelberg 2015
 86. Stephanie Zdanov, Magis Mandapathil, Rasha Abu Eid, Saudat Adamson-Fadeyi, Willie Wilson, Jiahua Qian, Andrea Carnie, Nadya Tarasova, Mikayel Mkrtychyan, Jay A. Berzofsky, Theresa L. Whiteside and **Samir N. Khleif**. The role of mutant Kras in conversion of conventional T cells into regulatory T cells, *Can Immunol Res*, April, 2016
 87. Rahma O, Knuk PR, **Khleif SN**. Biologic Basis of Molecular Targeted Therapy. Khleif SA, Rix O, Skeel RT, (Eds.). *Handbook of Chemotherapy (8th ed.)*, Philadelphia, Walter Kluver, 2016.
 88. Rasha Abu Eid, Ghazaleh Shoja E. Razavi, Mikayel Mkrtychyan, John Janik, **Samir N Khleif**, Old School Chemotherapy in Immunetherapeutic Combination in Cancer, A LowCost Drug Repurposed, *Cancer Immunol Res*. 2016 May;4(5):377-82. doi: 10.1158/2326-6066.CIR-16-0048. Epub 2016 May 1
 89. Kaufman HL, Butterfield LH, Coulie PG, Demaria S, Ferris RL, Galon J, Khleif SN, Mellman I, Ohashi PS, Overwijk WW, Topalian SL1, Marincola FM1. Society for immunotherapy of cancer (SITC) statement on the proposed changes to the common rule. *J Immunother Cancer*. 2016 Jun 21;4:37. doi: 10.1186/s40425-016-0142-0. eCollection 2016.
 90. Ascierto PA, Agarwala S, Botti G, Cesano A, Ciliberto G, Davies MA, Demaria S, Dummer R, Eggermont AM, Ferrone S, Fu YX, Gajewski TF, Garbe C, Huber V, **Khleif S**, Krauthammer M, Lo RS, Masucci G, Palmieri G, Postow M, Puzanov I, Silk

- A, Spranger S, Stroncek DF, Tarhini A, Taube JM, Testori A, Wang E, Wargo JA, Yee C, Zarour H, Zitvogel L, Fox BA, Mozzillo N, Marincola FM, Thurin M. Future perspectives in melanoma research : Meeting report from the "Melanoma Bridge". Napoli, December 1st-4th 2015. *J Transl Med*. 2016 Nov 15;14(1):313.
91. Hinz T, Kallen K, Britten CM, Flamion B, Granzer U, Hoos A, Huber C, **Khleif S**, Kreiter S, Rammensee HG, Sahin U, Singh-Jasuja H, Türeci Ö, Kalinke U. The European Regulatory Environment of RNA-Based Vaccines. *Methods Mol Biol*. 2017;1499:203-222.
92. Shamim Ahmad, Rasha Abu-Eid, Rajeev Shrimali¹, Mason Webb, Vivek Verma, Atbin Doroodchi, Zuzana Berrong, Raed Samara, Mikayel Mkrtychyan, **Samir N. Khleif**. Functional dichotomy of PI3K isoforms in CD4 T cells provides a strategy for selectively targeting regulatory T cells to enhance anti-tumor immunotherapy, *Cancer Research*, 2017 Apr 15;77(8):1892-1904.
93. Simmerman EL, Thomson NB 3rd, Dillard TA, Hao Z, Sadek RF, **Khleif SN**, Schroeder C. Free Lung Cancer Screening Trends Toward a Twofold Increase in Lung Cancer Prevalence in the Underserved Southeastern United States. *South Med J*. Mar;110(3):188-194, 2017
94. Gnjatic S, Bronte V, Brunet LR, Butler MO, Disis ML, Galon J, Hakansson LG, Hanks BA, Karanikas V, **Khleif SN**, Kirkwood JM, Miller LD, Schendel DJ, Tanneau I, Wigginton JM, Butterfield LH. Identifying baseline immune-related biomarkers to predict clinical outcome of immunotherapy. *Journal for ImmunoTherapy of Cancer*. 2017 May 16;5:44. doi: 10.1186/s40425-017-0243-4. eCollection 2017. Review.
95. Zhang Y, Edwards J, Williams H, Hao Z, **Khleif S**, Pucar D. Unusual Contiguous Soft Tissue Spread of Advanced Malignant Mesothelioma Detected by FDG PET/CT. *Nucl Med Mol Imaging*. 2017 Jun;51(2):178-181. doi: 10.1007/s13139-016-0425-x. Epub 2016 Jun 6.
96. Abu-Eid R, Ahmad S, Lin Y, Webb M, Berrong Z, Shrimali RK, Kumai T, Ananth S, Rodriguez PC, Celis E, Janik JE, Mkrtychyan M, **Khleif SN**. Cancer Res. Enhanced therapeutic efficacy and memory of tumor specific CD8 T cells by ex-vivo PI3K- δ inhibition. *Cancer Research* 2017 Jun 14. pii: canres.1925.2016. doi: 10.1158/0008-5472.
97. James Gulley, Jay A. Berzofsky, Marcus O. Butler, Alessandra Cesano, Bernard A. Fox, Sacha Gnjatic, Sylvia Janetzki, Shyam Kalavar, Vaios Karanikas, Samir N. Khleif, Ilan Kirsch, Peter P. Lee, Cristina Maccalli, Holden Maecker, Jeffery Schlom, Barbara Seliger, Janet Siebert, David F. Stroncek, Mafdalena Thurin, Jianda Yuan and Lisa H. Butterfield. Immunotherapy Biomarkers 2016: Overcoming the barriers. *Journal for ImmunoTherapy of Cancer* 2017, 5:29
98. Rajeev K Shrimali, Shamim Ahmad, Vivek Verma, Peng Zeng, Sudha Ananth, Rachel M Gittelman, Erik Yusko, Catherine Sanders, Harlan Robins, Scott A. Hammond, John E. Janik, Mikayel Mkrtychyan, Seema Gupta, **Samir N. Khleif**. Concurrent PD-1 blockade negates the effects of OX40 agonist antibody in a combination immunotherapy approach. *Cancer Immunol Res*. 2017 Sep;5(9):755-766. doi: 10.1158/2326-6066.17-0292
99. Rajeev Shrimali, Shamim Ahmad, Zuzana Berrong, Grigori Okoev, Adelaida Matevosyan, Ghazaleh Shoja E Razavi, Robert Petit, Mikayel Mkrtychyan, Samir N. Khleif Agonist anti-GITR antibody significantly enhances the therapeutic efficacy of

- Listeria monocytogenes-based immunotherapy, *Journal of Immunotherapy of Cancer*. 2017 Aug 15;5:64. doi: 10.1186/s40425-017-0266-x. eCollection 2017.
100. Ascierto PA, Agarwala SS, Ciliberto G, Demaria S, Dummer R, Duong CPM, Ferrone S, Formenti SC, Garbe C, Halaban R, **Khleif S**, Luke JJ, Mir LM, Overwijk WW, Postow M, Puzanov I, Sondel P, Taube JM, Thor Straten P, Stronck DF, Wargo JA, Zarour H, Thurin M. Future perspectives in melanoma research “Melanoma Bridge”, Napoli, November, *J Transl Med*. 2017 Nov 16;15(1):236. doi: 10.1186/s12967-017-1341-2.
 101. Zuzana Berrong, Mikayel Mkrtichyan, Shamim Ahmad, Rasha Abu Eid, Mason Webb, Grigori Okoev, Adelaida Matevosyan, Abdeljabar El Andaloussi, Rajeev Shrimali, Ross Stewart, Scott Hammond, John Janik, **Samir N. Khleif**. Inhibition of IDO in the microenvironment Markedly Enhances the Immune and Anti-Tumor Effect of Anti-OX40 Agonist Antibody, *Cancer Immunol Res*. 2018 Feb;6(2):201-208. doi: 10.1158/2326-6066.CIR-17-0223. Epub 2018 Jan 5.
 102. Asha Nayak-Kapoor, Zhonglin Hao, Ramses Sadek, Robin Dobbins, Lisa Marshall, Nicholas N. Vahanian, W. Jay Ramsey, Eugene Kennedy, Mario R. Mautino, Charles L. Link, Ray S. Lin, Stephanie Royer-Joo, Xiaorong Liang, Kari M. Morrissey, Sami Mahrus, Bruce McCall, Andrea Pirzkall, David H. Munn, John E. Janik, **Samir N. Khleif**, Phase Ia Study of the Indoleamine 2,3-dioxygenase 1 (IDO1) Inhibitor Navoximod (GDC-0919) in Patients with Recurrent Advanced Solid Tumors, *Journal of Immunotherapy of Cancer* 2018, 6:61
 103. Houssein A Sater, John Janik, **Samir N. Khleif**, Clinical Trial Design in Immunology in Novel Designs of Early Phase Trials for Cancer Therapeutics. 1st Edition. Ed. Shivaani Kummar, Chris Takimoto, Academic Press, May 22, 2018
 104. Tanusree Sen, Raed N Samara, Shamim Ahmad, Rasha Abu Eid, Maher Y Abdalla, Kevin M Friedman, Zuzana Berrong, Mason Webb, Bernard A Fox, Shawn M Jensen, Mikayel Mkrtichyan, **Samir N Khleif**. Akt isoform, as a single molecule, commits CD4 T cells to become T regulatory cells. (*Revising manuscript, Science Immunology*)
 105. Vivek Verma, Shamim Ahmad, Peng Zeng, Mikayel Mkrtichyan, Simon Barry, Paulo Rodriguez, John Janik, **Samir N. Khleif**. MAP Kinase Inhibition Induces Metabolic Reprogramming in CD8+ T-cells Leading to Induction of Stem Cell Memory Enhancing Anti-Tumor Potency of Adoptive Therapy and Anti-OX40 Antibody (*Submitted for Publication*)
 106. Shamim Ahmad, Mason Webb, Vivek Varma, Alpana Kumari, Sudha Ananth, Pankaj Gaur, Rasha Abu-Eid, Mikayel Mkrtichyan, John Janik, Samir N. Khleif. IL-6 regulates the balance between Th17 and Tregs through modulation of PI3K isoforms signaling, providing new targets for immunotherapy (*Submitted for Publication*)
 107. Rajeev Shrimali, Tanbir Najrana, Shamim Ahmad, Lotta Gustaffsson, Mikayel Mkrtichyan, Youcef Rustum, **Samir N. Khleif**. Methylselenocysteine enhances the therapeutic efficacy of anti-cancer vaccine by decreasing regulatory T cells through ubiquitination and proteasomal degradation of FoxP3 and T cell function (*Submitted for Publication*)
 108. S. Antonia, A. Balmanoukian, J. Brahmer, S-H. Ou, M. Hellmann, S.W. Kim, W.J. Hwu, S. Ahn, D.W. Kim, M. Gutierrez, S. Liu, P. Schöffski, D. Jäger, R. Jamal, J. Leach, G. Jerusalem, J. Lutzky, J. Nemunaitis, L. Calabro, J. Weiss, S. Gadgeel, J. Bhosle, P.A. Ascierto, M.C. Rebelatto, R. Narwal, M. Liang, Y. Gu, J. Antal, A.K.

- Gupta, **S.N. Khleif**, N.H. Segal, Clinical Activity and Tolerability of Durvalumab (MEDI4736), an Anti-Programmed Cell Death Ligand-1 (PD-L1) Antibody, in Patients with NSCLC (*Submitted for publication*)
109. Neil H. Segal, Sai-Hong Ou, Ani Balmanoukian, Matthew G. Fury, Erminia Massarelli, Julie Brahmer, Jared Weiss, Patrick Schoffski, Scott J. Antonia, Christophe Massard, Dan P. Zandberg, **Samir N. Khleif**, Feng Xiao, Marlon C. Rebelatto, Keith E. Steele, Paul B. Robbins, Natasha Angra, Xuyang Song, Shaad Abdullah, Marcus Butler, Safety and Efficacy of Durvalumab, an Anti-programmed Cell-death Ligand 1 (PD-L1) Antibody, in Patients with Head and Neck Squamous Cell Carcinoma: Results from a Phase 1/2 Expansion Cohort (*Submitted for publication*)
 110. Namju Chong, Stephanie Zdanov, Laurent Ozbun, Jay A. Berzofsky, Michiko Shimoda and **Samir N. Khleif** (*Submitted for Publication*). CD40-mediated IL-15 expression in human monocyte-derived dendritic cells is differentially regulated by the P38 MAPK and ERK pathways.
 111. Qian J, Dong Y, Hong Y, **Khleif SN**. Anti-CD40 as local adjuvant mediates the expansion of high avidity antigen-specific CD8 memory cell is IL-15 dependent (*submitted for publication*)
 112. Namju Chong, Stephanie Zdanov, Laurent Ozbun, Jay A. Berzofsky, Michiko Shimoda and Samir N. Khleif. CD40-mediated IL-15 expression in human monocyte-derived dendritic cells is differentially regulated by the P38 MAPK and ERK pathways.
 113. Qian J, Dong Y, Hong Y, **Khleif SN**. Anti-CD40 as local adjuvant mediates the expansion of high avidity antigen-specific CD8 memory cell is IL-15 dependent (*submitted for publication*)
 114. Qian J, Hong Y, Dong Y, Yuk-Ying Pang S, Jiang Y, Berzofsky JA and **Khleif SN**. A novel vaccine targeting HPV E2, an antigen expressed in pre-malignant CIN lesions (*submitted for publication*)
 115. Jiang, Y, Dong Y, Qian J, Fu YX, **Khleif SN**. Endothelial cells expressing LIGHT induce immunity against melanoma tumor (*submitted for publication*)

Selected Abstracts

1. Trempe JT, Myers T, Yang A, **Khleif SN**. Mutation analysis of the adeno-associated virus *rep* gene. Proceedings of the American Society of Virology Annual Meeting, 1990.
2. **Khleif SN**, Gazdar A, Bates SE. P-glycoprotein (Pgp) expression and function in an adrenocortical carcinoma cell line: A model for studying the normal function of Pgp. Proceedings of the American Association for Cancer Research Annual Meeting, 1991.
3. Kashanchi F, **Khleif SN**, Radonovich MF, Duvall JF, Weinmann R, Brady JN. Interaction of HIV-1 transactivator TAT with TFIID. Cold Spring Harbor, 1994.
4. Khleif SN, Kashanchi F, Weinmann R, Howley PM. Interaction of HPV 16E6 with the cellular transcription factor TFIID. Proceedings of the International Papillomavirus Meeting, 1994.
5. Otterson GA, **Khleif SN**, Chen W, Coxon AB, Kaye FJ. Induction of p16^{INK4} protein expression in lung cancer samples following treatment with the de-methylating agent 5-aza 2'deoxyctidine. Cancer Genetics and Tumor Suppressor Genes, Frederick, MD, 1995.
6. **Khleif SN**, Abrams S, Allegra C, Bastian A, Chen A, Chung Y, Hamilton JM, Morrison G, Schlom J. Vaccine therapy and detection of immunologic responses with tumor specific mutated ras peptides in adult cancer patients with solid tumors. Proceedings of the Society for Biological Therapy Annual Meeting, 1995.
7. **Khleif SN**, Behan K, Drake J, Allegra CJ, Johnston PG. Thymidylate Synthase (TS) decreases the rate of p53 degradation *in vitro*, and may interact with the p53 protein in colon carcinoma cells. Proceedings of the American Association for Cancer Research, 1996.
8. Otterson GA, Chen W, **Khleif SN**, Coxon AB, Kaye, FJ. Molecular basis for familial retinoblastoma with incomplete penetrance. Proceedings of the American Association for Cancer Research, 1996.
9. **Khleif SN**, Abrams S, Allegra C, Bastian A, Bergmann E, Chen A, Chung Y, Hamilton M, Kohler D, Morrison G, Schlom J. Induction of T-cell responses after vaccination with specific Ras mutant peptides in cancer patients. Proceedings of the American Society of Clinical Oncology Annual Meeting, 1996.
10. Abrams SI, **Khleif SN**, Bergmann-Leitner ES, Schlom J. Production of CD4+ and CD8+ cell lines from patients vaccinated with mutated Ras peptides. Society for Biological Therapy Annual Meeting, 1996.
11. **Khleif SN**, Abrams S, Allegra C, Bastian A, Bergmann E, Chen A, Chung Y, Hamilton JM, Kohler DR, Morrison G, Schlom J. The generation of CD4+ and CD8+ T cell responses from patients vaccinated with mutant ras peptides corresponding to the patient's own *ras* mutation. American Society of Clinical Oncology, Denver, CO, 1997.
12. Otterson GA, Chen W, Geradts J, Niklinska W, **Khleif SN**, Coxon AB, Kaye FJ. Characterization of FHIT protein expression and analysis of growth suppression in human cancer cells. Proceedings of the American Association for Cancer Research, 1997.
13. Chen W, Otterson GA, Lipkowitz S, **Khleif SN**, Coxon AB, Kaye FJ. Apoptosis coincides with cleavage of a 5 kDa fragment from RB which mimics dephosphorylation

and modulates E₂F binding. Proceedings of the American Association for Cancer Research, 1997.

14. Coxon AB, Ward J, Otterson GA, **Khleif SN**, Chen W, Zajac-Kaye M, Kaye FJ. Genetic analysis of a mouse model for neuroendocrine tumors. Proceedings of the American Association for Cancer Research, 1997.
15. Parr A, Drake J, Behan K, Allegra CJ, **Khleif SN**. Thymidylate synthase (TS) can partially inhibit p53 degradation and cleavage *in vitro*. Proceedings of the American Association for Cancer Research, 1998.
16. **Khleif SN**, Abrams S, Bastian A, Bergmann E, Chen A, Chung Y, Hamilton JM, Kohler DR, Morrison, Schlom J, Allegra C. A phase I trial with mutant Ras peptide vaccination of cancer patients carrying Ras mutations. The 10th NCI-EORTC Meeting, 1998.
17. Khong H, Berzofsky JA, Allegra C, Gur S, Fox B, Smith J, Urba W, **Khleif SN**. Mutant p53-specific T-lymphocytes recognize and lyse tumor cells endogenously expressing the same mutation. FDA-NCI First Conference on Tumor Vaccine Strategies, 1999.
18. Wojtowicz M, Hamilton JM, Khong H, Contois D, Bernstein SA, Cooley D, Chatfield S, Allegra CJ, Berzofsky JA, **Khleif SN**. Vaccination of Cervical Cancer Patients with Human Papillomavirus Type 16 E6 and E7 Peptides. Proceedings of the American Society of Clinical Oncology Annual Meeting, 1999.
19. Khong H, Gur S, Chun J, Allegra CJ, Berzofsky JA, **Khleif SN**. Combining co-stimulatory molecule B7.1-DNA with E7 peptide vaccination enhances the antigen's immunological effect. Proceedings of the American Association for Cancer Research, 1999.
20. Wojtowicz M, Hamilton JM, Bernstein SA, McNally D, Chatfield S, Edison M, Allegra CJ, **Khleif SN**. Phase II trial of mutant RAS peptide vaccination along with GM-CSF or IL-2 in patients with advanced solid tumors. Proceedings of the American Society of Clinical Oncology Annual Meeting, 2000.
21. Behrens RJ, Bernstein SA, Edison M, Grollman F, Hamilton JM, Herrin VE, Rucker S, **Khleif SN** (NCI, Bethesda, MD). Phase II/pilot trial of adjuvant therapy in pancreatic and colorectal cancer patients with mutant ras vaccine. Proceedings of the American Society of Clinical Oncology Annual Meeting, 2002.
22. Herrin VE, Behrens RJ, Achar MS, Monahan BP, Bernstein SA, Brent-Steel TB, Maruffi CM, Whiteside T, Wieckowski E, Berzofsky JA, **Khleif SN** (NCI, Bethesda, MD). Wild-type p53 peptide vaccine can generate a specific immune response in low burden ovarian adenocarcinoma. Proceedings of the American Society of Clinical Oncology Annual Meeting, 2003.
23. Hamilton J, Behrens RJ, Achar MS, Herrin VE, Bernstein SA, Brent-Steele TB, Yancey M, Maruffi CM, **Khleif SN** (GlaxoSmithKline, Philadelphia, PA and the National Cancer Institute, Bethesda, MD). An adjuvant phase II pilot trial of mutant Ras peptide vaccine in stage II and III pancreatic cancer and Dukes C and D colorectal cancer. Proceedings of the American Society of Clinical Oncology Annual Meeting, 2003.
24. Achar MS, Behrens RJ, Herrin VE, Bernstein SA, Brent-Steel TB, Maruffi CM, Berzofsky JA, **Khleif SN** (NCI, Bethesda, MD). Mutant Ras vaccine in advanced cancers. Proceedings of the American Society of Clinical Oncology Annual Meeting, 2003.

25. Behrens RJ, Achar MS, Herrin VE, Bernstein SA, Brent-Steel TB, Maruffi CM, Berzofsky JA, **Khleif SN** (NCI, Bethesda, MD). Phase I/II mutant P53 vaccination in advanced malignancies. Proceedings of the American Society of Clinical Oncology Annual Meeting, 2003.
26. Ibrahim RA, Achar MS, Herrin VE, Gause B, Bernstein SA, Brent-Steel TB, Maruffi CM, Berzofsky JA, **Khleif SN** (NCI, Bethesda, MD). Mutant p53 vaccination of patients with advanced cancers generates specific immunological response. Proceedings of the American Society of Clinical Oncology Annual Meeting, 2004.
27. Achar MS, Ibrahim RA, Herrin VE, Gause B, Bernstein SA, Brent-Steel TB, Maruffi CM, Berzofsky JA, **Khleif SN** (NCI, Bethesda, MD). Vaccine therapy with tumor specific mutated VHL peptides in adult cancer patients with renal cell carcinoma. Proceedings of the American Society of Clinical Oncology Annual Meeting, 2004.
28. Dong Y, Qian J, Ibrahim R, Berzofsky JA, **Khleif SN**. Synthetic peptide epitopes derived from mouse VEGFR2 inhibit tumor associated angiogenesis. American Association for Cancer Research Annual Meeting, 2005.
29. Qian J, Pang YS, Buck C, Dong Y, Berzofsky JA, Schiller J, **Khleif SN**. Induction of a CD8+ T cell response to HPV16 E2 in HLA-A2 transgenic mice. American Association for Cancer Research Annual Meeting, 2005.
30. Ibrahim R, Achar M, Herrin V, Gause B, Bernstein S, Grollman F, Contois D, Steinberg S, Berzofsky J, **Khleif SN**. Autologous PBMCs pulsed with HPV16 E6 as an immunotherapeutic agent for patients with advanced cervical cancer. American Society of Clinical Oncology Annual Meeting (ASCO), 2005.
31. Achar MS, Ibrahim R, Herrin VE, Gause B, Steinberg S, Grollman F, Rahma O, Bernstein SA, Maruffi CM, Berzofsky JA, **Khleif SN**. Pre-immature dendritic cells pulsed with human papillomavirus 16 E7 peptide vaccine in advanced cervical cancer. American Society of Clinical Oncology (ASCO) Annual Meeting 2005.
32. Toubaji A, Achar M, Herrin V, Provenzano M, Bernstein S, Brent-Steel T, Marincola F, **Khleif SN**. Immunotherapeutic role of mutant ras peptide-based vaccine as an adjuvant in pancreatic and colorectal cancer. American Society of Clinical Oncology (ASCO), Annual Meeting, 2005.
33. V. E. Herrin¹, M.S. Achar, S.M. Steinberg, T.L. Whiteside, E. Wieckowski, M. Czystowska, C. Visus, J.A. Berzofsky, **S.N. Khleif**. A randomized phase II p53 vaccine trial comparing subcutaneous direct administration with intravenous peptide-pulsed dendritic cells in high risk ovarian cancer patients. American Society of Clinical Oncology (ASCO), Annual Meeting Chicago, IL, 2007.
34. Moujahed S. Achar, Antoun Toubaji, Vincent E. Herrin, Michael Hamilton, Barry Gause, Seth Steinberg, Frank Grollman, Sarah Bernstein & **Samir N. Khleif** Phase II clinical trial of mutant Ras vaccine peptide in combination with GM-CSF and IL-2 in advanced cancer patients. American Society of Clinical Oncology (ASCO), Annual Meeting Chicago, IL, 2007.
35. Mikayel Mkrtichyan, Yana G. Najjar, Estella C. Raulfs, **Samir N. Khleif**. Defining a novel mechanism of α -PD1 synergy with vaccine to induce potent anti-tumor effects, MRS-AACR Conference on Metastasis and the Tumor Microenvironment, Philadelphia, PA, 2010.
36. Maher Abdalla, Raed Samara, **Samir Khleif**, Foxp3 protein is regulated by the Akt isoforms. 2nd American Association for Cancer Research (AACR)'s Dead Sea

- Conference” International Conference on Advances in Cancer Research: From the Laboratory to the Clinic in Jordan,” Dead Sea, Jordan, March, 2010.
37. Raed N Samara, Yujun Dong, Jiahua Qian, Yufei Jiang, Maher Y Abdalla, **Samir N Khleif**. Inhibition of PI3K-Akt axis can selectively modulate signaling in regulatory T cells for the lack of ZAP-70 and ERK1/2 signaling. Keystone Symposia, Breckenridge, CO, 2010.
 38. Samara RN, Dong Y, Abdalla MY, Mkrtychyan M, Ozbun L, Jiang Y, Qian J, **Khleif SN**. CD4⁺Foxp3⁺ Regulatory T cells are dependent on PI3K pathway allowing for their selective inhibition. International Society of Biologic Therapy, Washington, DC, 2010.
 39. Raed N. Samara, Maher Abdalla, Mikayel Mkrtychyan, Laurent Ozbun, **Samir N Khleif**. Role of the PI3K pathway in regulation and selective inhibition of CD4⁺Foxp3⁺ regulatory T cells. Tumor Immunology: New Perspective. American Association for Cancer Research (AACR). Miami, Florida, December 2-5, 2010
 40. Shamim Ahmad^{1*}, Mikayel Mkrtychyan¹, Rasha Abu Eid¹, Rajeev Shrimali¹, Atbin Doroodchi², Samir N Khleif¹. Functional redundancy of PI3K isoforms in conventional T cells provides a selective Treg-targeting strategy through inhibition of PI3K-delta isoform From Society for Immunotherapy of Cancer 29th Annual Meeting. National Harbor, MD, USA. 6-9 November 2014
 41. Rasha Abu Eid, Kevin Friedman, Mikayel Mkrtychyan, Samir N Khleif. AKT inhibition mitigates terminal differentiation and preserves central memory phenotype of CD8 T cells. From Society for Immunotherapy of Cancer 29th Annual Meeting. National Harbor, MD, USA. 6-9 November 2014
 42. Zuzana Berrong, Shamim Ahmad, Rasha Abu Eid, Abdeljabar El Andaloussi, Tanusree Sen, Ross Stewart, Scott A Hammond³, Rajeev Shrimali, Mikayel Mkrtychyan, Samir N Khleif¹. From Immune combinational therapy targeting OX40 and IDO synergistically enhances efficacy of a cancer vaccine Society for Immunotherapy of Cancer 29th Annual Meeting. National Harbor, MD, USA. 6-9 November 2014