Oncology Dose-Finding Workshop Part 3

W. Washington DC Hotel
Washington, DC
July 20, 2017

Workshop Cochairs

Amy E. McKee, MD; *Supervisory Associate Director, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research, FDA*

Dr. McKee is a Supervisory Associate Director of the Office of Hematology and Oncology Products (OHOP) in the Center for Drug Evaluation and Research of the United States Food and Drug Administration. Prior to this position, she was a clinical team leader in the Division of Oncology Products 1/OHOP for breast and gynecologic oncology products. Dr. McKee received her B.A. in Russian and East European Studies from Middlebury College. Before obtaining her medical degree at Tulane University School of Medicine, Dr. McKee was a reporter for Elsevier's medical industry trade journal "The Pink Sheet." She completed her pediatric training at the Floating Hospital for Children/New England Medical Center and her pediatric hematology/oncology training at the combined Johns Hopkins University/National Cancer Institute fellowship program, where she continued basic research on neuroblastoma in the laboratory of Carol Thiele, Ph.D. prior to joining the FDA. Since joining the FDA, she has reviewed numerous new molecular entities for marketing approval in oncology; authored several manuscripts on new approvals, on targeted therapy drug development, and on clinical trial endpoints for regulatory applications; and chaired workshops on dose-finding in oncology and accelerating new product development for ovarian cancer.

Elizabeth M. Jaffee, MD; *AACR President-elect 2017-2018; The Dana and Albert "Cubby" Broccoli Professor of Oncology; Deputy Director, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins; Co-Director, Gastrointestinal Cancer Program at the Johns Hopkins School of Medicine and is Co-Director of the Skip Viragh Center for Pancreas Cancer.*

AACR President-elect, Elizabeth M. Jaffee, M.D. is the Dana and Albert "Cubby" Broccoli professor of oncology and professor of pathology at Johns Hopkins University School of Medicine and the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. After graduating magna cum laude from Brandeis University, Jaffee received her medical degree from New York Medical College. She completed her internship and residency at University of Pittsburgh, Presbyterian-University Hospital, then received a National Institutes of Health Research Training Grant as a research fellow and principal investigator at the University of Pittsburgh under the guidance of Fran Finn, Ph.D., research director. After that, Jaffee came to The Johns Hopkins University School of Medicine (JHUSOM) in Baltimore, Md., where she completed simultaneous fellowships as a senior clinical/research fellow in oncology and senior oncology fellow from 1989 – 1992. In 1992, Jaffee was appointed assistant professor of oncology at JHUSOM. In 1995, Jaffee was appointed to a faculty position in the Graduate Program in Immunology, and also holds a faculty position in the Graduate Program in Pharmacology Dr. Jaffee established and became medical director of the Johns Hopkins Oncology Center Cell Processing and Gene Therapy cGMP Facility.

In 2007, she was appointed deputy director for the Institute for Clinical and Translational Research at JHUSOM. She has also served as chair of the Clinical Research Committee at the Sidney Kimmel Comprehensive Cancer Center at Johns

Hopkins and as a member of the National Cancer Institute (NCI) Board of Scientific Counselors and the RAID NCI Program Oversight Committee. In addition to her many Johns Hopkins administrative committee appointments, Jaffee has held many roles for the American Association for Cancer Research (AACR), including chairing the AACR Cancer Immunology Working Group (CIMM), co-organizer for the AACR Special Conference on Cancer Immunology in 2010 and 2012, 2017 Annual Meeting Planning Committee and 2017 Annual Meeting Education Committee chair. Other memberships include American Society for the Advancement of Science, American Society of Clinical Oncology, American Association of Immunologists, and Society of Immunotherapy for Cancer.

Jaffee currently serves as chair of the National Cancer Advisory Board. She recently co-chaired the NCI Blue Ribbon Panel for the National Cancer Moonshot Initiative, and now serves on the Biden Cancer Initiative Board of Directors. Dr. Jaffee is a member of the Cancer Vaccine Collaborative (CVC). Other external advisory boards include the Scientific Advisory Board of the Abramson Cancer Center at the University of Pennsylvania and on the External Advisory Boards of both the Seattle Cancer Consortium Breast SPORE and the University of Pittsburgh Cancer Institute Head and Neck Cancer SPORE. She has mentored 21 postdoctoral fellows and 12 graduate students, has over 130 peer-reviewed publications, and is a nationally and internationally recognized guest lecturer. Jaffee holds six vaccine patents, has been an investigator on many immunotherapy clinical studies, and has amassed millions of dollars in grants and sponsorships for the study of the immunotherapy of pancreatic cancer.

Workshop Speakers and Panelists

Joaquim Bellmunt, MD, PhD; *Associate Professor of Medicine, Harvard Medical School; Director, Bladder Cancer Center, Dana-Farber Cancer Institute*

Dr. Bellmunt is Director of the Bladder Cancer Center at Dana-Farber Cancer Institute and Dana-Farber/Brigham and Women's Cancer Center, Harvard University, Boston, MA. He graduated in Medicine and Surgery from the Autonomous University of Barcelona in 1982 and obtained his PhD cum laude in 1989 from the same university. After undergoing the residency in Medical Oncology at the Hospital Universitari Vall d'Hebron in Barcelona, he completed his studies obtaining the European Certificate in Medical Oncology in London in 1989 and rotating at the Clinical Immunology Service, Division of Medical Oncology at Memorial Sloan-Kettering Cancer Center in New York in 1987 and 1989. Dr. Bellmunt joined the Department of Medical Oncology, Hospital Vall d'Hebron taking over the Uro-oncology Clinic. In January 2006, he was appointed Chief of the Solid Tumor Oncology Service of the Hospital del Mar in Barcelona. Since 2008 and as a result of his collaboration with the Dana-Farber Cancer Institute (DFCI) until late 2012, he has been a Visiting Professor at Harvard University, Boston, MA. On March 2013, Dr. Bellmunt was appointed Director of the DFCI Bladder Cancer Clinic and Associate Professor at Harvard.

As a genitourinary (GU) medical oncologist, Dr. Bellmunt has been involved in, and led urothelial cancer trials for over 15 years in Europe and continues doing so at DFCI. He has focused on the development of new systemic treatment for GU cancers, in particular bladder cancer (BC) and has been a key investigator in several trials conducted in this patient population. Dr. Bellmunt developed the MCAVI schedule for unfit patients, reported the superiority of cisplatin versus carboplatin, designed the three drug regimen of paclitaxel, cisplatin and gemcitabine (PCG), and was the Principal Investigator (PI) of the phase III trial comparing PCG with CG (EORTC 30987, European Organization for Research and Treatment of Cancer). He was also the Co-PI of the EORTC 30986 study in unfit patients. In the second line setting, he chaired the phase III study of vinflunine versus placebo that led to the approval of vinflunine in Europe. Dr. Bellmunt has also been involved in research on clinical and biological prognostic factors in both first- and second-line treatment settings. At DFCI, he has analyzed the molecular profile of a bladder cancer patient series from Spain and Greece looking for new targets for therapeutic intervention. Currently and based on the findings of PI3K mutations, he is studying in preclinical models the efficacy of PI3K and TOR1/2 inhibitor drugs in BC cell lines. He is undergoing a clinical trial with a TOR1/2 inhibitor (IST) and another one combining pazopanib and everolimus. The goal is to study the synergistic activity

of paclitaxel and MLN128 in patients failing first-line chemotherapy for bladder cancer. The prospective CRIS clinical/biological (online) database has been built, which will boost translational research in BC patients.

Recently, his research at the Bladder Cancer Center has focused on the role of checkpoint inhibitors in the treatment of GU malignancies (bladder and kidney). In this context he has investigated the role of PD-L1 expression as a prognostic factor in advanced BC patients. Dr. Bellmunt is now implementing prospective data collection of patients included in the immunotherapy trials in order to understand the underlying genetic and biological mechanisms of response and resistance.

Dr. Bellmunt is a member of the American Association for Cancer Research (AACR), American Society of Clinical Oncology (ASCO), the European Society of Medical Oncology (ESMO) and the Spanish Society of Medical Oncology (SEOM). He has been part of the ASCO Congress Scientific Committee of the American Society of Clinical Oncology-Genitourinary (ASCO GU) where he has been involved in conferences as a Faculty Member. Dr. Bellmunt is also involved in most European guidelines for GU malignancies, including ESMO, SEOM and the European Association of Urology (EAU) (bladder, kidney and prostate cancer). In the U.S., he is involved in the Society for Immunotherapy of Cancer (SITC) immunotherapy guidelines for BC.

René Bruno, PhD; *Staff Scientist, Clinical Pharmacology, Genentech Early Research and Development, Genentech/Roche.*

René Bruno provides scientific leadership in the development and application of Modeling and Simulation (M&S) in drug development, with a special focus in oncology and immuno-oncology supporting various early and late stage projects. René has over 30 years of experience in academia, industry, and consulting business, including University of Marseilles (Assistant Professor 1982-85), Syntex (1985-87), Rhone-Poulenc Rorer (1987-2000), Genentech (2000-2003 as Sr. Scientist, Head of Pharmacometrics) and Pharsight/Certara Consulting Services (2003-2016 as Managing Director) where he provided Modeling and Simulation as well as Clinical Pharmacology consultation for leading pharmaceutical companies worldwide.

René's specific research interest has been in oncology tumor growth inhibition modeling, including linking tumor response to outcomes data such as Overall Survival, and application of these models to trial design and development decisions. He has published 70+ peer-reviewed research articles, 16 invited book chapters, reviews, and commentaries, and delivered 50+ invited lectures at global scientific conferences and universities. René is one of the founding members of the Population Approach Group in Europe (PAGE) and hosted for the 1st meeting in 1993 in Paris. Rene currently serves as the president of the International Society of Pharmacometrics (ISoP).

R. Todd Bunch, PhD; *Group Director, Drug Safety Evaluation Department, Bristol-Myers Squibb*

Dr. R. Todd Bunch is currently a Group Director in the Drug Safety Evaluation Department of Bristol-Myers Squibb, where he serves as the Therapeutic Area Head for Immuno-Oncology, supporting the nonclinical development strategy and testing for BMS's immuno-oncology assets. Dr. Bunch received a BA in Chemistry from Williams College and a Ph.D. in Pharmacology/Toxicology from the Medical College of Virginia / Virginia Commonwealth University. Dr. Bunch has over 20 years of pharmaceutical industry experience and worked at G.D. Searle/Pharmacia/Pfizer and Amgen prior to joining BMS. Dr. Bunch has authored/co-authored over 30 publications including peer-reviewed articles and book chapters and has been an active member of the Society of Toxicology since 1998.

Daniel S. Chen, MD, PhD; *Vice President, Global Head of Cancer Immunotherapy Development, 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."

Leisha A. Emens, MD, PhD; *Associate Professor of Oncology, Bloomberg-Kimmel Institute for Cancer Immunotherapy, Johns Hopkins University School of Medicine*

Leisha A. Emens, M.D., Ph.D., is an Associate Professor of Oncology at the Kimmel Cancer Center at Johns Hopkins and a member of the Bloomberg-Kimmel Institute for Cancer Immunotherapy. After receiving her B.A. in Biochemistry and Cell Biology from the University of California at San Diego, she spent two years in industry at Hybritech, Incorporated, a monoclonal antibody company. She then joined the Medical Scientist Training Program (MSTP) at Baylor College of Medicine, pursuing graduate work in immunology and cell biology. At Baylor, Dr. Emens served on the operating committee of the MSTP, and was named to the Alpha Omega Alpha (AOA) medical honor society. She then completed a postdoctoral fellowship in oncology at the National Cancer Institute in 1993, and internal medicine residency training at the University of Texas at Southwestern before joining the fellowship programs in hematology and oncology at Johns Hopkins University in 1998. She trained in tumor immunology as a senior clinical and research fellow before joining the faculty at Johns Hopkins University in 2001. Dr. Emens is currently board certified in internal medicine and medical oncology. She is a medical oncologist with an outpatient service focused on breast cancer, and is internationally recognized for her work in developing innovative combination immunotherapies that include standard and novel treatments for breast cancer. Dr. Emens currently serves as a member of the Board of Directors of the Society for Immunotherapy of Cancer (SITC). She served as chair of the Clinical Research Committee at the Kimmel Cancer Center at Johns Hopkins. She serves on the scientific advisory boards of MolecuVax and eTheRNA. She is a former member the editorial board of the Journal of Clinical Oncology, is currently on the editorial board of Cancer Research and the Breast Journal. She serves as section editor for Journal for the Immunotherapy of Cancer (JITC), the voice of SITC. She is a former Chair of both the Communications Committee and the Stakeholder's Council for SITC, and remains on the SITC Stakeholder's Council. Dr. Emens was a member of the FDA Advisory Committee on Cellular, Tissue, and Gene Therapies (CTGTC) 2012-2016, and remains an advisor to the FDA. She is an active member of ASCO, AACR, and SITC, and is a member of the Cancer Immunology (CIMM) Working Group of the AACR. Dr. Emens was awarded the President's Award by the YWCA of Greater Baltimore and the Maryland Governor's Citation for her work.

Laura L. Fernandes, PhD; *Mathematical Statistician, Division of Biostatistics V (DBV), OB, OTS, CDER, FDA*

Dr. Laura Fernandes is a statistical reviewer in the office of biostatistics and supports the division of oncology product teams at the FDA. Her PhD thesis in biostatistics at the University of Michigan, Ann Arbor, focused on adaptive dose-finding clinical trial designs in oncology. Prior to her PhD research, she worked at GlaxoSmithKline (GSK) as a SAS programmer analyzing clinical trial data.

Bernard A. Fox, PhD; *Chief, Molecular and Tumor Immunology, Earle A. Chiles Research Institute, Oregon Health and Sciences University*

Bernard A. Fox, PhD, is the Harder Family Chair for Cancer Research, Member and Chief of the Laboratory of Molecular and Tumor Immunology, Robert W. Franz Cancer Research Center within the Earle A. Chiles Research Institute at

Providence Portland Medical Center; Co-founder and CEO of UbiVac, a clinical stage immuno-oncology company; and Adjunct Faculty, Department of Molecular Microbiology and Immunology and member of the Knight Cancer Institute, Oregon Health and Science University, Portland, Oregon.

Dr. Fox received his B.S. in Biology and M.S in Immunology from the University of Detroit and his Ph.D. from Wayne State University, Detroit, Michigan. His postgraduate training was with Dr. Steven A. Rosenberg, Surgery Branch, NCI, NIH. Dr. Fox has spent more than 30 years studying how to use a patient's immune system to fight cancer. His research efforts are divided between preclinical animal models, the development, performance and monitoring of immunotherapy trials for patients with cancer and the training of the next generation of translational investigators. He is currently involved with translational immunotherapy trials for patients with melanoma, prostate, breast, head and neck and non-small cell lung cancer. He is the Co-PI for the Providence Cancer Center participation in the NCI, Cancer Immunotherapy Network (CITN) and the Bristol-Meyers Squibb International Immuno-Oncology Network. Dr. Fox has served as a member of review committees for the NIH, FDA, philanthropic and governmental organizations in the USA, Europe and Asia, and is a member of the American Association for Cancer Research (AACR), American Society of Clinical Oncology (ASCO), American Association of Immunologists (AAI), and the Society for Immunotherapy of Cancer (SITC). Dr. Fox is the current Chair of the World Immunotherapy Council and past President SITC. www.finishcancer.org

Chao Liu, PhD; *Pharmacometrics Reviewer, Division of Pharmacometrics, Division of Pharmacometrics (DPM), Office of Clinical Pharmacology(OCP), OTS, CDER, FDA*

Dr. Chao Liu is currently a Reviewer in the Division of Pharmacometrics, Office of Clinical Pharmacology at the U.S. FDA. Prior to becoming a reviewer at OCP, he was an ORISE Fellow at FDA. Dr.Liu received his Ph.D. degree in Immunology and Microbiology from the University of Florida, Gainesville in 2014. His Ph.D. study focused on immunological mechanisms in autoimmune disease. During that period, Dr. Liu also earned a Master's degree in Statistics. Dr. Liu earned a B.S in biological science from Nankai University, China. In his current role at the FDA, Dr. Liu works in the areas of oncology products. His current interest is focused on applying pharmacometrics for dose optimization and description of disease progression in oncology.

Qi Liu, PhD; *Clinical Pharmacology Team Leader, Division of Clinical Pharmacology V, OCP, OTS, CDER, FDA*

Dr. Qi Liu is currently a team leader at Division of Clinical Pharmacology V, Office of Clinical Pharmacology, CDER, FDA. Prior to joining FDA, Dr. Liu worked as a senior pharmacokineticist at Merck & Co. Inc. She obtained her Ph.D. degree in Pharmaceutics (focus on Pharmacokinetics/Pharmacodynamics Modeling and Simulation) from the University of Florida, Gainesville in 2004. During that period, Dr. Liu also earned a Master's degree in Statistics. Dr. Liu also earned a Master's degree in Pharmaceutics and a B.S in Pharmacy from West China University of Medical Sciences.

In her current role at the FDA, Dr. Liu works in the area of oncology products. Her current interest is focused on applying clinical pharmacology principles, including quantitative methods, to optimize the development (such as dose selection and study design) of oncology drug products.

Israel Lowy, MD, PhD; *Vice President Global Clinical Development, Head of Translational Science and Clinical Oncology at Regeneron Pharmaceuticals, Inc.*

Dr. Lowy graduated magna cum laude from Princeton University with an AB in Biochemical Sciences (1977), and from Columbia University with an MD (1984) and PhD in Biochemistry and Molecular Biophysics (1991). He took clinical training at Columbia-Presbyterian Medical Center in Internal Medicine and Infectious Diseases, and held faculty positions in Medicine and Infectious Diseases at Columbia University (1988-1995) and Mount Sinai School of Medicine (1995-2002). He led laboratory research on the genetic and biochemical basis of resistance of HIV to antiretroviral inhibitors, and clinical research in AIDS, with a particular interest in immunotherapy to enhance immune control of HIV infection.

Lowy joined Medarex Inc. in 2002 to develop novel antibody based therapeutics for infectious diseases, including immunotherapies to control chronic infections, and remained through its 2009 acquisition by BMS. Among efforts in infectious diseases, he led a landmark phase 2 study of anti-Clostridium difficile mAbs to prevent recurrent diarrheal disease that were subsequently licensed to Merck. The antibody to toxin-B, (ZINPLAVA™ (bezlotoxumab), was approved by the FDA in October 2016 to prevent recurrence of C. difficile diarrhea. At Medarex, Lowy also led pioneering clinical efforts in immunotherapy in oncology (as well as infectious diseases). These included early studies with anti-CTLA-4 (MDX-010, ipilimumab) in many non-melanoma indications, either as monotherapy or in combinations with radiation, vaccines, or chemotherapy. He designed and led the first single dose and landmark multi-dose clinical studies of anti-PD-1 (MDX-1106, nivolumab) (in collaboration with Ono Pharmaceuticals), and anti-PD-L1 (MDX-1105). He designed and initiated the landmark first combination study of ipilimumab and nivolumab prior to moving to Regeneron. This foundational body of work contributed to subsequent approvals of anti-CTLA-4, Yervoy™ and anti-PD-1 Opdivo™ each as monotherapy as well as in combination for melanoma, and for anti-PD-1 in a growing number of cancer indications.

Lowy joined Regeneron in 2010, and has been a central driver in Regeneron's commitment to anti-tumor immune therapy, leading efforts to advance a broad portfolio of new antibody based therapeutics to the clinic, which has been further supported by a nearly $2B commitment with partner Sanofi announced in 2015.

Regeneron's first IO agent in the clinic is REGN2810, an anti-PD-1 fully human antibody, which is being developed to serve as a foundational element for future combination strategies. REGN2810 is currently in multiple registration trials, as well as exploratory trials including combinations with novel agents in collaboration with other companies. The second agent is REGN1979, a CD20xCD3 fully human bispecific full length antibody, in clinical trials for CD20+ B cell malignancies. REGN1979 is the first full length bispecific antibody developed by Regeneron, using an innovative flexible platform amenable to generating bispecifics targeting a variety of tumor and effector cells, and employing standard manufacturing processes. REGN3767, a fully human mAb to LAG-3, entered the clinic in late 2016 as both a monotherapy and in combination with anti-PD-1. Additional new agents have been selected from a large panel of targets for entry into the clinic in 2017-2018 as monotherapies and in combinations.

Lowy represents Regeneron in the Cancer Research Institute Cancer Immunotherapy Consortium. He is pleased to participate in this FDA-AACR symposium to discuss optimal duration of therapy with immunotherapies, in particular PD-1/PD-L1 blockers.

David F. McDermott, MD; *Director, Biologic Therapy and Cutaneous Oncology Programs at Beth Israel Deaconess Medical Center Leader, Dana Farber/Harvard Cancer Center Kidney Cancer Program Associate Professor of Medicine Harvard Medical School*

David F. McDermott, MD, is Director of the Biologic Therapy and Cutaneous Oncology Programs at Beth Israel Deaconess Medical Center (BIDMC), Leader of the Dana Farber/Harvard Cancer Center (DF/HCC) Kidney Cancer Program and co-Principal Investigator of the National Cancer Institute, Specialized Programs of Research Excellence (SPORE) grant, focusing on kidney cancer. Dr. McDermott is Director of the Cytokine Working Group, an innovator in the field of solid tumor immunotherapy and Associate Professor of Medicine at Harvard Medical School.

Dr. McDermott is a nationally and internationally recognized oncologist, clinical researcher and expert in three fields of research and clinical management: cancer immunotherapy, melanoma and kidney cancer. Dr. McDermott has particular interest in therapies that enhance the immune response to cancer. His immunotherapy research has focused on approaches to improve the therapeutic index of interleukin-2 and developing "targeted" immunotherapies for patients with solid tumors. Dr. McDermott has served on the Program Committee for the American Society of Clinical Oncology, the Medical Advisory Board for the Kidney Cancer Association, the National Cancer Institute Genitourinary Steering Committee and currently serves on the Kidney Cancer Task Force of the National Cancer Institute.

Lei Nie, PhD; *Statistical Team Leader, DBV, OB, OTS, CDER, FDA*

Dr. Lei Nie is a lead mathematical statistician of the Division of Biometrics V in the Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). He has authored/coauthored more than 80 peer reviewed journal papers. As a regulatory reviewer, he has review experiences in dose finding. Dr. Nie received his Ph.D. in Statistics from the University of Illinois at Chicago. Prior to coming to FDA, Dr. Nie was a faculty member at the University of Maryland Baltimore country from 2002 - 2005 and Georgetown University from 2005 - 2007.

Tiffany K. Ricks, PhD; *Pharmacology/Toxicology Reviewer, DHOT, OHOP, OND, CDER, FDA*

Dr. Ricks is a Pharmacology/Toxicology Reviewer in the Division of Hematology Oncology Toxicology (DHOT) supporting the Division of Oncology Products 1 in the Center for Drug Evaluation and Research (CDER) at the US Food and Drug Administration. Prior to joining the FDA, Dr. Ricks was a postdoctoral fellow at the National Institute of Arthritis and Musculoskeletal and Skin Diseases at the National Institutes of Health, where she studied immune cell signaling and the pathogenic role of innate immune cells in mouse models of systemic lupus erythematosus. Dr. Ricks received her PhD in Pharmacology from the University of North Carolina at Chapel Hill in 2010. Her doctoral research focused on mechanisms of G protein signaling and receptor trafficking.

Amit Roy, PhD; *Group Leader, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb*

Dr. Amit Roy is currently Group Director in the department of Clinical Pharmacology & Pharmacometrics at Bristol-Myers Squibb, where he serves as the Head of Pharmacometrics for Oncology. Amit received his undergraduate degree in Chemical Engineering from the University of Michigan, in Ann Arbor, MI, and his PhD in Chemical & Biochemical Engineering from Rutgers University in 1997, following which he was Assistant Professor in the Department of Community Medicine at the University of Medicine and Dentistry of New Jersey. Prior to joining BMS in September 2004, Amit worked as a clinical pharmacologist at Vertex Pharmaceuticals, in Cambridge, MA, where he supported the development of several immunology compounds.

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

Dr. Rubin has focused on cancer drug development for over 20 years, initially as a faculty member at the Dana-Farber Cancer Institute, then as a senior leader of the Cancer Institute of New Jersey. In 2008, Dr. Rubin was recruited to Merck as Vice-President, Oncology Clinical Research. He led the development of the anti-PD-1antibody 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 for Cancer Research (AACR) and the American Society of Clinical Oncology. In addition, he is an active member of the AACR's Regulatory Science and Policy subcommittee.

Marc R. 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.

Robert H. Vonderheide, MD, D Phil; *Director*, *Abramson Cancer Center, Perelman School of Medicine at the University of Pennsylvania*

Robert H. Vonderheide, MD, DPhil, is Director, Abramson Cancer Center, Perelman School of Medicine at the University of Pennsylvania and the John H. Glick, MD Abramson Cancer Center's Director Professor. Dr. Vonderheide graduated from Oxford University as a Rhodes Scholar, and Harvard Medical School. He completed training in internal medicine and medical oncology at the Massachusetts General Hospital and the Dana Farber Cancer Institute. Dr. Vonderheide is a distinguished scientist and clinician who has deciphered mechanisms of cancer immune surveillance and developed novel cancer therapeutics, particularly in pancreatic cancer. He is well-recognized for driving the development of agonist CD40 antibodies, now in later stage clinical trials as potential immune therapy of cancer. Dr. Vonderheide discovered telomerase as a universal tumor antigen and has led the efforts to develop telomerase vaccination for both therapy and the prevention of cancer in healthy individuals. He has helped lead a team to show that stereotactic radiation therapy in combination with dual checkpoint blockade represents a synergistic path for immune activation in cancer. Dr. Vonderheide merges his clinical investigations with rigorous studies in mouse models or other laboratory systems. Dr. Vonderheide has been continuously funded by the NCI, and his high-impact findings have been published in Nature, Science, Cell and the New England Journal of Medicine.

Nolan A. Wages, PhD; *Associate Professor, Division of Translational Research & Applied Statistics, University of Virginia (UVA) School of Medicine*

Dr. Wages is an Associate Professor in the Division of Translational Research & Applied Statistics in the Department of Public Health Sciences at the University of Virginia (UVA) School of Medicine. As a member of this division, the majority of his research effort is related to cancer research and its applications. Dr. Wages is an active member of the UVA Cancer Center Biostatistics Shared Resource, for which he works with cancer center members on the design and analysis of clinical trials. His current methodological research involves the design and analysis of early-phase clinical trials, with a particular focus on studies of drug combinations.