Workshop on Product Development for CNS Metastases

Co-Sponsored by the FDA and National Brain Tumor Society
In Collaboration With
Accelerate Brain Cancer Cure, American Brain Tumor Association,
Friends of Cancer Research, Kidney Cancer Research Alliance,
LUNGevity Foundation, Melanoma Research Alliance
Metastatic Breast Cancer Alliance,
Response Assessment in NeuroOncology, and
Society for NeuroOncology

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Speaker Bios

Lauren Abrey, MD

Dr. Abrey is an oncology pharma executive with expertise in drug development, regulatory interactions, business development and medical affairs. She is currently Vice President and Global Medical Affairs Franchise Head for Solid Tumors at Novartis Oncology, based in Basel Switzerland. Prior to joining industry, Lauren served as Vice Chair of Neuro-oncology at Memorial Sloan Kettering Cancer Center where she was an attending physician for more than a decade.

Manmeet Ahluwalia, MD

Dr. Ahluwalia is the Dean and Diane Miller Family Endowed Chair in NeuroOncology in the Rose Ella Burkhardt Brain Tumor and Neuro-Oncology Center (BBTC) where he subspecializes in treatment of patients with brain tumors and brain metastases. He is a Professor in the Department of Medicine, Clinic Lerner College of Medicine of Case Western Reserve University (CCLCM). He serves as the Director, Brain Metastasis Research Program and the Associate Director and Head of Operations in the BBTC of the Neurological Institute of Cleveland Clinic. He has joint appointments in the Taussig Cancer Institute, Cleveland Clinic and in the Developmental Therapeutics Program, Case Comprehensive Cancer Center. He also serves as the Program Director of Neuro-Oncology fellowship at Cleveland Clinic.

Dr. Ahluwalia's research focuses on the development of new therapies for patients with brain tumors and brain metastases. He is currently leading several clinical trials involving immune therapies including vaccines, viral based therapies and immune check point inhibiters as well as targeted therapies. His results have been presented nationally and internationally and have resulted in over 150 editorials, manuscripts and book chapters. Dr. Ahluwalia serves as the Associate Editor on Tumor Section of Neurosurgery, the official Journal of Congress of Neurological Surgeons (CNS). He is the Associate Editor of ASCO Post, the newsletter of ASCO. He is the Section Editor of NeuroOncology for HemOnc Today. He serves as a reviewer on multiple journals including Cancer, NeuroOncology, Cancer Research, Clinical Cancer Research, BMC Cancer, Molecular Cancer Research.

Dr. Ahluwalia has been recipient of several prestigious awards such the National Cancer Institute/ CTEP Career Development Award for Clinical Trial in American Brain Tumor Consortium (ABTC), American Society of Clinical Oncology (ASCO) Leadership Development Program award, Crain’s 40 Under 40 award and has been nominated to the Leading in Healthcare, Cleveland Clinic.

Laleh Amiri-Kordestani, MD

Dr. Amiri-Kordestani is the associate 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. Amiri-Kordestani earned her medical degree from the University of Tehran Medical Sciences. She did a year of post-doctoral research fellowship in Molecular Genetics Laboratory at the National Institutes of Health. She completed a residency in internal medicine at the Georgetown University/Washington Hospital Center, followed by a fellowship in hematology and oncology at The National Cancer Institute. Under the direction of Dr. Sandra Swain, she became familiar with the design and implementation of breast cancer oncology clinical trials and at the NCI, she worked with Dr. Susan Bates focusing on early phase clinical trials and wrote two clinical protocols for patients with breast cancer and brain metastases.

At the FDA, Dr. Amiri served as medical officer and clinical team leader of the Breast Cancer Group prior to assuming her role as associate director in DOP1. She is also an assistant professor at Georgetown University Hospital where remains clinically active, practicing inpatient medicine.

Carey Anders, MD

Dr. Anders is the Medical Director of the Duke Brain and Spine Metastases Program, a Translating Duke Health Scholar, and a member of the Neuro-Oncology (primary) and Breast Cancer (secondary) Programs within the Duke Cancer Institute. Dr. Anders is a leading expert in the clinical care of patients with breast cancer of all stages, with a research focus in breast cancer that spreads to the central nervous system (CNS). In her role at Duke, she is expanding her clinical and research focus to brain metastases arising from solid tumors, more globally, alongside a state-of-the-art multidisciplinary team. Prior to her arrival at Duke, Dr. Anders was an Associate Professor at the University of North Carolina at Chapel Hill where she established herself as a translational/clinical investigator in the field of breast oncology. Over a decade at UNC, she focused on the biologic underpinnings of breast cancer brain metastases, was involved in many preclinical studies evaluating promising new therapies in models of breast cancer brain metastases, and designed, implemented, and completed numerous, novel clinical trials for patients with breast cancer brain metastases.

Terri Armstrong, PhD

Dr. Armstrong is a Senior Investigator and Deputy Branch Chief in the Neuro-Oncology Branch (NOB), Center for Cancer Research (CCR), National Cancer Institute (NCI), National Institutes of Health (NIH). Her program of research focuses on clinical outcomes assessment in clinical trials, exploring the biologic basis of symptoms and toxicity and developing prediction modeling and biologically based interventions for symptom management. She also co-leads the Moonshot funded NCI-CONNECT program. She is a graduate of The Ohio State University with a master's in oncology and post-master's certificate as an adult nurse practitioner. She has been an advanced practice provider for over 28 years at several academic institutions, including MDACC for 17 years. She has been the PI of several research studies with over 4.5 million in grant support. She was inducted as a Fellow in the American Academy of Nurse Practitioners in 2009 and as a Fellow in the American Academy of Nursing in 2013.

David Arons, JD

David Arons is the Chief Executive Officer of National Brain Tumor Society. He previously served as the Director of Government Relations for the American Cancer Society in Minnesota and was the co-founder and Co-Director of the Center for Lobbying in the Public Interest in Washington D.C. As an attorney, he previously represented patients facing disabilities and serious health conditions. He serves on the National Cancer Institute's Council of Research Advocates and Clinical Trials Advisory Committee. In 2016, Mr. Arons was a member of the National Cancer Moonshot's Blue-Ribbon Panel, led by former Vice President Joe Biden.

Michael Atkins, MD

Dr. Atkins is an internationally recognized leader in translational and clinical research working in melanoma, kidney cancer and cancer immunotherapy for over 30 years. He began his career at Tufts Medical Center before moving to Beth Israel Deaconess Medical Center and being appointed Professor at Harvard Medical School where he served as leader of the Biologic Therapy and Cutaneous Oncology Programs at Beth Israel Deaconess Medical Center, Co-PI of the Harvard Skin Cancer SPORE, leader of the Dana Farber Harvard Cancer Center Kidney Cancer Program and Director of the Kidney Cancer SPORE.

In 2012, he moved to Georgetown where he is the Deputy Director of the Georgetown Lombardi Comprehensive Cancer Center and William M. Scholl Professor and Vice Chair of the Department of Oncology. His research interests include immunotherapy, anti-angiogenic therapy, molecularly targeted therapy and predictive biomarker development particularly in melanoma and kidney cancer. He leads the Lombardi Immunotherapy Initiative and co-leads the Melanoma Disease Group within the MedStar Georgetown Cancer Institute. He has published over 450 original research and review articles and 3 books and has lectured extensively on these topics.

He is past president of the Society for Immunotherapy of Cancer (SITC) and past member of the NCI Recombinant DNA Advisory Committee. He is Chair of the Medical Advisory Panel for the Melanoma Research Alliance, co-chair of the Scientific Advisory Committee for the Melanoma Research Foundation, and a member of the Scientific Advisory Board for the Kidney Cancer Foundation, the SITC Policy Committee and the ASCO Nominating Committee.

Kimberly Blackwell, MD

Since March 2018, Kimberly L Blackwell, MD, has served as Vice President of Early Phase and Immuno-oncology at Eli Lilly and Company. In this role, she oversees all clinical development strategies for early phase assets. Prior to joining Lilly, Kim was a Professor of Medicine and Assistant Professor of Radiation Oncology at Duke University Medical Center. She served as the Co-Director of the Duke Cancer Institute's Women's Cancer Program, Associate Director for Strategic Relations at the Duke Cancer Institute, Global Research Scholar for the Susan G. Komen for the Cure, and Senior Strategist for the Duke Innovation and Entrepreneurship Program. Her clinical and research interests included various topics in breast cancer including antibody drug conjugates, novel HER2 therapies, breast cancer vaccines, and other experimental therapeutics. She has studied and served as the PI on studies that led to approval of four approved agents- lapatinib (2009), T-DM1 (2012), and two G-CSF biosimilars (2015). Because of her work, she has received numerous awards including being named one of TIME magazine's 100 most influential people in the world in 2013.

Priscilla Brastianos, MD

Originally from Vancouver, British Columbia, Dr.Priscilla Brastianos received her BSc in biochemistry and chemistry from the University of British Columbia, where she graduated as her class valedictorian. She received multiple awards, including the Science Scholar Award, the Canadian Society for Chemistry Prize and the Violet and Blythe Eagles Undergraduate Prize in Biochemistry. She completed her medical school training and her internal medicine residency training at Johns Hopkins School of Medicine. While at Hopkins, she received the Johns Hopkins Medical Student Award for Excellence in Research, the national Leah J. Dickstein, MD, award for leadership and scholarship, and the Bradley Benton Davis Research Award from the American Brain Tumor Association. Following her training at Johns Hopkins, she pursued her fellowship training in hematology/oncology and neuro-oncology at the Dana-Farber Cancer Institute and Massachusetts General Hospital. She is now Director of the Central Nervous System Metastasis Program at Massachusetts General Hospital. As a physician-scientist, she received an ASCO Young Investigator Award, a Susan G. Komen Postdoctoral Fellowship Award, a Susan G. Komen 'Dare' Award, an American Brain Tumor Association Postdoctoral Fellowship, a Terri Brodeur Foundation Fellowship Award, AACR 'NextGen Star', a Damon Runyon Clinical Investigator Award, a Breast Cancer Research Foundation Award and a Susan G. Komen Career Catalyst Award.

Dr. Brastianos' research focuses on understanding the genomic mechanisms that drive brain tumors. She lead the studies which identified novel therapeutic targets in meningiomas, craniopharyngiomas and brain metastases. She and her collaborator, Scott Carter, have done pioneering work in brain metastases and they have demonstrated that brain metastases have branched evolution, and harbor clinically significant drivers that are distinct from clinically sampled primary tumors. Dr. Brastianos has translated her scientific findings to national multicenter trials. She also leads a multidisciplinary central nervous system metastasis clinic at Massachusetts General Hospital/Harvard Medical School.

Caroline Chung, MD

Dr. Chung is an Associate Professor and Director of Imaging Technology & Innovation within the Division of Radiation Oncology with cross-appointment to Diagnostic Radiology at The University of Texas MD Anderson Cancer Center. In her leadership role, Dr. Chung facilitates collaborative, multidisicplinary research studies of MR-guided radiotherapy including the use of MR for target delineation, real-time MR image guidance of radiation delivery and multimodal/multiparametric imaging biomarkers of response to treatment. She transitioned about 3 years ago from her position as a clinician-scientist at Princess Margaret Canada Centre in Toronto, Canada where she was the clinical and research lead for the Multidisciplinary Brain Metastasis Clinic and lead of the Robert and Andree Fitzhenry Brain Metastasis Program. Dr. Chung's clinical practice focuses on primary and secondary brain tumors. Her major research focus is to utilize advanced imaging to measure and predict response and toxicity to treatment in order to optimize personalized, adaptive treatment approaches. This has included preclinical investigation in orthotopic brain tumor models, retrospective multiparametric image analyses and ongoing clinical trial investigation of imaging biomarkers of tumor and normal tissue response following radiation treatment. Internationally, Dr. Chung is involved in efforts to improve the quality and standardization of imaging to facilitate meaningful measurement and interpretation of imaging biomarkers in clinical trials as co-chair of the Dynamic Contrast Enhanced-MRI Task Force for the Radiological Society of North America Quantitative Imaging Biomarker Alliance, member of the Jumpstarting Brain Tumor Drug Development Coalition's Imaging Standardization Steering Committee, and Co-Chair of the Neuro-imaging Subcommittee in the Alliance for Clinical Trials in Oncology.

Michael Davies, MD, PhD

Dr. Davies is the Deputy Chairman and associate professor in the Department of Melanoma Medical Oncology at the University of Texas MD Anderson Cancer Center. Dr. Davies is a physician-scientist whose research utilizes integrated approaches to study the regulation and clinical significance of oncogenic signaling networks in cancer, particularly in therapeutic resistance and in the molecular pathogenesis of brain metastases. Dr. Davies has been the principal investigator of both individual and team science peer-reviewed grants from several organizations, including the National Cancer Institute (NCI), the US Department of Defense, the American Society of Clinical Oncology (ASCO), the Melanoma Research Alliance, and the Melanoma Research Foundation. He has served as the principal investigator of several clinical trials for patients with metastatic melanoma, and has authored or co-authored >150 original research manuscripts in peer-reviewed journals including *Cell, Cancer Cell, Science, Cancer Discovery, Lancet Oncology, Cancer Research,* and *Clinical Cancer Research*. Dr. Davies is a member of the American Society for Clinical Investigation, the Melanoma Research Foundation Breakthrough Consortium, and the International Melanoma Working Group.

Ralph DeVitto

Mr. DeVitto is responsible for leading ABTA's dedicated staff, while increasing the value of the organization to patients, caregivers, healthcare profressionals, scientists, donors, sponsors, partners, and other key influencers. He enhances the ABTA's already strong reputation as the go-to source on brain tumor related science and treatments, and leads efforts to further develop learning resources, tools, and activities related to information availability and treatment for patents, survivors, and caregivers.

Mr. DeVitto brings extensive experience in association management, including strategic planning, fundraising, volunteer mobilization and partnership building. Previously, Mr. DeVitto served in numerous leadership roles during his 21 years with the American Cancer Society, including the CEO of the Florida Division and the interim Executive Vice President of the Southeast Region, where he oversaw the merger of operations in five states and Puerto Rico to create the Region.

Victoria Ebiana, MD

Dr. Ebiana is a clinical director in oncology at Merck, where she focuses on thoracic malignancies and advises on neuro-oncology trials. She is a board- certified neurologist who recently completed a fellowship in neuro-oncology at Memorial Sloan Kettering Cancer Center. She earned her medical degree from Columbia University and completed an internship in Internal Medicine at Yale University. She completed her neurology residency at the University of California Los Angeles. She has been involved in glioma research for over ten years and has been published in multiple journals. She is a current and active member of Society for Neuro-Oncology.

Benjamin Ellingson, MD

Dr. Ellingson is the Director of the UCLA Brain Tumor Imaging Laboratory (BTIL), Co-Director of the Center for Computer Vision and Imaging Biomarkers, and a member of the UCLA Brain Tumor Program. Dr. Ellingson serves as the imaging chair for multiple brain tumor consortia and clinical trials. Dr. Ellingson's research involves the development, testing, and implementation of advanced MRI and PET imaging biomarkers for the characterization of brain tumor biology and response evaluation in clinical trials.

Shelly Engfer-Triebenbach

Shelly was diagnosed with stage 4, nsclc in 2013. The ALK mutation was not discovered until four months after diagnosis. Her treatment thus far has been: 12 rounds of two different chemotherapies, 9 months on Crizotinib, 28 months on the Brigatinib (Alunbrig) trial, currently on month 20 of the Lorlatinib trial. She has also had one SRS treatment in 2018.
As a patient activist, Shelly mentors the newly diagnosed and feels empowered raising her voice on Capital Hill. She also enjoys working with pharmaceutical companies, serving on their patient advisory panels and speaking to their sales representatives. Shelly also partners with many lung advocacy groups including: A Breath of Hope, IASLC, LCA, LCFA and Lungevity. She is especially excited to be a founding member of the patient group ALKFusion: "Patient centric research with a focus on collaboration and disease management."

Vinai Gondi, MD

Dr. Gondi is the Director of CNS Radiation Oncology at the Northwestern Medicine Cancer Center Warrenville and Director of Research & Education at the Northwestern Medicine Proton Center. He specializes in the radiotherapeutic management of brain and spine tumors, and his research focuses on the development of advanced radiotherapy techniques to optimize tumor outcomes. He has served as the co-Principal Investigator on multiple NCI-sponsored cooperative group trials through NRG Oncology, including trials of hippocampal avoidance during whole-brain radiotherapy for brain metastases.

Chitkala Kalidas, PhD

Dr. Kalidas is Vice President and Head of Global Regulatory Affairs for Oncology and in vitro diagnostics at Bayer. Dr. Kalidas leads a team of Global Regulatory Strategists who are responsible for developing appropriate global strategies for programs in all stages of drug development and for the registration of companion diagnostics as well. Programs in her group include VITRAKVI® (larotrectinib), STIVARGA® (regorafenib), XOFIGO® (Radium 223), ALIQOPA® (copanlisib) and NEXAVAR® (sorafenib), among others. Precision medicine is an area of interest for her group as well as novel development strategies including tissue agnostic development, novel clinical trial design, pediatric development in Oncology and drug development in special populations. Dr. Kalidas has over 18 years of experience in drug development. Prior to joining Bayer, Dr. Kalidas worked at Merck & Co. Inc. where she worked across therapeutic areas and geographic regions. She has a PhD in Microbiology from Cornell University.

Paul Kluetz, MD

Dr. Kluetz is a medical oncologist and the Associate Director of Patient Outcomes in the Oncology Center of Excellence at the U.S. FDA. His interests include trial design and endpoint selection to define clinical benefit in oncology trials. Recent work includes efforts to advance pragmatic and decentralized trials and explore digitally sourced clinical outcome information from patient reported outcomes (PRO), wearable technologies, and other methods in both the clinical trial and “real-world” settings. He is currently leading a team to develop regulatory science and policy initiatives to advance patient-focused drug development across cancer products in the Oncology Center of Excellence. Dr. Kluetz remains clinically active seeing patients and supervising medical residents at the Georgetown University Hospital.

Benjamin Levy, MD

Dr. Levy is a thoracic medical oncologist and the clinical director of medical oncology for the Johns Hopkins Sidney Kimmel Cancer Center at Sibley Memorial Hospital, as well as an associate professor of oncology for Johns Hopkins Unicersity School of Medicine. Dr. Levy is board certified in medical oncology and hematology by the American Board of International Medicine. He practices out of the Johns Hopkins Sidney Kimmel Center at Sibley Memorial Hospital.

Dr. Levy is a physician scientist who is interested in innovative immunotherapeutic approaches for advanced stage lung cancer patients and biomarkers that help define those patients more likely to respond to such agents. He has an expertise in thoracic malignancies, including non-small cell lung cancer, small cell lung cancer and thymic malignancies, as well as head and neck cancer.

Dr. Levy earned his medical degree from Medical College of Georgia. He completed an internal medicine residency at Georgetown University Hospital, followed by a hematology/oncology fellowship at New York Presbyterian/Weill Cornell Medical Center, where he received the Department of Medicine Research Fellow of the Year Award and the 2009 American Society of Clinical Oncology Young Investigator Award for his clinical research in prostate cancer. Dr. Levy previously worked as an assistant professor at the Icahn School of Medicine, medical director of thoracic oncology for Mount Sinai Health Systems and associate director of the Cancer Clinical Trials Office for Mount Sinai Hospital in New York City.

Nancy Lin, MD

Dr. Lin is the Associate Chief of Breast Medical Oncology for the Susan F. Smith Center for Women's Cancers at Dana-Farber Cancer Institute, Director of the Metastatic Breast Cancer Program, and an Associate Professor of Medicine at Harvard Medical School. Her research is focused upon developing novel therapies for patients with metastatic breast cancer and in understanding mechanisms of therapeutic resistance.

Dr. Lin received her undergraduate degree from Stanford University and medical degree from Harvard Medical School. She subsequently completed her residency in Internal Medicine at Brigham and Women's Hospital and fellowships in hematology and medical oncology at Dana-Farber Cancer Institute.

She has led multiple trials of novel systemic approaches for metastatic breast cancer, including patients with breast cancer brain metastases. She has had national and international leadership roles, including serving as the overall PI of several multi-center studies, co-chair of the Response Assessment in Neuro-Oncology metastatic working group, Chair of the Friends of Cancer-American Society Modernizing Eligibility Criteria Project-Brain Metastasis Working Group, and membership in national and international guidelines committees for the management of metastatic breast cancer.

Dr. Lin is also experienced in tissue- and blood-based translational research, and with the construction and analysis of clinical databases. She is the PI of the breast oncology-specific tissue banking protocol at Dana-Farber, Co-Chair of the Dana-Farber/Harvard Clinical Data and Tissue Users' Committee, and PI of active protocols allowing prospective consent for research biopsies with linked clinical data across all stages of breast cancer, and of the EMBRACE (Ending Metastatic Breast Cancer for Everyone) metastatic cohort study. She serves as the DF/HCC institutional PI for the Translational Breast Cancer Research Consortium.

Kim Margolin, MD

Dr. Margolin is a professor in the department of medical oncology at City of Hope, specializing in melanoma and skin cancers as well as germ cell cancer. She is a founding member and co-leader of the Cytokine Working Group and has also collaborated with the Melanoma Research Foundation, SWOG, the California Cancer Consortium and the Melanoma Research Alliance. She was co-principal investigator for the first grant cycle of the Cancer Immunotherapy Trials Network and PI of one of their original trials. She is currently serving as secretary-treasurer of the Society for the Immunotherapy of Cancer.

Dr. Margolin's principal research interests are the immunotherapy of advanced melanoma, with a particular focus on the biology, immunology and therapy of metastases to the brain, which is the greatest threat to survival and quality of life among melanoma patients. She also continues to work on the application of novel cytokines and many other immunomodulatory therapies for melanoma and other malignancies.

Shanthi Marur, MD

After attending medical school at the Coimbatore Medical College in Tamilnadu, India, Dr. Marur completed her Internal Medicine residency and a year of Chief Residency at Sinai-Grace Hospital/Wayne State University (July 2000- June 2004) . She then completed fellowship training in Hematology and Medical Oncology at Barbara Ann Karmanos Cancer Institute, Wayne State University (July 2004- June 2007). Subsequently, she joined the full-time faculty at the Johns Hopkins University attaining the position of Assistant Professor in Hematology/Oncology at Johns Hopkins School of Medicine and Sidney Kimmel Comprehensive Cancer Center (July 2007-Nov 2016).

As a member of the Head and Neck Research team at Johns Hopkins her research was focused on conducting institutional, national and global trials in prevention, diagnosis, treatment, toxicity of treatment and quality of life aspects of head and neck cancer. Dr.Marur was a member of the NCI established Head and Neck Cancer Specialized Programs of Research Excellence (SPORE), the Head and Neck Cancer Group for the Mayo Clinic Phase II Consortium and the Eastern Cooperative Oncology Group (ECOG) Head and Neck Cancer Core Committee. While at Hopkins, she was the lead investigator and study chair for an Eastern Cooperative Oncology Group (ECOG) trial, E1308**,** the first national trial to de-escalate radiation in HPV associated head and neck cancer patients. Dr.Marur served on the Institutional Research Board for oncology trials at Johns Hopkins.

Dr.Marur, joined the Oncology Center of Excellence at the Food and Drug Administration (FDA) in 2016. Since joining the FDA she has been involved with efforts to develop, enrich and publicize FDA's initiatives in Head and Neck and Lung Cancer in a variety of approaches. Dr.Marur has represented FDA at meetings designed to align key stakeholders' understanding of the regulatory challenges stemming from lung and head and neck cancer clinical studies.

Pallavi Mishra-Kalyani, PhD

Dr. Mishra-Kalyani is a Team Leader in the Division of Biometrics V in the Office of Biostatistics in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). She received a Ph.D. in Biostatistics from Emory University and a Master's degree in Epidemiology from the T.H. Chan School of Public Health at Harvard University. Her research interests include statistical methods for observational data, causal inference, and non-randomized trial design.

Richard Pazdur, MD

Dr. Pazdur is director of FDA's Oncology Center of Excellence (OCE), which leverages the combined skills of FDA's regulatory scientists and reviewers with expertise in drugs, biologics, and devices to expedite the development of novel cancer products. In this role, Dr. Pazdur leads the effort to develop and execute an integrated regulatory approach to enhance cross-center coordination of oncology product clinical review.

Prior to joining FDA in 1999, Dr. Pazdur was professor of medicine at The University of Texas M.D. Anderson Cancer Center. From 1982 to 1988, he served on the faculty of Wayne State University. He received his bachelor's degree from Northwestern University, his M.D. from Loyola Stritch School of Medicine, and completed clinical training at Rush-Presbyterian St. Luke's Medical Center and University of Chicago Hospitals and Clinics.

Dr. Pazdur has published more than 600 articles, book chapters, and abstracts. He was recognized in Fortune magazine's 2015 list of "50 World's Greatest Leaders," and in 2017, as one of The Bloomberg 50. In 2016, he was named to Massachusetts General Hospital Cancer Center's "The One Hundred" list. He received the American Society of Clinical Oncology Service Recognition Award (2009) and Public Service Award (2013); American Association for Cancer Research Distinguished Public Service Award (2015); National Coalition for Cancer Survivorship Public Service Leadership Award (2015); LUNGevity Foundation Face of Hope Award (2015); American Society for Clinical Pharmacology and Therapeutics Gary Neil Prize for Innovation in Drug Development (2018); National Organization for Rare Disorders Rare Impact Award (2018); and Reagan-Udall Foundation Leadership Award (2018).

Tatiana Prowell, MD

Dr. Prowell is Breast Cancer Scientific Liaison in FDA's Office of Hematology & Oncology Products and Assistant Professor of Oncology in the Breast Cancer Program at the Johns Hopkins Kimmel Comprehensive Cancer Center. She was the principal architect of FDA's policy on accelerated approval using pathological complete response as a novel regulatory endpoint in the neoadjuvant high-risk breast cancer setting, and was a member of the Biden Cancer Moonshot Blue Ribbon Panel Cancer Immunology Working Group. She is a frequent public speaker and a three-time recipient of FDA's Excellence in Communication Award, as well as a Giants of Cancer Care Award finalist. A passionate medical educator and mentor, she is Chair-Elect of the 2020 ASCO Annual Meeting Education Committee and has served on the faculty of the Vail Methods in Clinical Cancer Research Workshop, the Society for Translational Oncology Fellows' Forum, the Dana Farber Clinical Investigator Seminar Series, and the FDA-ASCO Fellows' Day Workshop among several others. She sees patients in the Johns Hopkins Second Opinion Breast Cancer Clinic and teaches in the medical school and medical oncology fellowship training program. Dr. Prowell received her BA degree from Bard College in Languages and Literature and her MD degree from the Johns Hopkins School of Medicine with election to the Phi Beta Kappa and Alpha Omega Alpha honor societies. She completed her residency and fellowship at Johns Hopkins Hospital.

Derrick Queen

Three years ago, Derrick Queen received bad news after an MRI of his brain. Doctors told him the severe headaches that he'd been having were due to three tumors in his brain. One was the size of a clementine and was pushing everything from the left to the right side of his head. Surgery for this large tumor confirmed the source was metastatic melanoma, an advanced form of skin cancer that had spread to his lungs and brain.

Around that time, the median survival time for melanoma patients like Derrick was less than five months. There were roughly a dozen clinical trials for a melanoma cure. However, due to his brain tumors, Derrick was unable to get access to these advanced therapies.

Fortunately, for Derrick, he responded positively to a novel approach to a combination of an approved immunotherapy drug, pembrolizumab, and stereotactic radiation.

Recognizing that he was one of the lucky patients to survive stage IV melanoma, Derrick is focused on changing outcomes for the millions of people who will be diagnosed with cancer in the years to come.

Last spring, he spoke at a fundraiser which raised over $2 million for cancer research. In addition to his fundraising efforts, Derrick often advises cancer patients about ways to treat their disease and improve their quality of life. Derrick has spent 25 years investing for a variety of institutional equity investment firms and hedge funds. He currently lives in New York with his wife and two boys.

Greg Riely, MD

Dr. Gregory Riely is a medical oncologist in the Department of Medicine at Memorial Sloan Kettering Cancer Center, where he is Vice Chair, Clinical Research. His primary research focus is in clinical research of patients with non-small cell lung cancer, focusing on patients with oncogene-driven cancers (EGFR, ALK, BRAF, and KRAS). He is an Associate Professor at Weill Cornell Medical College. He completed fellowship training in Medical Oncology at Memorial Sloan-Kettering Cancer. Dr. Riely received his PhD and MD degrees from Case Western Reserve University. He has authored and co-authored numerous peer-reviewed articles, which have appeared in *Blood, Clinical Cancer Research, Journal of Clinical Oncology, Lancet Oncology, and The New England Journal of Medicine*.

Wendy K.D. Selig

Wendy is Founder and CEO of WSCollaborative, a firm that focuses on defining and implementing strategies for establishing winning cross-sector collaborations in the health care arena. Selig is President of the National Coalition of Cancer Research (NCCR) and a member of the Board of Directors of the Rising Tide Foundation for Clinical Cancer Research (RTFCCR). She has held leadership roles in numerous coalitions, including founding president of United for Medical Research (UMR) and chair of One Voice Against Cancer (OVAC). She has served on the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG), the Patient Leadership Council of the Clinical Trials Transformation Initiative (CTTI), the Government Affairs Committee of the Prostate Cancer Foundation (PCF), and the National Comprehensive Cancer Network's (NCCN) Tissue Allocation Subcommittee.

From 2009-2015, Selig served as President and CEO of the Melanoma Research Alliance (MRA), where she led and managed MRA's strategic priorities, research portfolio, engagement with 90 corporate and non-profit Allies, and day-to-day operations. Prior to that, Selig spent nearly a decade in leadership positions at the American Cancer Society (the Society) and its advocacy affiliate, the American Cancer Society Cancer Action Network (ACS CAN). Most recently, she served as ACS CAN's Vice President of External Affairs & Strategic Alliances where she built strategic partnerships. Her work at the Society began in 2000, when she served first as Managing Director, Federal Government Relations and later Vice President for

Legislative Affairs. From 1989-2000, Selig served on Capitol Hill as a senior staff member for U.S. Representative Porter J. Goss (R-FL), the House Rules Committee and the House Permanent Select Committee on Intelligence (HPSCI).
A native of Princeton, NJ, Selig is a Magna Cum Laude graduate of Princeton University and holds a Masters in Science (With Distinction) from Northwestern University's Medill School of Journalism.

Joohee Sul, MD

Dr. Sul is Medical Officer and Scientific Liaison for Brain and CNS Malignancies in the Office of Hematology and Oncology Products (OHOP) at the FDA. Dr. Sul completed her fellowship in neuro-oncology at Memorial Sloan-Kettering Cancer Center in 2007. Prior to joining the FDA, Dr. Sul was a Staff Clinician at the National Cancer Institute (NCI). Dr. Sul has worked with multiple stakeholders, including advocacy groups, to support development of products for CNS malignancies.

Hussein Tawbi, MD, PhD

Hussein Tawbi is Associate Professor of Medical Oncology, Investigational Cancer Therapeutics, and Director of Melanoma Clinical Research and Early Drug Development at the Department of Melanoma Medical Oncology at the University of Texas MD Anderson Cancer Center. Dr. Tawbi joined MD Anderson in 2015 and in addition to being a melanoma clinician, he develops and conducts multiple clinical trials with translational endpoints in melanoma, sarcoma, and immunotherapy. His role at MD Anderson includes providing the vision and direction of clinical translational research at the Department of Melanoma Medical Oncology and enhance the operations of the clinical research staff.
Dr. Tawbi obtained his MD in 2001 from the American University of Beirut, Beirut, Lebanon. Dr. Tawbi completed my training in Internal Medicine and Hematology/Oncology at the University of Pittsburgh and joined the faculty ranks at the University of Pittsburgh as an Assistant Professor in 2007 and was promoted to Associate Professor in 2014. His clinical training was coupled with formal instruction in Clinical and Translational Research that culminated in a PhD degree in Clinical and Translational Science in 2011. Dr. Tawbi joined the University of Texas MD Anderson Cancer Center as Associate Professor in the Departments of Melanoma Medical Oncology and Investigational Cancer Therapeutics in November 2015, and recently appointed Director of Melanoma Clinical Research and Early Drug Development. The primary focus of his research has been early phase studies of novel agents in melanoma and sarcoma.

Luke Walker, MD

Dr. Walker is a medical oncologist who received his medical degree from the University of Oklahoma, followed by training in internal medicine, hematology/oncology, and hematopoietic stem cell transplant at Oregon Health Sciences University. He was a practicing hematologist and oncologist in the community for several years in Seattle, where he led the multidisciplinary Thoracic Oncology Clinic and the Anticoagulation Clinic before joining Oncothyreon as Medical Director in Seattle in 2011. He began work on the tucatinib program in 2013, where he worked on designing early tucatinib clinical trials to include patients with active brain metastases. He continued to lead the tucatinib program as Senior Vice President at Cascadian Therapeutics until 2018, developing a pivotal clinical trial to include patients with active brain metastases. He now continues on the tucatinib program with Seattle Genetics as Vice President of Clinical Development and Global Development Lead of Tucatinib."

Lynda Weatherby

Lynda Weatherby has been living with Metastatic Breast Cancer (MBC) for 6 years and is an active MBC patient advocate living in Seattle, Washington. She co-founded the Northwest Metastatic Breast Cancer Conference (NWMBCC), now in its fourth year and hosted by Amazon Web Services. This conference was one of the first events in the country just for patients living with MBC, and the first to live-stream its important content for MBC patients. In the past two years NWMBCC has had over 75,000 day-of livestream views of sessions covering the latest in clinical advances, support services, and clinical trials information for MBC.

Lynda works collaboratively with the leading MBC organizations, including serving on the Executive Group of the Metastatic Breast Cancer Alliance, and METAvivor. She called for, helped co-found, and serves on a new MBC Advisory Committee to the CEO of Susan G. Komen.

Lynda was diagnosed with MBC in 2013, 12 years after her first diagnosis at age 36 of Stage 0 DCIS and a bilateral mastectomy. After several YEARS of small, accelerating but dismissed symptoms, she was finally diagnosed with metastatic lesions throughout her skeleton, spine, brain, and on her trigeminal facial nerve (which brought her much too close to a leptomeningeal disease diagnosis). Lynda received Gamma Knife radiosurgery twice, along with radiation to her spine and endocrine therapy. She is thankful to be doing well on her current treatments. There are few waking hours not spent pondering MBC – either in terms of lifestyle, advocacy, or the loss of too many friends who lost their lives much too early to MBC.

She remains deeply, eternally grateful for the ongoing, state-of-the-art, outstanding care she receives from her team at Seattle Cancer Care Alliance and University of Washington.

Jeffrey Wefel, MD

Dr. Wefel is a tenured Associate Professor and Chief of the Section of Neuropsychology with joint appointments in the Department of Neuro-Oncology and the Department of Radiation Oncology at The University of Texas MD Anderson Cancer Center.

He obtained his PhD in Clinical Psychology (Neuropsychology) from the University of Houston, completed his residency at the University of Chicago, and subsequently his fellowship in the Department of Neuro-Oncology at MD Anderson.

Dr. Wefel's extramurally funded research seeks to characterize the prevalence, pattern, course, risks, and biologic and neural substrates for the development of cognitive dysfunction associated with cancer and cancer therapies. Ultimately, this will lead to identification and testing of interventions to prevent and/or minimize cognitive dysfunction. He is the cognitive study chair on numerous cooperative group, industry sponsored and investigator initiated trials involving patients with central nervous system and non-CNS cancer, many of which integrate cognitive and neuroimaging outcomes as well as exploration of genetic moderators of cognitive and brain outcomes. He has published over 100 manuscripts and book chapters.

Dr. Wefel is a Founder of the International Cognition and Cancer Task Force, Member of the National Brain Tumor Society (NBTS) Medical Advisory Board, Steering Committee Member of the NBTS Jumpstarting Brain Tumor Drug Development Coalition and FDA Clinical Trials Clinical Outcome Assessment Endpoints workshop, Executive Board Member of the RTOG/NRG Oncology Brain Tumor Committee and Patient Centered Outcome Committee, and an Executive Committee Member of the Brain Tumor Center at MD Anderson. He has been appointed as Executive Editor of the journal *Neuro-Oncology Practice.*

Chana Weinstock, MD

Dr. Weinstock is a Genitourinary Cancers Team Lead in DOP1 who serves as the FDA's scientific liaison for renal cell carcinoma. She continues to see patients at the Baltimore Veterans' Affairs Medical Center's oncology clinic, where she supervises medical oncology fellows from the University of Maryland Medical Center. She graduated with high distinction from the University of Toronto before completing her medical degree at the Albert Einstein College of Medicine. She completed her internal medicine residency Beth Israel Medical Center and her medical oncology and hematology fellowship at the University of Maryland Medical Center. She then practiced thoracic and GU oncology at the University of Maryland Medical Center and the Baltimore Veterans' Affairs Medical Center for four years prior to joining the FDA in May 2015. She has been involved in oncology research for many years, presenting her first ASCO abstract in 1999 while still a college student. Since then, her original oncology research has been published in peer-reviewed journals and presented at national meetings including ASCO, ASTRO, RSNA, SABCS, and CAMO, including at oral poster discussion sessions at ASCO in 2016 and 2017. She has recently been involved in organizing workshops and minisymposia on clinical trial design and endpoint definition in the era of immunotherapy.

Patrick Wen, MD

Dr. Wen is currently the President of the Society For Neuro-Oncology. He is a Professor of Neurology at Harvard Medical School, Director of the Center for Neuro-Oncology at Dana-Farber Cancer Institute, Co-PI of the National Cancer Institute supported Adult Brain Tumor Consortium, and member of the Steering Committee of the Response Assessment in Neuro-Oncology (RANO) Working Group. He was previously Editor-In-Chief of Neuro-Oncology and is currently the SNO Executive Editor of Neuro-Oncology.

Nicole Willmarth, PhD

Nicole Willmarth joined the American Brain Tumor Association (ABTA) in 2015 as Chief Science Officer with oversight of the strategic direction, expansion and operation of the ABTA's scientific and research grants program, which supports the development of innovative ideas across a broad range of disciplines and fosters collaborative research to improve the lives of people living with a brain tumor. In August 2018, Nicole stepped into her new role of Chief Mission Officer, where she leads a team in developing and executing ABTA's investment toward the mission, which includes advancing brain tumor research as well as patient support and education. Prior to joining the ABTA, Nicole worked at Susan G. Komen® where she oversaw the business and science management of Komen's portfolio of funded research program grants. Nicole began her career in scientific grant management with the American Association for Cancer Research (AACR) where she developed, launched and managed several mechanisms as part of AACR's donor-directed research grant programs. Before joining AACR, Nicole received her Ph.D. in Cellular and Molecular Biology at the University of Michigan and conducted research in the oncology field for 8 years. Over the course of those studies, she published research in a number of peer reviewed scientific journals. She currently resides in Chicago, Illinois with her husband and two children.

Arvin Yang, MD, PhD

Dr. Yang is currently the Development Lead for Melanoma/Genitourinary (GU) Cancers at Bristol-Myers Squibb Company. In this role, Arvin is responsible for the vision and growth strategy for Melanoma and Genitourinary (GU) cancers including Renal Cell Carcinoma, Bladder, and Prostate Cancer. He joined BMS in 2010 and with prior roles including Early Asset Oncology Development Lead, as well the Nivolumab-Ipilimumab Life Cycle Management Medical Lead.

Arvin has spent over 15 years focused on the development of immuno-oncology agents. He received his M.D. and PhD in Tumor immunology from the University of Medicine and Dentistry of New Jersey. He completed his residency in Internal Medicine Residency at Beth Israel Deaconess Medical Center/Harvard Medical School Teaching Hospital followed by a Medical Oncology Fellowship at Memorial Sloan Kettering Cancer Center.

Peggy Zuckerman

Life changed for Peggy Zuckerman when she was diagnosed with Stage IV kidney cancer, following a long misdiagnosis. She responded to an immune therapy, now 14 years in remission. Grateful to be well when so many others were struggling and dying, she vowed to teach others about the disease and how to advocate for themselves. She has been called an "Expert Patient" able to help translate vital information into patient-friendly language. She a patient mentor in multiple forums, blogs at www.PeggyRCC.com, consults as to patient needs in professional organizations, and brings the voice of the patient to life.

She is the first Kidney Cancer Patient Advocate for SWOG, an oncology research and clinical trial network. Keenly interested in research in kidney cancer, she is peer reviewer of grant applications, and helps shape trials to be more inclusive. She serves as a board member of KCCure.

In addition, Peggy serves on the Scientific Ethics Advisory Group for Roche/Genentech, as well for Patients Like Me in their Ethics and Compliance Advisory Board. She emphasizes the need to respect the autonomy of the patients and to provide patients information which can make shared decision-making and informed consent possible.

The challenge of diagnosis and patient engagement led her to the Society to Improve Diagnosis in Medicine and the Society for Participatory Medicine. She was the lead author of the Patient ToolKit, developed for the SIDM Patient Committee, designed to help patients play an active role in diagnosis