Immuno-Oncology Drug Development Workshop

Hyatt Regency Washington on Capitol Hill
Columbia A&B Ballroom
Washington, DC
October 13 - 14, 2016

Workshop Co-Chairs

Maitreyee Hazarika, MD, *Medical Officer, Division of Oncology Products 2, Office of Hematology Oncology Products, Center for Drug Evaluation and Research, FDA*

Dr. Hazarika is a Senior Medical Officer in the Melanoma and Sarcoma Team in the Division of Oncology Products 2 (DOP2) of the Office of Hematology and Oncology Products (OHOP) in the Center for Drug Evaluation and Research (CDER) of the United States Food and Drug Administration (FDA). As a regulatory reviewer, she has reviewed new molecular entities for marketing approvals in solid tumors and hematological malignancies, which have included immunotherapies, targeted kinase inhibitors, immunomodulators and folate analog metabolic inhibitors. She has presented FDA review findings as a speaker at oncology drug advisory committee meetings and has authored manuscripts presenting summaries on FDA drug approvals. In addition to the regulatory experience at FDA, she has experience in global clinical drug development while an Associate Medical Director, Clinical Development at Celgene International and also provided consulting services as a subject matter expert in oncology and on regulatory and clinical aspects of pharmaceutical drug development while a Principal Consultant at Parexel Consulting. Dr. Hazarika received her MBBS and MD degrees in India and completed her internship and residency in Internal Medicine and fellowship in Medical Oncology and Hematology at the New York University School of Medicine. As a fellow, she co-authored a book chapter while active in clinical research in ovarian cancer.

Marc Theoret, MD, *Lead Medical Officer, Division of Oncology Products 2, Office of Hematology Oncology Products, Center for Drug Evaluation and Research, FDA*

Dr. Marc Theoret is a medical oncologist and in 2009 joined the FDA where he is currently serving as the Lead Medical Officer of the Melanoma/Sarcoma Team in the Division of Oncology Products 2, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research.

Dr. Theoret received his medical degree from the Penn State College of Medicine. As a medical student in the Howard Hughes Medical Institute-National Institutes of Health Medical Student Research Fellowship program, he developed and studied murine models to investigate cellular therapies for the treatment of melanoma in the Surgery Branch, National Cancer Institute (NCI). After completing an internship and residency in Internal Medicine at the Beth Israel Deaconess Medical Center, Dr. Theoret began fellowship training in Hematology/Oncology at the Medical Oncology Branch, NCI. While in fellowship, he conducted translational research in the Surgery Branch, NCI, to investigate novel immunotherapeutic strategies to treat patients with melanoma and other advanced solid tumors. He was awarded an ASCO Cancer Foundation Young Investigator Award in 2008 to support these studies.

As a Lead Medical Officer at FDA, Dr. Theoret serves as the clinical team leader of the group of primary medical officers responsible for reviewing new drugs in all stages of development for melanoma and sarcoma. In this role he also interacts with various stakeholders to provide a regulatory perspective with the goal of furthering development of new drugs in

melanoma. His regulatory research interests include evaluation of novel endpoints for development of cancer immunotherapies and novel trial designs to expedite drug development in oncology.

Suzanne L. Topalian, MD, *Member, AACR Regulatory Science and Policy Subcommittee; Professor, Surgery and Oncology, Johns Hopkins University School of Medicine; Director, Melanoma Program, Johns Hopkins Kimmel Cancer Center; Associate Director, Bloomberg-Kimmel Institute for Cancer Immunotherapy*

Dr. Topalian received her medical degree from the Tufts University School of Medicine and completed a general surgery residency at the Thomas Jefferson University Hospital in Philadelphia. She was a research fellow and then a Senior Investigator in the National Cancer Institute, NIH. She joined the Johns Hopkins faculty in 2006 to become the inaugural director of the Melanoma Program in the Kimmel Cancer Center. Dr. Topalian is a physician-scientist whose studies of human anti-tumor immunity have provided a foundation for the clinical development of cancer vaccines, adoptive T cell transfer, and immune-modulating monoclonal antibodies. Her current research focuses on manipulating "immune checkpoints" such as PD-1 in cancer therapy, discovering biomarkers predicting clinical outcomes, and developing effective treatment combinations. Dr. Topalian has been recognized for these contributions. She was named one of Nature's 10 in 2014, received the Karnofsky Award from the American Society of Clinical Oncology in 2015, was elected to the American Association of Physicians in 2016, and received the 2016 Taubman Prize for landmark discoveries in immunotherapy. Her work has opened new avenues of scientific investigation in cancer immunology and immunotherapy, and has established this treatment approach as a pillar of oncology.

Jedd D. Wolchok, MD, PhD, *Lloyd J. Old/Virginia and Daniel K. Ludwig Chair in Clinical Investigation Chief; Melanoma & Immunotherapeutics Service Director; Parker Institute for Cancer Immunotherapy at MSK; Associate Director, Ludwig Center for Cancer Immunotherapy; Member, Ludwig Cancer Research*; Professor of Medicine, Weill Medical College of Cornell University; Memorial Sloan Kettering Cancer Center

Dr. Wolchok is the Lloyd J. Old and Daniel K. Ludwig Chair in Clinical Investigation, Chief of the Melanoma and Immunotherapeutics Service, Attending Physician at Memorial Sloan-Kettering Cancer Center (MSK) with an expertise in the treatment of metastatic melanoma. He received his undergraduate degree from Princeton University and both M.D and Ph.D. from New York University, where he also fulfilled his residency program. He completed his fellowship at MSK and remained on faculty with an appointment in the Melanoma and Immunotherapeutics Service, which he now leads. Dr. Wolchok has helped establish MSK as a leader in the discovery and treatment of cancers with novel immunotherapies. Dr. Wolchok was instrumental in the clinical development leading to the approval of ipilimumab for advanced melanoma and recently designed and led a global phase 3 trial of combined checkpoint blockade for melanoma. He has been at the forefront of cancer immunotherapy, as an active clinician scientist exploring innovative immunotherapeutic strategies in laboratory models and as a principal investigator in numerous pivotal clinical trials. In 2011, he established the Immunotherapeutics Clinical Core, a specialized phase 1 outpatient unit at MSK that is focused on the conduct of novel immunotherapy trials, with a specific emphasis on pharmacodynamic biomarker identification. This group treats patients with a broad spectrum of malignancies and has become a model for similar efforts by other major cancer centers throughout the world.

Workshop Speakers and Panelists

Keaven Anderson, PhD, *Distinguished Scientist, Merck Research Laboratories*

Keaven Anderson is a Distinguished Scientist at Merck Research Laboratories and a fellow of the ASA.
He has a long history in the pharmaceutical industry and also worked at the Framingham Heart Study with the NHLBI and at the Harvard School of Public Health after receiving his PhD from Stanford University. He has designed many trials with group sequential designs, and has consulted on many designs with biomarker subgroups of interest in oncology.

David Berman, MD, PhD, *Senior Vice President and Head of Medimmune Oncology Innovative Medicines*

David Berman, M.D., PhD. is Senior Vice President and Head of Medimmune Oncology Innovative Medicines. David has spent the last 11 years developing immune-oncology therapies for a variety of cancers. Prior to joining industry, David was an attending pathologist at the National Cancer Institute of the National Cancer Institute.

A graduate of the Massachusetts Institute of Technology, David earned his Ph.D. in the laboratory of Dr. Alfred Gilman at the University of Texas Southwestern Graduate School and his M.D. from the University of Texas Southwestern Medical School. He completed his residency in anatomic pathology at the National Cancer Institute and was a pathology fellow at The Johns Hopkins Hospital.

Jan Bogaerts, PhD, *Methodology Director, EORTC*

Jan Bogaerts gained his degree in mathematics (1986) and his PhD in mathematics (1993) at the Free University of Brussels (Belgium). In 1988 he also gained a degree in management at the Free University in Brussels.

He joined BMS in 1993 as statistician. Later, as Associate Director Statistics he worked on several drugs in oncology, including several FDA and EMEA submissions.

In 2004 he joined the EORTC as statistician of the EORTC Breast Cancer Group. He now has the role of Methodology Director. He contributed to the development of RECIST and is on the RECIST Steering Committee. Another key role of his is statistician of the MINDACT trial EORTC 10041 – BIG 3-04 which has reported primary results at AACR 2016.

Current statistical interests include the use of and methodological issues around Progression Free Survival, alternative ways to use changes in tumor measurements as predictive markers, and the correct evaluation of the contribution of new markers to existing prognostic risk evaluation. He also has a high interest in closing the gap between clinical trials and day-to-day practice, and in increasing scientific learning from merging multiple data sources.

Renzo Canetta, MD, *Bristol-Myers Squibb (Retired)*

During his early years at the Istituto Nazionale Tumori in Milan, Italy (1974-1980), Dr. Canetta's focus was on clinical trials in lymphomas and gastrointestinal tumors, among others. Since joining Bristol-Myers Squibb (BMS) in 1980, Dr. Canetta has held numerous roles of increasing responsibility and leadership, including head of clinical cancer research; head of development, life cycle management; vice president, oncology global clinical research; and, finally, as vice president, global R&D oncology policy. His experience can be summarized with the introduction of 18 new BMS drugs to the general medical use (two outside of oncology) and the approval of over 50 regulatory dossiers for additional indications/formulations, including some outside of oncology. Dr. Canetta retired from BMS on August 14, 2015.

EDUCATION: Universita' degli Studi, Milan, Italy. Graduate, Medicine and Surgery (M.D.), 1976; Istituto Nazionale Tumori, Milan, Italy. State Certification, Clinical Oncology, 1977; Universita' degli Studi, Milan, Italy. Board Certification, Clinical and Laboratory Hematology, 1979.

AREA OF EXPERTISE: Cancer patient care, diagnosis and experimental treatment of hematologic malignancies and solid tumors, methodology of clinical trials, new drug development, and regulatory policy.

Daniel Chen, MD, PhD, *Vice President, Global Head of Cancer Immunotherapy Development, Genentech/Roche*

Daniel S. Chen, MD, PhD, is the Vice President, Global Head of Cancer Immunotherapy Development at Genentech/Roche. He received a BS degree in Biology from the Massachusetts Institute of Technology (1990), a PhD in Microbiology & Immunology (1996) and MD (1998) from the University of Southern California. Daniel completed an Internal Medicine Residency and Medical Oncology Fellowship at Stanford University (2003). He went on to complete a Post-doctoral fellowship with Mark Davis in Immunology, where he was a Howard Hughes Medical Institute Associate. He also ran the metastatic melanoma clinic at the Stanford Cancer Center from 2003-2006. In that time, he studied human anti-cancer immune responses pre- and post- cancer vaccination and cytokine administration to determine why anti-tumor immune responses were not more clinically effective. He received a U19 grant to develop better immunologic tools to interrogate human immune responses and ultimately patented the MHC cellular microarray to detect and functionally characterize antigen-specific T cell states. He continued as Adjunct Clinical Faculty at Stanford from 2006-2016, where he cared for melanoma patients. Since joining Genentech in 2006, Daniel has focused on the clinical development of anti-angiogenic

and immune modulatory targeted therapies in both early and late development, as well as the diagnostic tools to aid their development. He is a reviewer for Nature, Immunity and Clinical Cancer Research, co-chair of the CRI cancer Immunotherapy consortium and gave the keynote presentation at the AACR NCI EORTC Annual Meeting 2014. He has continued to publish with academic and Genentech collaborators in the field of cancer immunotherapy, including the often referenced Chen and Mellman manuscript, "Oncology meets Immunology: the Cancer-Immunity Cycle."

Tai-Tsang Chen, PhD, *Executive Director in the Department of Global Biometric Sciences, Bristol-Myers Squibb*

Dr. Tai-Tsang Chen is an Executive Director in the Department of Global Biometric Sciences (GBS) at Bristol-Myers Squibb. He had been in oncology and hematology drug development for 16 years before he became the Head of GBS in Medical and Market Access in 2015. Dr. Chen's primary research interests lie in the economic modeling and novel statistical methodology for cancer immunotherapy trials, as well as missing data problems.

David Clarke, PhD, DABT, *Drug Safety R&D Therapeutic Area Lead for Vaccines, Pfizer*

David Clarke, PhD, DABT is currently the Drug Safety R&D Therapeutic Area Lead for Vaccines, located in Pearl River, NY, supporting projects within the Vaccines Research & Early Development and Immunotherapeutics units. Previous roles at Pfizer have included Regulatory Strategy Lead within DSRD supporting primarily oncology and vaccines programs, and head of Regulatory Toxicology, Discovery Interface, and Therapeutic Area Head for Oncology within the Wyeth organization. Previous to Wyeth I held positions with Nycomed Pharma in Linz Austria, and at the Parke-Davis Research Institute, Sheridan Park, Canada. I have a PhD in Pharmacology and Toxicology from Queen's University, Kingston, Canada, am a diplomat of the American Board of Toxicology, and have over 25 years experience working within toxicology in the pharmaceutical industry.

David Feltquate, MD, PhD, *Head of Early Clinical Development – Oncology, Bristol Myers Squibb*

Dr. Feltquate is currently Head of Early Clinical Development - Oncology at Bristol Myers Squibb (BMS) focusing on the strategy, design, execution and analysis of clinical studies for new Oncology compounds. He joined the Oncology Development organization at BMS in 2006 and has held several positions of increasing responsibility. Most recently, he was the Development Lead for Ipilimumab/Nivolumab Life Cycle Management focusing on the development of both compounds in a variety of tumors including GI malignancies, GBM, HCC, GYN malignancies, and Hematologic malignancies. Prior to this, he was the Clinical Lead for nivolumab leading the clinical group in the strategy, design, execution, and analysis for the initial registrational program of nivolumab in Melanoma, RCC, and NSCLC including the first approval of an IO-IO combination (Ipi/Nivo in Melanoma).
Dr. Feltquate received his undergraduate degree in Biology from MIT and MD, PhD (Immunology) degrees from the University of Massachusetts Medical School. He conducted residency training in Internal Medicine at Dartmouth Hitchcock Medical Center where he also served as Chief Medical Resident. He received his Oncology Fellowship training at Memorial Sloan-Kettering Cancer Center with a focus in GU Oncology.

Xin (Cindy) Gao, PhD, *Statistical Reviewer, Division of Biometrics V, CDER, FDA*

Xin (Cindy) Gao earned a M.S. and Ph.D. in Biostatistics from the University of Michigan, Ann Arbor. She joined the Division of Biometrics V in CDER at FDA as a statistical reviewer in 2013. Her statistical methodology interests focus on oncology clinical trial design, surrogacy analysis, survival analysis and causal inference.

Stephanie L. Goff, MD, *Surgeon, Surgery Branch, National Cancer Institute, National Institutes of Health*

Stephanie L. Goff is a surgeon on the senior staff of the Surgery Branch of the National Cancer Institute at the NIH. Her research interests include adoptive cell therapy for the treatment of solid tumors, building on the backbone of success in patients with metastatic melanoma to investigate the strategy in patients with metastastic breast cancer. Current and recent protocols have included the administration of TIL, TCR, and CAR to treatment of patients with metastatic melanoma, lymphoma, or other epithelial cancers. After training in tumor immunology under Dr. Steven Rosenberg, she completed her General Surgery residency at Columbia University followed by a Surgical Oncology fellowship at the combined Dana-Farber/Brigham&Women's/Massachusetts General Hospital program.

Kun He, PhD, *Mathematical Statistician, Division of Biometrics V, Office of Biostatistics, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)*

Kun He is a mathematical statistician in the Division of Biometrics V, Office of Biostatistics, CDER, FDA. He received a PhD in statistics from Cornell University, and previously served on the faculties of the University of Minnesota and the University of Kansas. Since joining FDA in 1999, he has provided statistical support for the clinical division of neurology, psychiatry, and hematology and oncology. Currently, he is a statistical team leader supporting the Division of Oncology Products 2, Office of Hematology and Oncology Products.

Whitney Helms, PhD, *Pharmacology Supervisor, Pharmacology/Toxicology Team, Division of Hematology Oncology Toxicology, Division of Oncology Products 2, CDER, FDA*

Whitney Helms is the pharmacology supervisor for the pharmacology/toxicology team of the Division of Hematology Oncology Toxicology supporting the Division of Oncology Products 2 in CDER at the FDA. She started at the Agency as a pharmacologist in the Division of Drug Oncology Products following a postdoctoral fellowship at UAB where she worked on Th17 cell commitment in the laboratory of Dr. Casey Weaver. Before moving to UAB, she completed her Ph.D. in immunology at UNC-Chapel Hill working on G alpha 13 pathway signaling in T cell development and activation.

Danuta Herzyk, PhD, *Distinguished Scientist, Program Development, Immunology & Oncology Therapeutic Area Leader Department of Safety Assessment & Laboratory Animal Resources (SALAR)*

Dr. Danuta Herzyk earned her MS degree in Pharmaceutical Sciences and Ph.D. in Clinical Immunology and Biochemistry from the Medical University of Wroclaw, Poland. She was a postdoctoral fellow at the Ohio State University (with Dr. Richard Mortensen in the Department of Microbiology and Immunology from 1985-1986 and with Dr. Mark Wewers in the Department of Pulmonary and Critical Care Medicine from 1987-1991). Dr. Herzyk joined the Department of Safety Assessment at GlaxoSmithKline R&D in 1992 and overtime became a Director of Immunologic Toxicology Laboratory. Her work involved mainly immunotoxicology testing of immunomodulatory biopharmaceuticals.

In 2007, Dr. Herzyk took a position of Senior Scientific Director in the Department of Safety Assessment at Merck & Co. where her work continued in the preclinical development and safety assessment of biopharmaceuticals and vaccines. Her main role was to oversee all biologic and vaccine programs that needed support from Safety Assessment. In 2013 her role has been transitioned to the Immunology and Oncology Therapeutic Area Leader. Currently, Dr. Herzyk provides guidance and support to SALAR representatives who are core members of development teams working on Immunology as well as Oncology programs. In addition, she is a chair of Immunotoxicology Council at Merck Research Laboratories.

Dr. Herzyk is author/co-author of over 45 peer-reviewed articles and book chapters, and co-editor of two books, "Immunotoxicology Strategies for Pharmaceutical Safety Assessment" (2008) and “Nonclinical Development of Novel Biologics, Biosimilars, Vaccines and Specialty Biologics” (2013). She serves on the Editorial Board of Journal of Immunotoxicology and is an active member of Immunotoxicology Specialty Section (ITSS) and BioTechnology Specialty Section (BTSS) of the Society of Toxicology.

Axel Hoos, MD, PhD, *Senior Vice President, Therapeutic Area Head for Oncology R&D, Head of Immuno-Oncology, GlaxoSmithKline Pharmaceuticals*

Dr. Axel Hoos is Senior Vice President, Therapeutic Area (TA) Head for Oncology R&D and Head of Immuno-Oncology at GlaxoSmithKline Pharmaceuticals (GSK). In this role he leads the Oncology TA and builds the immuno-oncology portfolio of GSK across the modalities of antibodies, small molecules, bispecific molecules and cell & gene therapies, for which he directs discovery and development.

Dr. Hoos also serves as Chairman of the Board of Trustees of the Sabin Vaccine Institute (SVI), a Global Health organization, Director on the Board of Imugene, a biotech company, Co-Director of the Cancer Immunotherapy Consortium (CIC) and Scientific Advisory Board Member of the Cancer Research Institute (CRI).

His efforts in Medicines Development and Global Health focus on novel therapies for life-threatening diseases, scientific and procedural innovation, and broad collaboration across multiple constituents. Through his leadership a new paradigm for the development of cancer immunotherapies has been defined, which helped launch the field of Immuno-Oncology.

Previously, Dr. Hoos was the Global Medical Lead in Immunology/Oncology at Bristol-Myers Squibb (BMS) where he developed Yervoy (Ipilimumab), the first life-extending therapy in Immuno-Oncology. Before BMS, Dr. Hoos was Senior Director of Clinical Development at Agenus Bio (previously Antigenics), a biotech company.

Dr. Hoos holds an MD from Ruprecht-Karls-University and a PhD in molecular oncology from the German Cancer Research Center (DKFZ) both in Heidelberg, Germany. He trained in surgery at the Technical University in Munich, Germany and further in surgery, molecular pathology and tumor immunology at Memorial Sloan-Kettering Cancer Center in New York City. He is an alumnus of the Program for Leadership Development at Harvard Business School.

Kristina E. Howard, DVM, PhD, *Research Veterinary Medical Officer, Division of Applied Regulatory Science (DARS), OCP/OTS/CDER/FDA*

Kristina Howard is a scientist who directs research studies in the Division of Applied Regulatory Science, Center for Drug Evaluation and Research of the United States Food and Drug Administration. Her research focuses on evaluating the ability of humanized mouse models to better predict the safety of small and large molecule drug products in humans. She received her veterinary degree from the Virginia-Maryland Regional College of Veterinary Medicine and her doctorate degree in immunology from North Carolina State University. Prior to joining the FDA, she worked with a wide variety of animal models in research focused on immunotoxicity, viral pathogenesis and vaccine development.

Diko Kazandjian, MD, *Medical Officer/FDA-NCI Clinical Investigator, FDA Office of Hematology and Oncology Products*

Dr. Kazandjian received his undergraduate BA degree in Biology with distinction from Boston University (Summa cum laude) where his research interest was in viral oncogenesis. He remained at Boston University to receive his Medical Doctorate at which time his research focused on breast cancer. He was then commissioned as an officer in the US Air Force medical corps and completed an Internal Medicine residency at Wilford Hall Medical Center. After residency, Dr. Kazandjian remained on faculty as an active duty physician, attending internist, assistant professor, and conducted HIV-malignancy research on the role normal human genetic variation plays on HIV pathogenesis. After six years of active duty including a stent in support of Operation Iraqi Freedom as an intensivist, he continued his training at the NIH as a civilian and completed fellowships in Medical Oncology (NCI) and Hematology (NHLBI). His laboratory-based research involved understanding the role that long intergenic non-coding RNAs play in lung cancer. This was augmented by his clinical interest and patient care activities in multiple myeloma at the NCI. In the years following fellowship, he continued gaining oncology and clinical trial experience with the NCI multiple myeloma section.

He subsequently joined the FDA Office of Hematology and Oncology Products. He has represented the FDA at a number of meetings on topics including the accelerated approval of oncology drugs, breakthrough designation, and biomarkers. His particular regulatory interests include immune-therapies, and multi-arm target-based "master protocols." His clinical interest remains in multiple myeloma where he continues to be clinically active, treating patients and teaching fellows, residents, and students as an FDA-NCI Clinical Investigator where he is the principal investigator of the myeloma program under the NCI lymphoid malignancy section. His myeloma interests lie in treatment of precursor plasma cell disorders and the role of immunotherapy. He has recently been awarded grant to characterize molecularly the racial disparity seen in myeloma which he is conducting in collaboration with Memorial Sloan Kettering. Lastly, Dr. Kazandjian has been involved in a multitude of health care missions to Armenia focusing on improvement of medical oncology, education, and arranging for hematopoietic stem cell transplantation outside of Armenia.

Samir Khleif, MD, *Director, Georgia Cancer Center*

Dr. Samir N. Khleif is an internationally recognized cancer physician, scientist, administrator and educator whose diverse interests and experiences have allowed him to develop an unparalleled skillset. His medical background and research experience - which include high-profile posts at the National Cancer Institute (NCI), the King Hussein Cancer Centre, the

King Hussein Institute for Biotechnology and Cancer and the Georgia Cancer Center at Augusta University - has focused primarily on translational research and trials, with a focus on immune therapy and cancer vaccine programs. His work at NCI, for example, led to the first clinical trials in antigen-directed cancer vaccines.

As an administrator, he has a proven track record for not only leading and managing complex cancer-focused organizations, but establishing them as well. He served as Director General and CEO of the King Hussein Cancer Centre in Jordan, transforming the facility into a 'US-style' comprehensive cancer center. He also led the effort to establish and build the King Hussein Institute for Biotechnology and Cancer.

Dr. Khleif's success in program development, on a both national and international level, is well documented, as is his ability to establish and develop strong partnerships. His work with government agencies, the pharmaceutical community and aligned institutions regularly leads to groundbreaking research and care. As the Director of the Georgia Cancer Center, Dr. Khleif has attracted world-class physicians and researchers in fields such as neuro-oncology, radiation oncology, bone marrow transplant and breast cancer. He has also been instrumental in establishing a patient- and family-focused multidisciplinary team approach to clinical care.

Geoffrey Kim, MD, *Director, Division of Oncology Products1 (DOP1), OHOP, OND, CDER, FDA*

Geoff Kim is the director of the Division of Oncology Products 1 of the Office of Oncology Drug Products in the Center for Drug Evaluation and Research of the United States Food and Drug Administration. He is involved with numerous cross-center working groups, developing policies pertaining to *in vitro* companion diagnostics, combination products, and dose finding optimization strategies for oncology products. He received his bachelor's degree at UCLA, his medical degree at the New York Medical College, and completed his residency in internal medicine at the Montefiore Medical Center in the Bronx. Geoff completed his medical oncology fellowship at the National Cancer Institute where he was active in both laboratory and clinical research in the NCI molecular signaling section and the ovarian cancer clinic.

John M. Kirkwood, MD, *Usher Professor of Medicine, Dermatology & Translational Science Director, Melanoma and Skin Cancer Program, University of Pittsburgh*

Dr. John M. Kirkwood completed his MD at Yale University (1973) and postgraduate work at Yale and Harvard/Dana-Farber Cancer Institute (1978). He served as founding Associate Director for Medical Oncology at UPCI where he has directed the Melanoma and Skin Cancer Program of UPCI since 1986 and is the PI of the recently renewed Pittsburgh SPORE in Melanoma and Skin Cancer (2013-2018). He holds a T32 Training Grant for Melanoma and Skin Cancer (2014), and his research focuses upon the immunotherapy and molecular therapy of melanoma and its precursors where the role of the microbiome of the skin and the GI tract are now of interest in relation to multiple clinical trials of molecular therapeutics and immunotherapy. Dr. Kirkwood is Usher Professor of Medicine, Dermatology, and Translational Science at the University of Pittsburgh, and Senior Investigator for the University in ECOG-ACRIN and Chairman of the Melanoma Committee of ECOG-ACRIN (1989-present) and the International Melanoma Working Group (2006-present).

Alan J. Korman, PhD, *Vice President of Immuno-Oncology Discovery, Bristol-Myers Squibb*

Alan J. Korman received his Ph.D. degree from Harvard University (Cambridge, Massachusetts, USA) in 1984 and was a Whitehead Fellow at the Whitehead Institute, Massachusetts Institute of Technology (Cambridge, Massachusetts, USA) from 1984 to 1989. He was also a Chargé de Recherche at the Institut Pasteur (Paris, France) from 1990 to 1993. He has worked in the biotechnology and pharmaceutical industry since 1993 and is currently Vice President of Immuno-Oncology Discovery at Bristol-Myers Squibb (Redwood City, California, USA). He initiated the preclinical development of the checkpoint inhibitor antibodies, ipilimumab and nivolumab, as well as their combination.

Ed Korn, PhD, *Mathematical Statistician, National Cancer Institute*

Edward L. Korn, PhD, has been a statistician with the National Cancer Institute since 1989. Before that he was at the UCLA School of Medicine for 11 years where he held the title of Associate Professor. Dr Korn holds a BS degree in mathematics from the University of Maryland and a PhD degree in statistics from Stanford. He is a Fellow of the American Statistical Association and a Fellow of the AAAS, and co-winner of the 1996 B.F. and H.E. Dewel Award. He is co-author of over 200

publications including being co-author of two books. He is currently on the data safety and monitoring boards for the Southwest Oncology Group, the Alliance for Clinical Trials in Oncology, and the National Cancer Institute of Canada Clinical Trials Group. Dr. Korn is a Deputy Editor of Clinical Trials and a Statistical Editor of Journal of the National Cancer Institute, and serves on the NCI Thoracic Malignancy Steering Committee.

Nicholas Latimer, PhD, *Senior Research Fellow in Health Economics, NIHR Post-Doctoral Fellow, University of Sheffield*

Nicholas Latimer is a Senior Research Fellow in Health Economics at the School of Health and Related Research (ScHARR), University of Sheffield. He joined ScHARR in 2008, having previously worked as a health economist at NERA Economic Consulting, Queen Mary University of London (QMUL), and Roche Products Ltd.

His research expertise is in the area of survival analysis in economic evaluations – particularly the use of survival modeling techniques to extrapolate beyond clinical trial data, and the use of statistical methods for adjusting survival estimates in the presence of treatment switching. In 2012 Nick completed an National Institute for Health Research (NIHR) Doctoral Research Fellowship that focused upon these topics and in 2015 he was awarded an NIHR Post-Doctoral Fellowship to continue this research. Nick has authored two National Institute for Health and Care Excellence (NICE) Decision Support Unit technical support documents, on survival analysis (TSD 14) and the use of treatment switching adjustment methods (TSD16).

Nick has considerable experience of analyzing clinical trial data, and of conducting model-based and trial-based economic evaluation. He has led the Evidence Review Group (ERG) on NICE Technology Appraisals, has led the economic analysis on NICE Clinical Guidelines, has contributed to NICE Public Health guidelines, and has been the principal investigator on several research and consultancy projects. In 2011 Nick was invited to present his research to the NICE Methods Update Working Party, and he drafted sections on extrapolation and treatment switching for the 2013 NICE Methods Guide. He is an invited expert on the NICE Scientific Advice Programme.

Nick collaborates internationally, and has been involved in the development of technical guidance on survival analysis methods by the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia. He has links with IQWiG (Germany), the Canadian Agency for Drugs and Technologies in Health (CADTH), the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

Ke Liu, MD, PhD, *Chief of Oncology in the Office of Cellular, Tissue and Gene Therapies (OCTGT), FDA Center for Biologics Evaluation and Research; Attending Medical Oncologist, Washington Veterans Administration Medical Center*

Dr. Liu is Chief of Oncology in the Office of Cellular, Tissue and Gene Therapies (OCTGT) in FDA's Center for Biologics Evaluation and Research (CBER). This Office reviews, evaluates and approves most innovative cancer therapeutics with curative potential. Examples include chimeric antigen receptor (CAR) T-cells, dendritic cells, adoptive T cell therapies, tumor neoantigen-based personalized medicine (vaccine or cell therapy), natural killer cells, oncolytic viruses, therapeutic cancer vaccines, and combinations of these immune-oncologic therapeutics with checkpoint inhibitors and other agents. In addition, OCTGT reviews, evaluates, and approves products based on state-of-art technological platforms (e.g., gene therapies) for treatment of hematologic diseases, including coagulation disorders, anemias, immunodeficiencies and inherited metabolic disorders.

Dr. Liu is a medical oncologist and internist, certified by the American Board of Internal Medicine (ABIM). He received his M.D. from Henan Medical University in China. After working as an investigator in the National Institute of Pharmaceutical and Biologic Products (NICPBP) in China (then Chinese FDA equivalent), he moved to the United States in 1990 as a visiting scientist in the New York Blood Center, New York, NY. His research focused on the molecular biology of hepatitis C virus, leading to the publication of the first report on the genomes of Chinese HCV strains. Subsequently, he received his PhD degree in molecular biology from Cornell University Graduate School of Medical Sciences in New York City, New York.

He completed his internal medical residency training in Albert Einstein College of Medicine (Long Island campus) in New York City. In 1999, he pursued his medical oncology specialty training in National Cancer Institute (NCI), National Institutes

of Health located in Bethesda, Maryland. Upon completion of this oncology specialty training, he stayed in NCI focusing on the clinical research and development of cancer drugs and biologics.

During his tenure in National Cancer Institute, he served as associate investigators for multiple Phase 1 and 2 clinical trials investigating a variety of new cancer therapeutics. In particular, he served as protocol chairperson and was responsible for developing and conducting a Phase 1/2 clinical trial using genetically modified cells for the treatment of patients with cancer that formed the basis for a patent issued by the United States Patent and Trademark Office.

In 2003, Dr. Liu joined FDA's Center for Biologics Evaluation and Research (CBER) as a clinical reviewer and later became a lead medical officer. From 2008 to 2011, he served as a lead medical officer in FDA's Center for Drugs Evaluation and Research (CDER).

Dr. Liu is also a practicing medical oncologist and serves as an attending medical oncologist in Washington Veterans Administration Medical Center.

Timothy MacLachlan, PhD, DABT, *Global Head of Biologics Safety Assessment and Executive Director within the Department of Preclinical Safety, Novartis Institutes of Biomedical Research*

Tim MacLachlan, PhD, DABT, joined Novartis Institutes of Biomedical Research in 2010 and is currently the Global Head of Biologics Safety Assessment and Executive Director within the Department of Preclinical Safety. He is responsible for the oversight of the biologics portfolio including therapeutic proteins, monoclonal antibodies and gene and cell therapies. Prior to this Tim held roles of increasing responsibility in pharmaceutical preclinical safety assessment at Genzyme and Curagen. Tim is currently on the leadership committee and past-chair of "BIOsafe". Tim received his PhD from Thomas Jefferson University and performed his postdoctoral research at the University of Pennsylvania.

Sumithra Mandrekar, PhD, *Professor of Biostatistics and Oncology, Mayo Clinic*

Dr. Mandrekar is a Professor of Biostatistics and Oncology at Mayo Clinic, Rochester MN; and is the Associate Director of the Biostatistics Shared Resource of the Mayo Clinic Cancer Center. Her primary research interests include dose-finding trial designs for Phase I trials, designs for predictive biomarker validation (initial and definitive), and general clinical trial methodology related to identification of alternative Phase II cancer clinical trial endpoints. Her recent work in the early phase setting includes the development of a continuous toxicity score that captures information on not only severe, but also mild and moderate toxicities, both cycle 1 and from multiple cycles. Dr. Mandrekar has co-authored over 110 original papers, several book chapters and editorials, and has given numerous lectures, invited presentations and workshops on these topics. Her primary collaborative area is lung cancer and she is the faculty statistician for the NCI precision medicine trial: ALCHEMIST, a national screening trial to enroll >8000 early stage lung cancer patients. She is a voting member of the NCI thoracic malignancies steering committee and the NCI imaging steering committee, serves on the program committees of ASCO and society for clinical trials (SCT), is the co-chair for the education committee of SCT, and is the Biostatistics editor for the Journal of Thoracic Oncology.

Sirisha Mushti, PhD, *Statistical Reviewer, Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*

Sirisha Mushti is a statistical reviewer in office of Biostatistics at Center for drug evaluation and research, U.S. Food and Drug Administration. As a statistical reviewer at FDA, she is primarily involved with reviewing oncology drug related applications submitted to FDA and collaborates extensively with medical researchers on addressing statistical issues encountered in clinical trials designs. My research interests include design of clinical trials, group sequential designs, addressing multiplicity issues involved in clinical trial designs, and the emerging field of immunotherapies.
I received my Ph. D in statistics from Old Dominion University at Norfolk, Virginia in 2013 and Masters in Statistics from Central University of Hyderabad, India in 2006. After receiving Master's degree, she worked as a statistician in GSK pharmaceuticals, India.

David Porter, MD, *Jodi Fisher Horowitz Professor in Leukemia Care Excellence; Director, Blood and Marrow Transplantation, Hospital of the University of Pennsylvania*

Dr. Porter is the Jodi Fisher-Horowitz Professor of Leukemia Care Excellence at the Perelman School of Medicine and Abramson Cancer Center, and Director of the Blood and Marrow Transplantation and Cellular Therapeutics program at the Hospital of the University of Pennsylvania. He is a graduate of the University of Rochester and earned a medical degree at Brown University. He completed internship and residency at Boston University Hospital, and fellowship training at Brigham and Women's Hospital and Harvard Medical School in Boston.

He chairs or serves on numerous local, national and international committees focused on hematologic malignancies and hematopoietic stem cell transplantation. He is a member of the Board of Directors of the National Marrow Donor Program and the American Board of Internal Medicine Hematology Exam Committee. Dr Porter is a member of the American Society of Hematology, the American Society of Clinical Oncology, and the American Society of Blood and Marrow Transplantation. He has authored more than 170 research articles and book chapters, is an Associate Editor for the American Journal of Hematology and has served as a manuscript reviewer for numerous high impact medical journals. He is the recipient of several prestigious awards at the University of Pennsylvania including recognition for Professionalism and Mentorship. He is annually recognized as a "Top Doc" in Philadelphia Magazine and by Castle Connolly, and in 2007 was the recipient of the Leukemia and Lymphoma Society Service to Mankind Award.

Dr. Porter has expertise in development of novel cellular therapies, in the care of patients with hematologic malignancies including acute and chronic leukemia and in all aspects of hematopoietic SCT. He leads numerous local and national research activities. He is an accomplished clinical investigator with principal research interests in development of novel methods of cellular therapy, stem cell transplantation and allogeneic adoptive immunotherapy. Recent research highlights include the successful use of genetically modified T cells to treat B cell cancers like ALL and CLL, novel trials designed to prevent GVHD after allogeneic SCT by blocking lymphocyte trafficking, and studies to enhance graft-vs-tumor activity at the time of transplant, after non-myeloablative therapy, and for relapse after SCT.

Rodney Prell, PhD, *Principal Scientist/Toxicologist, Department of Safety Assessment, Genentech*

Rodney Prell is currently a principal scientist/toxicologist in the department of Safety Assessment at Genentech where he serves as the therapeutic area lead for cancer immunology. He received his PhD in Toxicology, specializing in immunotoxicology, from Oregon State University in 1997. He completed his post-doctoral training at Earle A. Chiles Research Institute in Portland, Oregon (1997-2001) where he studied antibody-based cancer immunotherapeutic approaches. Rod joined Genentech in 2007 and has served as a project toxicologist or team leader on over 15 biologic therapeutic candidates for infectious disease, oncology, immunology and cancer immunotherapy indications. Rod previously worked at Onyx Pharmaceutical, Cell Genesys and Cerus where he was responsible for leading nonclinical safety and pharmacology efforts using various cancer immunotherapy vaccine approaches. Rod was board certified in 2004.

Mark J. Ratain, MD, *Leon O. Jacobson Professor of Medicine, Director, Center for Personalized Therapeutics, Associate Director for Clinical Sciences, Comprehensive Cancer Center, The University of Chicago*

Dr. Ratain is a graduate of Harvard College (A.B., 1976) and Yale University School of Medicine (M.D., 1980). His postgraduate training was completed at Johns Hopkins Hospital (Internal Medicine, 1980-3) and the University of Chicago Hospitals (Hematology/Oncology, 1983-6). He has been a faculty member in the Department of Medicine at The University of Chicago since 1986, and is currently the Leon O. Jacobson Professor of Medicine, the Director of the Center for Personalized Therapeutics, and Chief Hospital Pharmacologist. In addition, he serves as the Associate Director for Clinical Sciences in the University's Comprehensive Cancer Center and leads the University of Chicago's phase I oncology trials program. Dr. Ratain's research focuses on the development of new oncology drugs and diagnostics, and he is an international leader in phase I clinical trials, pharmacogenomics, and clinical trial methodology, with over 280 original publications. He served as the first chair of the Steering Committee of the National Institutes of Health Pharmacogenetics Research Network, as well as one of the first co-chairs of the National Cancer Institute Investigational Drug Steering Committee. He currently serves as co-Editor of Pharmacogenetics and Genomics, and is a past Associate Editor of the

Journal of Clinical Oncology. He is the recipient of multiple awards, including the Research Achievement Award in Clinical Pharmacology and Translational Research from the American Association of Pharmaceutical Scientists, the Rawls-Palmer Progress in Medicine Award from the American Society for Clinical Pharmacology and Therapeutics, the Translational Research Professorship from the American Society of Clinical Oncology, a Honorary Fellowship from the American College of Clinical Pharmacology, and the Award in Clinical Excellence from the Pharmaceutical Research and Manufacturers Association Foundation.

Antoni Ribas, MD, PhD, *AACR Board Member; Professor of Medicine, Professor of Surgery, Professor of Molecular and Medical Pharmacology, University of California Los Angeles (UCLA); Director, Tumor Immunology Program, Jonsson Comprehensive Cancer Center*

Antoni Ribas, MD, PhD, is professor of medicine, professor of surgery, and professor of molecular and medical pharmacology at the University of California Los Angeles (UCLA), director of the tumor immunology program at the Jonsson Comprehensive Cancer Center (JCCC), and the chair of the melanoma committee at SWOG (formerly the Soutwest Oncology Group). He is the vice-president of the Society for Melanoma Research (SMR). Trained at the University of Barcelona, with postdoctoral research and clinical fellowships at UCLA, he is a member of the American Society of Clinical Investigation (ASCI).

Dr. Ribas is a physician-scientist who conducts laboratory and clinical research in malignant melanoma, focusing on gene engineered adoptive cell transfer (ACT) therapies, anti-CTLA4 antibodies, anti-PD-1 antibodies, BRAF and MEK inhibitors, and nanoparticle-siRNA. His NIH, State of California, and private foundation-supported research laboratory develops models of disease to test new therapeutic options and studies mechanism of action of treatments in patients.

David Rimm, MD, PhD, *Professor, Departments of Pathology and Medicine (Oncology), Yale University School of Medicine*

Dr. David Rimm is a Professor in the Departments of Pathology and Medicine (Oncology) at the Yale University School of Medicine. He is the Director of Yale Pathology Tissue Services. He completed an MD-PhD at Johns Hopkins University Medical School followed by a Pathology Residency at Yale and a Cytopathology Fellowship at the Medical College of Virginia. His research lab group focuses on quantitative pathology using the AQUA® technology invented in his lab with projects related to predicting response to therapy or recurrence in cancer. The work is supported by grants from the NIH, BCRF, and sponsored research agreements from biopharma. He also serves on the CAP Molecular Oncology committee and multiple scientific advisory boards for biotech and pharma. He is an author of over 300 peer-reviewed papers and 8 patents. He was a scientific co-founder of HistoRx, a digital pathology company (sold to Genoptix in 2012), Metamark Genetics, and Pixel Gear.

Eric Rubin, MD, *AACR Regulatory Science and Policy Subcommittee member; Vice-President and Therapeutic Area Head, Oncology Early Development, Merck Research Labs*

Dr. Rubin has focused on cancer drug development for over 25 years, initially as a faculty member at the Dana-Farber Cancer Institute, then as a senior leader of the Cancer Institute of New Jersey. His research efforts focused on mechanisms of resistance to DNA topoisomerase-targeting drugs and his laboratory cloned a novel topoisomerase I- and p53-interacting tumor suppressor gene, TOPORS. In 2008 Dr. Rubin was recruited to Merck as Vice-President, Oncology Clinical Research. He led the development of the anti-PD-1 antibody pembrolizumab, which was the first anti-PD-1 therapy approved in the U.S., and in the identification of the significant activity of this antibody across several additional cancer types. In his current role he oversees oncology early development and translational research activities at Merck.

Dr. Rubin has authored over 100 original, peer-reviewed publications and book chapters related to oncology translational research, clinical trials and drug development. He has served frequently as a member of National Cancer Institute and American Cancer Society study sections, as well as on program committees for the American Association of Cancer Research and the American Society of Clinical Oncology. In addition, he serves on several editorial boards, and is a deputy editor for Clinical Cancer Research. Dr. Rubin obtained his medical degree from the University of South Florida and completed residency at Yale-New Haven Hospital.

Lawrence Schwartz, MD, *Professor of Radiology, Chairman of the Department of Radiology, Columbia University College of Physicians and Surgeons*

Dr. Schwartz is a Professor of Radiology at Columbia University College of Physicians and Surgeons and Chairman of the Department of Radiology. Dr. Schwartz's academic interests are in the development of novel imaging biomarkers in oncology, both clinical care and drug discovery. He is an active member of the Quantitative Imaging Biomarker Alliance and the Oncology Biomarker Qualification Initiative. Dr Schwartz chairs the imaging committees of the NCTN groups Alliance and SWOG. In addition he is Principal Investigator of the FNIH VolPact Study and a member of the RECIST Committee.

His research has focused on new computational and functional techniques that utilize physiologic imaging and advanced image processing to assess and correlate imaging characteristics with molecular features of disease processes, in particular solid tumors of the chest, abdomen and pelvis.

Elad Sharon, MD, MPH, *Senior Investigator, Cancer Therapy Evaluation Program, National Cancer Institute*

Elad Sharon, MD, MPH, is a Senior Investigator in the Cancer Therapy Evaluation Program (CTEP) within the National Cancer Institute (NCI), where he co-directs immunotherapy drug development efforts within CTEP's networks. As an organization, CTEP sponsors over 900 clinical trials, primarily focused on the United States and Canada, but also through academic partners throughout the world. Immunotherapy is a rapidly expanding focus of NCI-sponsored clinical trials, and CTEP is expanding those efforts in rare tumors and explore novel combinations of immune therapies and targeted therapies. Dr. Sharon has a particular interest in expanding the scientific understanding of immune suppression and its relationship to cancer progression and metastasis as well as other questions of basic tumor immunology that can enhance the NCI's ability to anticipate the direction of future research efforts. In his role at CTEP, Dr. Sharon works with academic investigators as well as pharmaceutical company collaborators to carry out the clinical development of promising new cancer therapies. He serves as both an expert in immunotherapy and in clinical trial design, and his input is sought by industry and academic collaborators from across the globe. His current portfolio includes vaccines, immune stimulators, antibody-drug conjugates, and immune checkpoint inhibitors, as well as other targeted agents. As part of his efforts, he leads CTEP drug development project teams in conjunction with leading immunotherapy experts from across the United States and Canada. In addition, he serves as an associate investigator on several trials offered at the NCI's Developmental Therapeutics Clinic on the NIH main campus in Bethesda, Maryland. Dr. Sharon also oversees the Molecular Profiling based Assignment of Cancer Therapeutics, or M-PACT, trial, which is one of the first precision medicine initiatives to use a randomized trial design to assess if the assignment of treatment based on genetic screening can improve the rate and duration of response in patients with advanced solid tumors. His previous research at the NCI focused on mesothelioma and clinical trials of targeted therapies, including immunotoxins. Dr. Sharon also has a particular interest in clinical effectiveness, the evaluation of the economics of cancer care, and using big data efforts in healthcare to advance the NCI's mission. In 2008, Dr. Sharon worked as a guest at the Brookings Institution, helping plan and manage panels for the Friends of Cancer Research inaugural Conference on Clinical Cancer Research in conjunction with the Brookings Institution. The aim of the conference was to find consensus among stakeholders to find solutions to critical questions regarding the future of clinical cancer research, and it has continued every year since that time with the participation of some of the leading figures of the oncology community. More recently, Dr. Sharon has co-directed an educational course on the "Economics of Cancer Care" as an educational seminar and conference offered in conjunction with the 2015 and 2016 annual meetings of the American Society of Clinical Oncology. Dr. Sharon completed his undergraduate training at the University of Texas, and he received his M.D. from Baylor College of Medicine in Houston, Texas. He completed his internal medicine residency at Emory University. He obtained his hematology and medical oncology fellowship training at the National Institutes of Health, and during his fellowship, he obtained a Master of Public Health degree at the Harvard School of Public Health.

Lillian L. Siu, MD, *Professor of Medicine, Princess Margaret Cancer Centre, Toronto, Canada*

Dr. Siu is a senior medical oncologist at Princess Margaret Cancer Centre since 1998, and has been a Professor of Medicine at the University of Toronto since 2009. She is the Director of the Phase I Program and Co-Director of the Bras and Family Drug Development Program at Princess Margaret Cancer Centre. Dr. Siu currently serves on the Board of Directors for the

American Society of Clinical Oncology (ASCO) for a four-year term (2012-2016). She also served as a member of the Nomination Committee for the American Association for Cancer Research (AACR) (2014-2016).

Dr. Siu's major research focus is in the area of new anticancer drug development, particularly with respect to phase I trials and head and neck malignancies. She is the Principal Investigator of a phase I cooperative agreement UM1 award (2014-2019) sponsored by the United States National Cancer Institute. In addition to her active research in early phase clinical trials, she has been leading genomics initiatives and immuno-oncology trials at the Princess Margaret Cancer Centre.

Internationally, Dr. Siu was the recipient of the US NCI Michaele C. Christian Award in Oncology Drug Development in 2010. In 2016, she is awarded the University of Toronto Department of Medicine Eaton Scholar Researcher. She was the ASCO Conquer Cancer Foundation Grants Selection Committee Chair in 2009-10, and the Chairperson of the AACR Education Committee and Co-Chairperson of the Scientific Committee for the 2012 Annual Meeting. Dr. Siu has published over 240 peer-reviewed manuscripts, and she is currently a scientific editor for Cancer Discovery and is on the editorial board for the Journal of Clinical Oncology and JAMA Oncology.

Raji Sridhara, PhD, *Division Director of Division of Biometrics V, Office of Biostatistics, Office of Hematology Oncology Products and Division of Medical Imaging Products, Center for Drug Evaluation and Research, FDA*

Rajeshwari Sridhara, Ph.D. is the Division Director of Division of Biometrics V, Office of Biostatistics which supports Office of Hematology Oncology Products and Division of Medical Imaging Products at the Center for Drug Evaluation and Research. As a leader in the field, she routinely presents regulatory policies and scientific philosophy of the Office at national and international professional meetings including oncology drug advisory committee meetings. Dr. Sridhara has contributed in the understanding and addressing the statistical issues that are unique to the oncology disease area. She has worked on regulatory guidance documents and extensively published in refereed journals.

Mario Sznol, MD, *Professor of Internal Medicine, Associate Chief of Medical Oncology, Translational Research Leader of the Melanoma-Renal Cancer Disease-Associated Research Team, Co-Director of Yale SPORE in Skin Cancer, Yale University School of Medicine*

Dr. Mario Sznol graduated from Rice University and Baylor College of Medicine (BCM) in Houston, Texas. He trained in internal medicine at BCM and completed a medical oncology fellowship in the Department of Neoplastic Diseases, Mount Sinai Hospital, New York. He spent the next twelve years in the Biologics Evaluation Section (BES), Investigational Drug Branch (IDB), Cancer Therapy Evaluation Program of the National Cancer Institute, and was Head of the BES from 1994-1999. He attended on the inpatient units of the Biological Response Modifiers Program, NCI, from 1988-1996 and the Immunotherapy Service of the Surgery Branch, NCI, from 1997-1999. From 1999-2004 he served as Vice President of Clinical Development and Executive Officer of Vion Pharmaceuticals in New Haven, Connecticut. In 2004 he joined the medical oncology faculty of the Yale University School of Medicine as co-leader of the Melanoma Program and is currently Professor of Internal Medicine, Associate Chief of Medical Oncology, Translational Research Leader of the Melanoma-Renal Cancer Disease-Associated Research Team, and Co-Director of Yale SPORE in Skin Cancer. He has a long-standing interest in and focuses on phase 1 clinical trials of immunotherapy agents and new drug development for melanoma and renal cell carcinoma.

Shenghui Tang, PhD, *Team Leader, Division of Oncology Products 1 (Breast, Gynecologic/Supportive care, Genitourinary), Division of Biometrics V, Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*

Dr. Shenghui Tang is team leader for the Division of Oncology Products 1 (Breast, Gynecologic/Supportive care, Genitourinary) in the Division of Biometrics V of the Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration. Prior to becoming team leader he was a primary reviewer for Investigational New Drugs and New Drug Applications reviewed in the Office of Hematology and Oncology Products. He received his PhD from the University of Iowa. Dr. Tang has been with the FDA since 2003 and has expertise in the design and analysis of oncology trials.

Janis Taube, MD, MSc, *Director, Dermatopathology Division and Fellowship, Johns Hopkins University School of Medicine*

Dr. Taube is the director of Dermatopathology Division and Fellowship at Johns Hopkins University School of Medicine. Her research interests center on immune evasion by solid tumors, specifically studying the PD-L1/PD-1 axis, and the identification of potential biomarkers of response to novel immunotherapies. This requires a focus on immunohistochemical and molecular methods for identifying cell surface antigens and signaling pathways in paraffin-embedded tissue. Dr. Taube's laboratory described PD-L1 mediated adaptive immune resistance by melanoma, a finding that has now been extended to other tumor types. She also developed a robust immunohistochemistry assay and interpretation methods for studying PD-L1 as it relates to therapeutic response. Versions of this assay are now approved by the U.S. Food and Drug Administration for clinical use. Her ongoing research efforts focus on further characterizing the local tumor microenvironment with the aim of developing rational treatment combinations and improving patient selection algorithms.

Allen Wensky, PhD, *Pharmacology/Toxicology Reviewer, CBER, FDA*

Dr. Allen Wensky joined the Office of Cellular, Tissue, and Gene Therapies (OCTGT) in October 2008 and currently serves as a pharmacology/toxicology reviewer in CBER. He is responsible for the critical review of preclinical data for cellular and gene therapy (CGT) products at multiple stages during the development of these novel investigational products. In addition to his IND review activities, he has participated in advisory committees, CGT-related working groups, peer reviewed articles and books, and he has presented in workshops, meetings, and symposia on preclinical development for products regulated in CBER.

Hong Zhao, PhD, *Team Leader and Master Reviewer, Office of Clinical Pharmacology (OCP)/Office of Translational Sciences (OTS), Center for Drug Evaluation and Research, Food and Drug Administration*

Dr. Hong Zhao is team leader and master reviewer in the Office of Clinical Pharmacology (OCP)/Office of Translational Sciences (OTS), the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). Her team is responsible for the clinical pharmacology review of oncology drugs and biological products. She received her Ph.D. in Pharmaceutical Sciences from the School of Pharmacy, University of Connecticut, Storrs, CT. She joined FDA in 1998 and has worked both in CDER and CBER. Over the years, she has developed her expertise in clinical pharmacology review of biological products. She has initiated, instructed and conducted many regulatory science research projects including but not limited to product comparability, immunogenicity, biologic-drug interactions, biologics QT evaluation, biologics dosing strategy, biologics specific population studies, antibody-drug conjugates (ADCs) and biosimilars to develop regulatory recommendations for clinical pharmacology studies in the biological product development program. She has been frequently invited internally and externally to present the current regulatory perspectives on clinical pharmacology of biological product development. Because of her significant contributions, she received an FDA Outstanding Service award in 2013 for exceptional service and commitment to CDER through outstanding leadership in the area of therapeutic biological product regulatory review and approval.