FDA-AACR-SGO Workshop on Drug Development in Gynecologic Malignancies

June 14, 2018 | Silver Spring, MD

Workshop Cochairs

Rebecca Arend, MD, *University of Alabama at Birmingham*

Dr. Arend is an Assistant Professor in the Division of Gynecologic Oncology at University of Alabama in Birmingham and an Associate Scientist in the UAB Comprehensive Cancer Center Experimental Therapeutics Program. She completed her undergraduate degree and her residency at Columbia Presbyterian in New York, NY. She attended Albert Einstein School of Medicine for Medical School and completed her Gyn Oncology fellowship at UAB. Prior to fellowship, she did research in hormonal and molecular pathways associated with uterine carcinosarcoma in Susan Horwitz's Lab.
She received an AAOGF/ABOG Young Investigator Fellowship grant that supported the development of her lab during her first three years on faculty. She has recently been awarded a DOD Early Career Investigator Grant and a NCCN Young Investigator Grant to support her on-going research, which focuses on how pathways that are upregulated in cancer patients effect the immune microenvironment in ovarian cancer.
She is currently getting her Master's degree (MSPH) in Clinical and Translational Research and serves as the chair of UAB's Tissue Committee and as the co-chair of the Gynecologic Oncology Disease Oriented Working Group (DOWG) and the Precision Oncology Working Group (POWG).
She is a member of multiple professional societies and committees both regionally and nationally. She has authored numerous publications and been highly recognized for outstanding presentations.

Deborah K. Armstrong, MD, *Johns Hopkins Sidney Kimmel Comprehensive Cancer Center*

Dr. Armstrong works in the area of women's malignancies, with a particular emphasis on breast cancer, ovarian cancer and other gynecologic malignancies, and the genetics of breast and ovarian cancer. She directs the medical gynecologic oncology clinical trials program, overseeing therapeutic clinical trials in gynecologic cancers at Johns Hopkins Kimmel Cancer Center. Dr. Armstrong is co-principal investigator for the NCI National Clinical Trials Network (NCTN) Lead Academic Participating Site (LAPS) at Johns Hopkins, now the major avenue for adult oncology clinical trials in the country. Dr. Armstrong's clinical focus is on the development of new therapeutic approaches to the treatment of breast cancer and gynecologic malignancies with a specific interest in the use of immune focused therapy in endometrial and ovarian cancers and PARP inhibitors in ovarian cancer.

Dr. Armstrong directs the Kimmel Cancer Center's Breast and Ovarian Cancer Surveillance Service, a genetic counseling and testing service that focuses on detecting germline genetic alterations that guide cancer therapy, and identify patients at increased cancer risk to develop and implement strategies for cancer screening and prevention.

Dr. Armstrong is active in NRG/GOG, serving on Developmental Therapeutics and Phase I committees and as co-chair of the Medical Oncology Committee. She is co-chair of the Ovarian Cancer Task Force for the Gynecologic Cancer Steering Committee of the National Cancer Institute and chair of the Ovarian Committee for the National Comprehensive Cancer Network (NCCN). She is a former member and chair of the Oncology Drugs Advisory Committee (ODAC) to the FDA. She has been an Integration Panel Member of the DOD Ovarian Cancer Research Program since 2007 and currently chairs the Panel.

Sanjeeve Bala, MD, MPH, *U.S. Food and Drug Administration*

Dr. Bala began his oncology career as a Clinical Fellow in the Surgery Branch, NCI, where he investigated adoptive anticancer immunotherapy in a mouse model and treated patients on immunotherapy and surgical clinical trials under the direction of Dr. Steven Rosenberg. Following internal medicine training at Georgetown University Hospital, he returned to NCI to complete fellowships in hematology and medical oncology, and remained on faculty in the Medical Oncology Branch to continue the development and conduct of phase 1 and 2 clinical trials in a variety of solid tumors, including cervical cancer. In 2014, he transitioned to FDA, first as a Medical Officer and then as a Clinical Team Leader for gynecologic malignancies and radiation oncology. In this capacity, he leads Agency interaction with a variety of sponsors regarding clinical trial design and conduct, from first-in-human to pivotal trials leading to regulatory submission, and is involved in the review of submissions and the benefit-risk evaluations that the Agency undertakes for determining the approvability of applications and prescribing information.

Julia A. Beaver, MD, *U.S. Food and Drug Administration*

Dr. Beaver is director of the Division of Oncology Products 1 (DOP1) in the Office of Hematology Oncology Products in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA).

Dr. Beaver graduated magna cum laude from Princeton University and earned her medical degree from the University of Pennsylvania School of Medicine. She completed a residency in internal medicine at Johns Hopkins University School of Medicine, followed by a fellowship in medical oncology at The Johns Hopkins Sidney Kimmel Cancer Center.

At the FDA, Dr. Beaver served as clinical team leader of the Breast and Gynecologic Malignancies Group and associate director in DOP1 prior to assuming her role as director. She is also an assistant professor of oncology at Johns Hopkins University where she is a member of the Johns Hopkins Breast Cancer Group and sees patients with breast cancer at Johns Hopkins Oncology at Sibley Memorial Hospital.

Dr. Beaver serves on the Liquid Biopsy Blood Profiling Atlas in Cancer (Blood-PAC) committee, the ASCO Cancer Education Committee for Drug Development and Translational Research, and the ASCO/FoCR Eligibility Criteria Planning Committee. She also leads the FDA's next generation sequencing laboratory collaboration between OHOP and the Office of Biotechnology Products.

Robert L. Coleman, MD, FACOG, FACS, *UT MD Anderson Cancer Center*

Dr. Coleman is a Professor in the Department of Gynecologic Oncology and Reproductive Medicine at the University of Texas, M.D. Anderson Cancer Center and holds the Ann Rife Cox Chair in Gynecology and serves as Executive Director, Cancer Network Research. His research interests include drug discovery and novel therapeutics for ovarian, uterine, and cervical cancer, clinical trial development and statistical design. He is PI or co-PI for several CTEP-funded prospective clinical trials including those supporting the MDACC Ovarian and Uterine SPOREs, as well as, several partnered pharmaceutical sponsored trials. He is a project lead on the MDACC Gynecologic Cancer Moonshot. Dr. Coleman has authored or coauthored over 500 scientific publications, including over 280 peer-reviewed original research articles. In 2015, he served as President for the Society of Gynecologic Oncology and currently serves on the Gynecologic Oncology Group Foundation's Board of Directors.

Thomas Herzog, MD, *University of Cincinnati Cancer Institute*

Dr. Thomas Herzog is the Deputy Director of the University of Cincinnati Cancer Institute and the Barrett Cancer Center at the University of Cincinnati and the Paul and Carolyn Flory Endowed Professor of Obstetrics and Gynecology. He is also Vice-Chair of Quality and Safety for Obstetrics and Gynecology at the University of Cincinnati College of Medicine. For the previous 10 years, he served as the Division Director of Gynecologic Oncology and the Physicians & Surgeons Endowed Professor of Clinical Gynecology and Obstetrics at Columbia University Medical Center. Dr. Herzog was the

founding Director of the Fellowship in Gynecologic Oncology for Columbia/Cornell established in 2010. His research passion has been translational and clinical trial research in cancer with a focus on tumor suppressor genes, molecular genetics, cytokines, novel drug development and clinical trial designs. He currently serves on the Board of Directors of the clinical trial cooperative group, GOG Partners Foundation, in the position of Secretary-Treasurer. He has served as a Principal Investigator in a number of GOG trials as well as PI on multiple international trials. He was co-chair of the FDA workshop on Clinical Trial Endpoints in ovarian cancer in 2015. Dr. Herzog has had the privilege to serve in a variety of leadership roles for the Society of Gynecologic Oncology (Council, Program, Industry Relations, and Educational Committee Chairs), International Gynecologic Society (Board of Directors), American College of Surgeons (Board of Governors), Foundation for Women's Cancer (Board of Directors) and American College of Obstetrics and Gynecology (Co-chair Practice Committee). He is and has been an Editor-in-chief for two journals. He has been appointed to multiple journal editorial boards. He has received significant intra and extramural grant funding, He has been a Board member of the Gynecologic Oncology Division for the American Board of Obstetrics and Gynecology. Dr. Herzog has published over 275 peer reviewed articles plus numerous textbook chapters and one text book.

Gordon B. Mills, MD, PHD, *UT MD Anderson Cancer Center*

At the Knight Cancer Institute at the Oregon Health Sciences University, Dr. Mills is Director of Precision Oncology Director of SMMART trials and holds the Wayne and Julie Drinkward Endowed Chair in Precision Oncology.

In these roles, Dr. Mills is responsible for the implementation of an integrated program of tumor analysis, decision-making and implementation of novel precision oncology trials. The key goal will be to use serial tumor and liquid biopsies to evaluate and target adaptive responses in real time to interdict cancer evolution. Prior to moving to OHSU, at The University of Texas MD Anderson Cancer Center, Dr. Mills founded the Department of Systems Biology, which was the first Cancer Systems Biology department in the United States. He served as Co-Director of the Institute for Personalized Cancer Therapy (IPCT), the Head of the Kleberg Center for Molecular Markers and Co-Director of the Ovarian Cancer Moon Shot. His research ranges across: 1) translating the cancer genome through mechanistic studies determining the role of genomic and other aberrations present in patient tumors, 2) identification and validation of therapeutic targets emphasizing mechanisms of resistance and rational combination therapy to overcome emerging resistance in evolving cancers, 3) developing, validating, and implementing molecular markers; and 4) integrating data through a cancer systems biology approach into robust predictive mathematical models. The overarching goal is to perform deep molecular analysis of each patient "to let the patient teach us what is important". This process is facilitated by the implementation and integration of a comprehensive suite of high-throughput technologies including assessment of genomic aberrations, transcriptional profiles, functional proteomics and metabolomics, and drug screening using conventional and high content imaging systems. His lab has also implemented a comprehensive functional genomics program designed to distinguish drivers from passengers and identify their therapeutic liabilities. His efforts have been recognized in the Komen Foundation's Brinker Award for Scientific Excellence and the Finneran Family Prize for Translational Research. Dr. Mills have been very successful in supporting training, mentoring, and career development for young scientists including graduate students, fellows, and junior faculty. The majority of his trainees have developed successful research careers rising through the ranks to full professor, department chairs, and institute directors. Based on this role, he has been nominated for and awarded multiple mentoring awards, including the Stand Up 2 Cancer Laura Ziskin Prize for Mentoring. Dr. Mills received his MD and PhD degrees from the University of Alberta.

Workshop Speakers and Panelists

Alan D. D'Andrea, MD, *Dana-Farber Cancer Institute*

Dr. D'Andrea received his MD from Harvard Medical School in 1983. He completed a fellowship in hematology-oncology at the Dana-Farber Cancer Institute and Children's Hospital, Boston. Dr. D'Andrea also completed a research fellowship at the Whitehead Institute before joining the faculty at the Dana-Farber Cancer Institute in 1990. His laboratory investigates the pathogenesis of Fanconi anemia, a human genetic disease characterized by bone marrow failure and cancer predisposition.

Dr. D'Andrea is internationally known for his research in the area of DNA damage and DNA repair. He is currently the Fuller-American Cancer Society Professor of Radiation Oncology at Harvard Medical School and the Director of the Center for DNA Damage and Repair at the Dana-Farber Cancer Institute. A recipient of numerous academic awards, Dr. D'Andrea is a former Stohlman Scholar of the Leukemia and Lymphoma Society, and serves on their Medical and Scientific Advisory Board. Dr. D'Andrea is a Distinguished Clinical Investigator of the Doris Duke Charitable Trust, a Fellow of the American Association for the Advancement of Science, and a member of the National Academy of Medicine. He is also the recipient of the 2012 G.H.A. Clowes Memorial Award from the American Association for Cancer Research. Dr. D'Andrea participates in a wide range of clinical trials, largely focused on ovarian, breast, prostate, and bladder cancers. In 2017, he became the Director of the Susan F. Smith Center for Women's Cancers at the Dana-Farber Cancer Institute.

Annie E. Ellis, *Patient Advocate*

Annie Ellis is a 14-year survivor of recurrent ovarian cancer and is currently enjoying an unexpected third remission of over 10 years. In addition to serving as an FDA Patient Representative, Ms. Ellis serves as a patient advocate member of the NCI Gynecologic Cancer Steering Committee, the RPCI-UPCI Ovarian Cancer SPORE, CDMRP Ovarian Cancer Research Program (OCRP) programmatic panel and the Ovarian Cancer Research Fund Alliance Scientific Advisory Committee. Ms. Ellis has provided the patient perspective at various meetings and events and has participated in the American Association for Cancer Research Scientist↔Survivor Program (AACR SSP) and the Biennial Cancer Survivorship Research Conference Survivor-Researcher Mentor Program. Ms. Ellis provides peer support through SHARE's Ovarian Helpline and New York Presbyterian-Columbia's Woman to Woman Program.

Stephanie L. Gaillard, MD, PhD, *Johns Hopkins School of Medicine*

Stéphanie Gaillard, MD, PhD is a medical oncologist who specializes in the treatment of gynecologic malignancies, including ovarian, endometrial, and cervical cancers. She recently joined the faculty of the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center as Director of Gynecologic Cancer Trials.

Dr. Gaillard earned her MD and PhD in cancer biology from Duke University. Following medical school, she underwent residency training in Internal Medicine and fellowship training in Medical Oncology at the Johns Hopkins School of Medicine. Prior to joining the faculty at Johns Hopkins, she was a faculty member at Duke University Medical Center. She is board certified in Medical Oncology and Internal Medicine.

Dr. Gaillard's research focuses on the development of clinical trials aimed at improving outcomes by incorporating promising new biologic, targeted, and immune therapies into standard treatment regimens. Her translational research program focuses on understanding the immune environment associated with gynecologic cancers and mechanisms of resistance to current therapies.

Dr. Gaillard has been honored with several awards in her career, including the Liz Tilberis Early Career Award from the Ovarian Cancer Research Fund, the Young Investigator Award from the Conquer Cancer Foundation, and was a NIH BIRCWH (Building Interdisciplinary Research Careers in Women's Health) Scholar. She is the principal or co-author of numerous publications and book chapters and has traveled nationally and internationally to present her research.

David M. Gershenson, MD, *UT MD Anderson Cancer Center*

Dr. David M. Gershenson is Professor in the Department of Gynecologic Oncology and Reproductive Medicine at the University of Texas MD Anderson Cancer Center where he joined the faculty in 1979 after completing his fellowship training. He served as Chair of the department from 1998-2012. His major focus is on clinical and translational research of rare ovarian cancers.

Dr. Gershenson received his undergraduate degree from the University of Pennsylvania and his MD degree from Vanderbilt School of Medicine. He completed his residency in obstetrics and gynecology at Yale School of Medicine and his fellowship in gynecologic oncology at The University of Texas MD Anderson Cancer Center. He is board-certified in both obstetrics and gynecology and gynecologic oncology.

Dr. Gershenson has published over 410 peer-reviewed articles and over 175 invited articles, book chapters, and editorials. He has co-edited nine books, including Comprehensive Gynecology, which is in its 7th Edition

He has served as Chair of the NRG Oncology's Rare Tumor Committee (2005-2018), as a Co-Chair of the NCI's Gynecologic Cancer Steering Committee (2010-2016), and as Co-Chair Emeritus (2016-2017). He was Editor-In-chief of the journal, Gynecologic Oncology (1990-2007), and since 2008 has served as the journal's Editor Emeritus. He currently serves on the Editorial Board of the Journal of Clinical Oncology. He is also a member of the National Comprehensive Cancer Network Ovarian Cancer Panel. He served as Chairman of the Foundation for Women's Cancer (formerly the GCF) from 2009-2015. From 2002-2005 and 2006-2014, he served as a Director of the American Board of Obstetrics and Gynecology. He is Past President of the Felix Rutledge Society, the Houston Gynecological and Obstetrical Society, the Society of Gynecologic Oncology, and the American Radium Society. In 2016, he was appointed as a member of the Clinical Trials and Translational Research Advisory Committee of the National Cancer Institute.

Amreen Husain, MD, *Genentech*

Amreen Husain, MD is a group medical director at Genentech/Roche where she leads the clinical development of Atezolizumab in Breast and Gynecologic cancer. Dr. Husain is a board certified gynecologic oncologist, she trained in Obstetrics and Gynecology at the New-York Hospital and completed her fellowship at Memorial Sloan-Kettering Cancer Center, NY. She was an assistant and associate Professor at Stanford University in Gynecologic Oncology for 10 years and a lead investigator with the gynecologic oncology group. She has served on a variety of committees and leadership roles in national organization including ASCO and SGO. Dr. Husain joined Genentech in 2010 as medical director for Bevacizumab in gynecologic cancers as well as early pipeline molecules and in 2016 became the global development team leader for the immuno-oncology program in breast and gynecologic cancers.

Gwynn Ison, MD, *U.S. Food and Drug Administration*

Dr. Ison is a clinical reviewer in the Office of Hematology and Oncology Products in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA) where she has worked since 2008. Her specific areas of focus include gynecologic and breast oncology products.

Dr. Ison received her BS in natural sciences from Xavier University and her medical degree from the University of Nebraska College of Medicine. She completed her residency in internal medicine at the University of Maryland Medical Center and her medical oncology training at the National Cancer Institute, where she was involved in clinical research with idiotype vaccines in low-grade non-Hodgkin's lymphoma.

Since joining the FDA, she has reviewed numerous new drug applications for marketing approval in oncology, including products for gynecologic and urologic malignancies, has authored manuscripts on new approvals, and has spoken at workshops and meetings on gynecologic malignancies. She has also been the FDA lead on the ongoing Modernizing Eligibility Criteria Project.

Amir A. Jazaeri, MD, *UT MD Anderson Cancer Center*

Dr. Jazaeri is the Ad Interim Department Chair and the Director of the Gynecologic Cancer Immunotherapy Program in the Department of Gynecologic Oncology and Reproductive Medicine at the University of Texas MD Anderson Cancer Center.

Since his recruitment in 2014, Dr. Jazaeri has established a multidisciplinary and broad-based immunotherapy program for gynecologic cancers that include adoptive cell therapies and immune checkpoint inhibitors. His other areas of research interest include innovative clinical trial designs and translational research for identification of novel immunotherapy targets for gynecologic cancers.

Stephen Keefe, MD, MSCE, *Merck*

Steve leads global clinical development in gynecologic cancers for Merck. His team is focused on pembrolizumab, olaparib, and lenvatinib as well as on combination strategies with compounds in earlier stages of development. Prior to work in gynecologic oncology, Steve worked in GU cancers at Merck where he co-led global development and regulatory submissions for pembrolizumab in urothelial carcinoma. Before Merck, Steve was a clinical investigator serving on the faculty of the school of medicine at the University of Pennsylvania. He holds an MD from the University of Chicago and an MS in clinical epidemiology and biostatistics from Penn where he completed his residency in internal medicine and fellowship in medical oncology and where he continues to see patients in a limited clinical practice.

W. Michael Korn, MD, *University of California, San Francisco*

Dr. Korn is a medical oncologist with extensive experience in clinical and molecular oncology. Currently he serves as Chief Medical Officer at Caris Life Sciences. In this role, Dr. Korn guides Caris' research efforts and clinical strategies for innovative precision medicine tools and tumor profiling services. Dr. Korn is also Professor of Medicine in the Division of Hematology/Oncology at the University of California, San Francisco (UCSF) where he founded the Molecular Oncology Initiative at UCSF's Helen Diller Family Comprehensive Cancer Center (HDFCCC), and initiated and chaired the UCSF Molecular Tumor Board, a cross-disciplinary platform supporting clinical decision making based on Next-Generation Sequencing results.

Dr. Korn received his M.D. from Philipps University of Marburg, Germany. He performed a fellowship in medical oncology at the West German Cancer Center, University of Essen, Germany and completed post-doctoral training with Dr. Frank McCormick at UCSF.

Hisani Madison, MD, MPH, *U.S. Food and Drug Administration*

Dr. Hisani Madison is a Senior Scientific Reviewer in the Office of *In Vitro* Diagnostics and Radiological Health at the Center for Devices and Radiological Health in the Food and Drug Administration (FDA). Dr. Madison leads the review of submissions in the Molecular Pathology and Cytology Branch (MPCB) as part of the Division of Molecular Genetics and Pathology. MPCB is responsible for reviewing a wide range of devices including next generation sequencing technologies and hybridization-based molecular techniques to detect genetic alterations associated with cancer. Dr. Madison specializes in review of devices intended to aid in selection of therapy for patients with solid tumors.

Prior to her current position, Dr. Madison was a postdoctoral fellow in the Hormonal and Reproductive Epidemiology Branch of the Division of Cancer Epidemiology and Genetics at the National Cancer Institute where she conducted molecular epidemiologic research focusing on breast cancer etiology and heterogeneity. Dr. Madison obtained her PhD in Pathology from Duke University, where her doctoral research focused on identifying and characterizing genetic and epigenetic markers for the early detection, prognosis and prediction of breast and ovarian cancer. She also has an MPH from Johns Hopkins Bloomberg School of Public Health where she trained in epidemiology and biostatistics and received a Certificate in Health Disparities and Health Inequality.

Amy E. McKee, MD, *U.S. Food and Drug Administration*

Dr. McKee is the acting Deputy Director of the Oncology Center of Excellence and the 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 these positions, she was a clinical team leader in the Division of Oncology Products 1/OHOP for breast and gynecologic oncology products. Dr. McKee received her BA 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, PhD, prior to joining the FDA. She received the NCI Director's Innovation Career Development Award for her research on stem cells in cancer. 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.

Mary Scroggins, MA, *Patient Advocate*

Mary (Dicey) Jackson Scroggins, MA—an ovarian cancer survivor and health activist—is a writer, producer, and founding partner in Pinkie Hugs, LLC (a mother-daughter writing and film production firm specializing in social justice–focused documentaries). She is also co-founder of In My Sister's Care, an organization focused on improving gynecologic cancer awareness and care for medically underserved women and on eliminating health disparities. Her advocacy work is driven by a commitment to health equity.

She was the recipient of the 2016 AACR Distinguished Public Service Award. With longstanding relationships throughout the advocacy and research communities, Mary is a member of the AACR Minorities in Cancer Research Council, the executive committee for the "Globe-athon to End Women's Cancers," NCI's Investigational Drug Steering Committee, the leadership committee for the MD Anderson Cancer Center's "Women's Cancer Moon Shot Program," and the African Organisation for Research and Training in Cancer. She is also a member of the Board of Directors of the GOG Foundation and of the NRG Oncology Foundation and chair of the NRG Patient Advocate Committee and of the Advocate Advisory Board of a DoD-funded Consortium for Long-Term Ovarian Cancer Survival. Previously, she was a member of NCI's Gynecologic Cancer Steering Committee and its Cancer Prevention and Control Central Institutional Review Board, a co-chair of NCI's Patient Advocate Steering Committee, and a peer reviewer and integration panel member for the DoD Ovarian Cancer Research Program.

An eclectic writer, Mary has published essays and articles on topics such as cancer survivorship, health disparities, and medical ethics and social justice-infused fiction. She is on the editorial advisory board of *Cancer Today*.

The mother of three phenomenal women; the grandmother of Anwar, Sanaa, and Asha (who call her "Sugar" and brighten her life); and the wife and best friend of Kwame, Mary is a certified mediator and master facilitator with a master's degree in writing from Johns Hopkins University.

Anil K. Sood, MD, *UT MD Anderson Cancer Center*

Dr. Anil K. Sood is Professor in the Department of Gynecologic Oncology and Reproductive Medicine at the UT MD Anderson Cancer Center. He holds a joint appointment in Cancer Biology and is co-director of the Center for RNA Interference and Non-Coding RNA at the MD Anderson Cancer Center. He is also Director of the multi-disciplinary Blanton-Davis Ovarian Cancer Research Program and co-leads the Ovarian Cancer Moonshot Program. Dr. Sood received his medical degree from the University of North Carolina, Chapel Hill. A major and consistent theme of his scientific

research has been on understanding human cancer biology and converting lab discoveries into novel therapeutics. His research group has made several seminal research contributions in the fields of tumor microenvironment, nanomedicine, and neuroendocrine effects on cancer biology. Dr. Sood has received recognition for his research accomplishments including the Hunter Award, the Margaret Greenfield/Carmel Cohen Excellence in Ovarian Cancer Research Prize, and the GCF/Claudia Cohen Research Foundation Prize for Outstanding Gynecologic Cancer Researcher. Dr. Sood was selected as an American Cancer Society Research Professor in 2017.

Rajeshwari Sridhara, PhD, *U.S. Food and Drug Administration*

Dr. Sridhara is the Division Director of Division of Biometrics V, Office of Biostatistics which supports Office of Hematology Oncology Products at the Center for Drug Evaluation and Research (CDER). She joined the Food and Drug Administration (FDA) in 1999. Dr. Sridhara has contributed in the understanding and addressing the statistical issues that are unique to the oncology disease area such as evaluation and analysis of time to disease progression. Her research interests also include evaluation of surrogate markers and design of clinical trials. She has organized, chaired and given invited presentations at several workshops. She has worked on many regulatory guidance documents across multiple disciplines. She has extensively published in refereed journals and presented at national and international conferences. She is an elected fellow of the American Statistical Association. Prior to joining FDA, Dr. Sridhara was a project statistician for the AIDS vaccine evaluation group at EMMES Corporation, and she was an assistant professor at the University of Maryland Cancer Center.

Dmitriy Zamarin, MD, PhD, *Memorial Sloan Kettering Cancer Center*

Dr. Zamarin is an Assistant Attending Physician in Gynecologic Medical Oncology and Immunotherapeutics Services at the Memorial Sloan Kettering Cancer Center. Dr. Zamarin obtained his MD and PhD degrees from the Mount Sinai School of Medicine in New York, where he pursued his doctorate studies with Dr. Peter Palese, characterizing cellular and immune responses to influenza viral infection. He pursued further training with Dr. Yuman Fong at Memorial Sloan Kettering, working on development of genetically-engineered viruses as cancer therapeutics. He completed residency in Internal Medicine at the Mount Sinai Hospital and fellowship in Hematology/Oncology at the Memorial Sloan Kettering Cancer Center, where he worked under the mentorship of Dr. James Allison and Dr. Jedd Wolchok, studying the mechanisms of response and resistance to immunomodulatory antibody therapy and virus-based therapeutics.

Dr. Zamarin is currently a principal investigator on several clinical trials exploring various immunotherapeutic combinations in gynecologic cancers and other solid tumors. His clinical and laboratory research are focused on characterization of biomarkers in patients undergoing immunotherapy and on development of novel immunotherapeutic strategies using immunomodulatory antibodies and genetically-engineered oncolytic viruses. Specifically, by manipulating the oncolytic viruses and the immune system, Dr. Zamarin is exploring different ways to enhance the immune recognition of tumors and to develop novel treatment strategies that could overcome resistance to immune checkpoint blockade.