FDA/The Osteosarcoma Institute (OSI) Workshop: Advancing Osteosarcoma Drug Development – Connecting Research and Regulatory Pathways for Improved Outcomes

SPEAKER BIOGRAPHIES

Alphabetical order by last name

Fernanda Arnaldez, MD

Dr. Arnaldez is a physician-scientist and pharmaceutical executive with over twenty years of experience in drug development. She currently serves as Executive Medical Director of Oncology Research and Development at AstraZeneca, where she oversees efforts to advance innovative cancer treatments. Dr. Arnaldez trained as a pediatric oncologist at Johns Hopkins Hospital and the National Cancer Institute (NCI), with a focus on sarcoma biology and treatment. Her career in developmental therapeutics and oncology drug development spans leadership roles in academia, government, biotechnology, the pharmaceutical industry, as well as non-profit organizations. Her contributions have been recognized with multiple honors, including the NCI Director's Award, the Conquer Cancer Foundation (ASCO) Young Investigator Award, and the NIH Research Excellence Award.

Katie Barnett, MD

Dr. Barnett is a pediatric hematologist-oncologist and clinical reviewer in the Division of Clinical Evaluation Oncology in the Center for Biologics Evaluation and Research (CBER) at the FDA. Since joining the FDA, her work has focused on evaluation of cell therapies and other biologics for the treatment of malignant solid tumors. Dr. Barnett completed her fellowship in pediatric hematology/oncology at Johns Hopkins Hospital and the National Cancer Institute, followed by pediatric neuro-oncology fellowship at Johns Hopkins Hospital. She completed her pediatric residency training and received her medical degree from New York University School of Medicine.

Davy Chiodin, PharmD

Dr. Chiodin brings more than 20 years of pharmaceutical industry experience where he mostly focused on oncology drug development across tumor types, stages of development, and geographies. He is currently the Chief Development Officer at Day One Biopharmaceuticals, a biotech company founded to address the lack of new therapies resulting from the traditional drug development model, that has left children with cancer and their families waiting too long for new, life-changing treatments. Prior to joining Day One, Dr. Chiodin was at Acerta Pharma, a member of the AstraZeneca Group, where he was Vice President, Regulatory Science and Quality Assurance through the acalabrutinib global filings and the build of the AztraZeneca hematology franchise, as well as a member of the Pediatric Working Group. Prior to that, he spent more than 10 years at Roche/Genentech, assuming roles of increased responsibility in the regulatory function in both Europe and the United States, including two years fully dedicated to the pediatric oncology portfolio. He has remained an active contributor to the pediatric oncology community since then. Dr. Chiodin received his PharmD from the University of Grenoble, France, and a Master in Regulatory Affairs and Pharmacoeconomics from the universities of Lille and Paris, France.

Lara E. Davis, MD

Dr. Davis is an Associate Professor of Medicine in the Divisions of Medical Oncology and Pediatric Hematology/Oncology at Oregon Health & Science University (OHSU), where she is Co-Leader of the Knight Cancer Institute Translational Oncology Research Program and Sarcoma Program Director. Dr. Davis earned her undergraduate degree at Wellesley College and her medical degree from OHSU. Dr. Davis completed her clinical residency at Harvard Medical School and a fellowship in medical oncology and pediatric hematology/oncology at OHSU. Her translational and clinical research focuses on developing new therapeutic approaches for osteosarcoma, and she is a Strategic Advisory Board member of the Osteosarcoma Institute.

Martha Donoghue, MD
Dr. Donoghue is a pediatric oncologist and the Associate Director for Pediatric Oncology and Rare Cancers in the FDA Oncology Center of Excellence. She also serves as the Acting Associate Director for Pediatric Oncology in the FDA Office of Oncologic Diseases. In these roles, she oversees implementation of regulations designed to promote timely investigation of drugs and biological products for pediatric patients with cancer, supports work relating to pediatric oncology and rare cancer drug development across FDA, and works with stakeholders to address challenges and foster development of drugs to treat pediatric and other rare cancers. Prior to joining FDA in 2009, Dr. Donoghue completed a fellowship in pediatric hematology/oncology at the Children's National Medical Center after working for several years as a general pediatrician in private practice. She received her medical degree from Emory University and completed a residency in general pediatrics at the Georgetown University Medical Center.

Nicole Drezner, MD
Dr. Drezner is a pediatric oncologist and the Deputy Director of the Division of Oncology 2 (DO2) at the FDA. She joined the thoracic and head and neck oncology team in DO2 as a clinical reviewer in 2016, served as team lead of the thoracic and head and neck team from 2020-22, and began her role as Deputy Division Director in 2022. In her current role, Dr. Drezner oversees the development of drugs and biologics for most pediatric solid tumors, central nervous system tumors, and rare tumors. Dr. Drezner completed her residency in pediatrics at Cohen Children's Medical Center of NY and her pediatric hematology/oncology fellowship at Children's National Hospital. She remained at Children's National Hospital for an additional year as a pediatric neuro-oncology fellow prior to joining the FDA.

Michael Egge, Esq.
Mr. Egge is a pediatric cancer advocate, a member of the Board of Trustees of the Osteosarcoma Institute, a founder of the Osteosarcoma Collaborative, and proud father of Olivia, Luke, and Sophia Egge. His daughter Olivia is a fearless osteosarcoma survivor. Mike is committed to organizing collaboration among researchers, funding osteosarcoma research, and shining light on the fight against pediatric cancers. Mike is also a leading antitrust attorney with 34 years' experience shepherding strategic M&A deals through regulatory clearances worldwide. He is a partner and chair of the global antitrust group at Latham & Watkins, LLP, where he has also served as a member of the Executive Committee and as Washington Office Managing Partner. He is married to April Kinne Egge, and he and his wife reside in Arlington, Virginia.

Nancy Goodman, Esq.
Ms. Goodman founded Kids v Cancer and initiated and championed the Creating Hope Act Rare Pediatric Priority Review Voucher Program (PRV), which was passed into U.S. law in 2012. The Act has resulted in over 60 newly approved drugs for kids with life threatening illnesses. Vouchers now trade for $150 million. Kids v Cancer also initiated and championed the RACE for Children Act, passed into US law in 2017. Now, over 80% of all newly approved adult cancer drugs are studied in children. Kids v Cancer is now asking Congress to pass the Give Kids a Chance Act to provide for pediatric studies of combinations of new targeted cancer drugs and to reauthorize the PRV program. Nancy received her Juris Doctorate (JD) from the University of Chicago and her Master of Public Policy (MPP) from Harvard. Nancy's son, Jacob, died of medulloblastoma.

Ann Graham
Ms. Graham, Founder and Executive Director of MIB Agents Osteosarcoma Alliance, advocates for pediatric osteosarcoma patients. Her interest in the field stems from her own diagnosis with osteosarcoma at age 43 and subsequent treatment in a pediatric cancer center. This firsthand experience inspired her to address the critical lack of funding and awareness in pediatric cancers. In 2012, Ann founded MIB Agents to "Make It Better" for children with osteosarcoma. The organization achieves this through comprehensive patient and family programs, education for clinicians and patients, an annual conference, legislative work, and funding impactful research. Ann's dedication is further demonstrated by her extensive involvement in numerous memberships and service roles with prominent cancer organizations, including SARC, NCCN, CAC2, and the Alliance for Childhood Cancer. She is also a recognized voice in

publications and media, and a frequent speaker at significant forums like The White House (2021-2024) and industry gatherings, passionately advocating for improved outcomes for young cancer patients.

Lee Helman, MD
Dr. Helman is the Director of the Osteosarcoma Institute and has been studying the biology and caring for pediatric patients with sarcomas for over thirty years. Dr. Helman completed his postdoctoral training at the National Cancer Institute (NCI). He then became Head of the Molecular Oncology Section, Pediatric Oncology Branch, NCI, in 1993. He served as Chief of the Pediatric Oncology Branch from 1997-2007 and served as Scientific Director for Clinical Research in the Center for Cancer Research, NCI from 2007 to 2016. He joined Children's Hospital Los Angeles (CHLA) and the University of Southern California (USC) in 2017 as the Section Head of Basic and Translational Research within the Cancer and Blood Disease Institute (CBDI) and the Division of Hematology, Oncology and Blood and Marrow Transplantation. He remains an adjunct professor at CHLA. He has also trained many investigators in the field of pediatric sarcomas over the course of his career. He is currently focusing on improving outcomes in osteosarcoma.

Justin Ingram, PhD
Dr. Ingram is the Research Program Director at Alex's Lemonade Stand Foundation and oversees the strategic direction and administration of scientific funding initiatives aimed at accelerating progress in pediatric cancer research. With over six years of experience in pharmaceutical R&D across oncology, infectious diseases, and immunology, Dr. Ingram brings a robust background in drug discovery, scientific leadership, and collaborative research to his role at Alex's Lemonade Stand Foundation. He earned his PhD in Biomedical Sciences from the Lewis Katz School of Medicine at Temple University and conducted his thesis research at Fox Chase Cancer Center. He holds a BS in Microbiology from the University of Pittsburgh. Dr. Ingram is dedicated to advancing innovative science that improves outcomes for children with cancer.

Katherine Janeway, MD, MMSc
Dr. Janeway is an Associate Professor of Pediatrics and Harvard Medical School, Senior Physician at Dana-Farber/Boston Children's Cancer and Blood Disorders Center, and Director of Clinical Genomics at Dana-Farber Cancer Institute. Dr. Janeway's research is focused on genomics, precision oncology, and bone sarcomas. She leads clinical trials in osteosarcoma and Ewing sarcoma both as an independent investigator and as the Chair of the Children's Oncology Group (COG) Bone Tumor Committee. The Janeway Laboratory has uncovered the genomic events causing and sustaining difficult-to-treat childhood solid malignancies. The laboratory leads several studies, which have enrolled and sequenced more than 2,500 patients with childhood cancers. They are using this data to deepen the understanding of clinical and genomic factors explaining prognosis and treatment response and resistance with a focus on sarcomas. In collaboration with the Broad Institute and Count Me In, the group is innovating patient partnerships in sarcoma research. She received her MD and a Master of Medical Science from Harvard Medical School. She completed her pediatrics residency and pediatric hematology/oncology fellowship at Boston Children's Hospital and Dana-Farber Cancer Institute where she was Chief Resident and Chief Fellow.

MacKenzie Maddry
Ms. Maddry is an 18-year-old high school graduate with plans to become a nurse. She is also Vice President of the 2025 MIB Junior Advisory Board. MacKenzie lives in Northwest Arkansas and was diagnosed with osteosarcoma in her left femur at age 14, in December 2020. She underwent nine months of MAP chemotherapy with limb-salvage surgery midway through, during which a cadaver bone was placed. About a year after treatment, she developed an infection that required the removal and replacement of all hardware and the cadaver bone. That replacement took three surgeries—the last of which led to heart failure. Mackenzie spent 3.5 months in the hospital and received an LVAD (HeartMate 3) to pump her heart until transplant. She lived with the heart pump for 1.5 years before receiving a heart transplant in June 2024. During that time, MacKenzie also underwent two additional surgeries and now has a metal rod in her leg.

Amanda Marinoff, MD
Dr. Marinoff is a pediatric oncologist and clinician–scientist whose work focuses on advancing new treatment strategies for osteosarcoma. She cares for children and young adults with bone tumors and other solid malignancies and is actively involved in the early-phase clinical trials program. Her research links molecular profiling with clinical data to develop biomarkers that refine risk stratification and enable translation of novel therapeutic approaches into clinical trials. Dr. Marinoff leads cBOSS (Clinical Biomarkers for Osteosarcoma Stratification), an international working group that evaluates molecular classification strategies to advance precision medicine in osteosarcoma. She is an associate committee member of the Osteosarcoma Institute. Her overarching goal is to bring more effective, biology-driven therapies to patients with osteosarcoma that improve both survival and quality of life. Dr. Marinoff earned her medical degree at Harvard Medical School. She subsequently completed her residency in Pediatrics at Boston Children's Hospital. She completed her fellowship in pediatric hematology/oncology at UCSF Benioff Children's Hospitals, where she is now an Assistant Professor.

Melinda Merchant, MD, PhD
Dr. Merchant is the Chief Medical Officer at Normunity with over 20 years of experience in oncology drug development spanning academia and the biopharmaceutical industry. Her career as a physician scientist included principal investigator roles at Memorial Sloan Kettering Cancer Center and the National Cancer Institute, as well as leadership roles at AstraZeneca and oncology-focused biotech companies. She has expertise in immuno-oncology, translational strategy, and clinical trial design, with a strong track record of advancing therapies from first-in-human studies through Phase 3 trials. Her work has encompassed a broad range of modalities—including biologics, small molecules, and cell therapies—with a focus on translating scientific innovation into meaningful clinical impact for patients. Throughout her career, Dr. Merchant has championed collaborative, patient-first approaches to developing more-effective, less-toxic therapies for children and adults with cancer. She currently serves on the Osteosarcoma Institute's Strategic Advisory Board, helping advance research and trial strategies for patients with high-risk sarcoma.

Alli Murdoff
Ms. Murdoff is the co-founder of Battle Osteosarcoma, an organization established in memory of three children in her community who lost their lives to osteosarcoma. Battle Osteosarcoma is dedicated to funding critical research and driving meaningful change in the fight against this aggressive cancer. She also serves as a member of the Board of Trustees of the Osteosarcoma Institute. Professionally, Alli is a Partner at Section Partners, a growth-stage venture capital firm in Palo Alto, where she leads marketing, communications, events, human resources, and investor relations. Prior to Section Partners, Alli held similar leadership roles across investment banking, venture capital, and consulting firms. Her daughter Charlotte was diagnosed with osteosarcoma in her femur just days before turning 15. Charlotte bravely faced her diagnosis with remarkable courage, participating in clinical trials and experimental treatments. She passed away in 2021, during her senior year of high school. Alli is inspired daily by Charlotte's strength, resilience, and the gifts she gave to those who were fortunate to know her.

Mikaela Naylon
Ms. Naylon is 16 years old and lives in Southern Colorado. She is also a member of the 2025 MIB Junior Advisory Board. Mikaela was diagnosed with osteosarcoma in July 2020 at 10 years old. Her tumor was in her left ankle and spread to both of her lungs. She has done numerous treatments at Children's Hospital in Aurora, MD Anderson Cancer Center, and the Cleveland Clinic. Mikaela's leg was amputated below the knee in October 2020, and she has had many lung surgeries after that. She has always been involved in advocacy – on radio shows and local TV news advocating for childhood cancer! Mikaela loves hockey, cats, snowboarding, F1, and tennis.

Dr. Jose Ricardo Pérez-Torrealba
Dr. Pérez-Torrealba is a seasoned oncology leader with over 25 years of experience in medical affairs and clinical oncology. As Vice President at Exelixis, he leads the medical strategy for Cabozantinib and Zanzalintinib in genitourinary cancers. His career spans leadership roles at Novartis, where he directed global strategies for Ruxolitinib, Panobinostat,

and Zometa, and launched one of the largest Expanded Access Programs in Myelofibrosis. Dr. Pérez-Torrealba is a Clinical Oncologist and Internal Medicine Specialist trained in Venezuela, with deep expertise in solid tumors and sarcomas. He has contributed to multiple Phase II/III trials and led global investigator-initiated research programs. A frequent speaker at international oncology forums, he is a member of ASCO, ESMO, ASH, and other leading societies.

Harpreet Singh, MD
Dr. Singh serves as Chief Medical Officer of Precision for Medicine, a global leader in biomarker-driven clinical research and development. Dr. Singh was previously an Oncology Division Director at the U.S. Food and Drug Administration (FDA) and is responsible for medical strategy and oversight at Precision. She is an experienced leader with a demonstrated track record in building high performing cross functioning teams, developing and maintaining excellent working relationships with colleagues in academia, industry, and international regulatory bodies. Dr. Singh is scientifically driven, patient centered, with high academic integrity and a commitment to regulatory standards. Motivated by a desire to accelerate breakthrough treatments in oncology and rare disease, Singh has a multi-dimensional understanding of drug development along with deep experience as a medical oncologist, having trained at the National Cancer Institute and the University of Southern California Keck School of Medicine. Dr. Singh maintains an active public presence as a thought leader for important issues facing the life sciences industry.

Jasmine Smith, MD
Dr. Smith is a pediatric oncologist serving as a clinical reviewer in the Division of Oncology 3 (DO3), within the Office of Oncologic Diseases, at the FDA. She recently joined the FDA in 2024 and is a member of the review team that oversees development of drugs for patients with gastrointestinal malignancies, superficial cutaneous malignancies, melanoma, and sarcoma. She received her medical degree from the University of South Carolina School of Medicine Greenville in 2018. She then completed her pediatrics residency training at the University of Arizona, followed by the completion of her pediatric hematology/oncology fellowship training at St. Jude Children's Research Hospital. Stemming from the loss of her younger brother to osteosarcoma in 2016, she has a primary interest in sarcomas as well as the adolescent and young adult (AYA) patient population.

Tedi Soule, PharmD
Dr. Soule is a Medical Affairs leader with more than 15 years of U.S. and global biopharmaceutical experience. A PharmD by training, she brings deep expertise in translating clinical evidence into strategies that advance patient care. Dr. Soule has directed initiatives supporting drug development, launches, and lifecycle management, with emphasis on oncology and respiratory diseases. Passionate about advancing scientific knowledge, she is focused on shaping strategy and developing medical education and scientific communication to support decision-making for healthcare professionals. Dr. Soule has experience building collaborations with key opinion leaders, aligning global and regional teams, and ensuring scientific integrity across initiatives. Dr. Soule earned her Doctor of Pharmacy from Albany College of Pharmacy and Health Sciences and completed a fellowship in Drug Development & Clinical Research at the University of North Carolina, Chapel Hill.

Alejandro Sweet-Cordero, MD
Dr. Sweet-Cordero is a cancer biologist and practicing pediatric oncologist focused on basic and translational cancer research. He is a Benioff Professor of Children's Health at the University of California, San Francisco (UCSF) and serves as the chief of the division of pediatric oncology at Benioff Children's Hospitals in San Francisco and Oakland. He has led an NIH-funded laboratory for over 20 years. His laboratory focuses on pediatric sarcoma and lung cancer research. The lab's osteosarcoma work is focused on defining mechanisms driving metastatic progression and therapy resistance. He has extensive expertise in integrative genomic analysis (WGS, RNAseq, ATACseq) and functional genomic studies using CRISPR/CAS9 as well as lineage tracing studies applied to studying osteosarcoma progression. The lab also has deep experience in the use of mouse models to study sarcomas and lung cancer. This includes both human-in-mouse tumor models and genetically engineered mouse models.

McHenry T. "Mac" Tichenor, Jr.
Mr. Tichenor's younger son, Willie, died from osteosarcoma in 2006, after a three-year battle with the disease. That led to the creation of the What Would Willie Want (QuadW) Foundation, which has the funding of sarcoma research as a fundamental, but not exclusive, focus. For ten years, QuadW supported many important accomplishments within the field, but that did not include the development of new treatments for kids like Willie. This fact, coupled with advice from leaders in cancer and medical science generally, led to the creation of The Osteosarcoma Institute (OSI), a purpose-built and driven Institute, with the single goal of bringing effective new therapies to the clinic. In addition to serving as the President of OSI, Mac Tichenor is the President of Tichenor Ventures, LLC, a private investment company concentrating on early-stage investments in the life sciences and Director Emeritus of the QuadW Foundation.

Kristin Wessel, MD
Dr. Wessel is a pediatric hematologist/oncologist serving as a medical officer for the Division of Oncology 2 (DO2) within the Office of Oncologic Diseases, at the FDA on the team dedicated to neurologic, pediatric, and rare cancers. Prior to joining the FDA, Dr. Wessel completed her pediatric residency at the University of Chicago and went on to complete her pediatric hematology/oncology training at Johns Hopkins Children's Center and the National Cancer Institute (NCI) in Maryland. Dr. Wessel spent an additional year as an Advanced Clinical Fellow in the Pediatric Oncology Branch of the NCI, where she focused on translational research in pediatric sarcomas as well as early-phase clinical trials in pediatric patients with solid tumors.

Brigitte Widemann, MD
Dr. Widemann is Chief of the Pediatric Oncology Branch (POB), Center for Cancer Research (CCR) at the National Cancer Institute (NCI), and special advisor to the NCI Director for childhood cancer. She oversees an active basic, translational, and clinical research program for children and young adults with hematologic and solid malignancies. She joined the NCI in 1992 as a pediatric hematology/oncology fellow. Her research has been focused on drug development and early clinical trials for children with refractory solid tumors, rare tumors, and genetic tumor predisposition syndromes, in particular neurofibromatosis type 1 (NF1). She received tenure at the National Institutes of Health in 2009 and became the Chief of the POB in 2016. The work of her research team on NF1 resulted in the first FDA-approved medical therapy, the MEK inhibitor selumetinib, for children with NF1 and inoperable, symptomatic plexiform neurofibroma. Dr. Widemann is a member of the Association of American Physicians and recipient of the American Association of Cancer Research (AACR) Joseph H. Burchenal Award for Outstanding Achievement in Clinical Cancer Research.