

PROJECT LIVIN' LABEL

LABELING UNFOLDED - KNOWLEDGE RELEASED

AACR American Association
for Cancer Research*

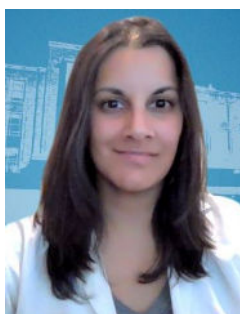
FDA U.S. FOOD & DRUG
ADMINISTRATION



Episode 11– fam-Trastuzumab Deruxtecan-nxki: The Backstory

Project Livin' Label Speaker Biographies

Preeti Narayan, MD – Breast and Gynecologic Malignancies Team Lead, Division of Oncology 1, Office of Oncologic Diseases, FDA



Preeti Narayan, MD, is a medical oncologist and Acting Team Leader on the Breast Cancer and Gynecologic Malignancies team within the Office of Oncologic Diseases (OOD) at the FDA. She also has served as an Acting Team Leader on the Melanoma/Sarcoma team. She completed her Internal Medicine residency at SUNY Downstate Medical Center and completed her Hematology and Oncology fellowship at the University of Florida. Since joining the FDA, she has reviewed multiple new drug applications for marketing approval in breast cancer and gynecological malignancies and has also presented at various meetings and workshops regarding drug development. Her professional interests include biomarker use in diagnosis, treatment and monitoring of solid tumors and the use of antibody drug conjugates in breast cancer.

Asma Dilawari, MD - Oncologist and Clinical Reviewer, Division of Oncology 1, Office of Oncologic Diseases, FDA



Asma Dilawari, MD, has been a medical oncologist for almost 15 years and worked in academic and community cancer centers before joining the FDA in 2022. She grew up in Memphis, TN and moved to the Washington D.C. area for her residency training at George Washington University. She went to New York for her oncology training at NYU and lived there for almost 10 years before moving back to the D.C. area to join the faculty at Georgetown. There she worked at Lombardi Comprehensive Cancer Center and MedStar Washington Hospital Center as a breast medical oncologist for several years before joining the FDA. She is certified in medical acupuncture and has an interest in integrative therapies, cancer survivorship, health disparities, and supportive care. She currently works as a Clinical Reviewer in the Division of Oncology at the FDA and has found the transition to regulatory work to be intellectually stimulating and rewarding. She is a member of the Project Equity and Project Silver, two initiatives at the FDA.

Gerold Meinhardt, MD, PhD - Global Team Lead for fam-trastuzumab deruxtecan-nxki, Daiichi Sankyo, Inc.



Gerold Meinhardt, MD, PhD, is currently Vice President, Asset & Portfolio Management at Daiichi Sankyo, where he joined in June 2020. In this role, he is responsible for the development of trastuzumab deruxtecan (DS-8201, ENHERTU), the company's lead ADC (co-developed with AstraZeneca), approved for different indications in multiple countries worldwide. Prior to Daiichi Sankyo, Dr. Meinhardt served in several different roles at Bayer Pharmaceuticals for more than 15 years, most notably as Vice President in Clinical Development leading the development of multikinase inhibitors sorafenib and regorafenib.

Dr. Meinhardt is a board-certified Medical Oncologist and Hematologist. After graduating from the Medical School at the Ludwig-Maximilians-University in Germany, he practiced at academic centers for many years, and after returning from three years as a Research Fellow at the Dana-Farber Cancer Institute in Boston, he also led a research laboratory at the University of Munich in parallel to his clinical responsibilities. Dr. Meinhardt has authored more than 50 PubMed-listed publications.

Naoto T. Ueno, MD, PhD, FACP - Director of University of Hawaii Cancer Center



Naoto Ueno, MD, PhD, FACP, serves as the Director of the University of Hawaii Cancer Center. Previously, he was the executive director of the MD Anderson IBC Research Program and Clinic and chief of the Section of Translational Breast Cancer Research in the Department of Breast Medical Oncology. Dr. Ueno's research includes the roles and underlying mechanisms of several signaling pathways that promote the aggressiveness of TNBC and IBC, as well as modulate the tumor microenvironment. In addition, he conducts numerous investigator-initiated clinical trials (Phase I/II) for patients with advanced breast cancer as a principal investigator based on his laboratory discoveries. Dr. Ueno received the Nylene Eckles Distinguished Professorship of Breast Cancer Research in 2012. In addition, he received The University of Texas System Regents' Outstanding Teaching Award for his mentoring contributions in 2014 and the MD Anderson Distinguished Clinical Faculty Mentor Award in 2019. He served as a standing member of the NIH's Drug Discovery and Molecular Pharmacology Study Section. In addition, he is the editor-in-chief of the Journal of Cancer and serves as an editorial board member of the Journal of the National Cancer Institute. As a two-time cancer survivor, he has a unique, comprehensive view of healthcare as a provider, a researcher, and a patient. This experience is why he is passionate about patient-centered and research-driven clinical care.

Kasey Hoggatt - Patient and Clinical Trial Participant



Kasey Hoggatt was diagnosed with metastatic stage 4 breast cancer in 2006. While her initial chemotherapy and stem cell transplant was successful and led to 13 years of being cancer-free, the cancer returned in 2019. Ms. Hoggatt then underwent treatment with a variety of therapies with varying results. In 2022, she was treated with trastuzumab deruxtecan, which resulted in rapid improvement in tumor markers. Ms. Hoggatt works full time as an Administrative Manager for the Coffeyville Area Chamber of Commerce in Coffeyville, KS and is enjoying life with her family.

Debora (Debbie) Geary, MS, BSN, RN, OCN, CCRP - Research Nurse Specialist, Sylvester Comprehensive Cancer Center at University of Miami Health System



Debora (Debbie) Geary, MS, BSN, RN, OCN, CCRP, graduated with her Master of Science degree in Clinical Research during the COVID Pandemic. Debbie has been working as an oncology nurse for over 40 years and presently works as a Research Nurse, at the University of Miami, Miami FL. She continues to maintain her national certifications as an Oncology Certified Nurse, (OCN) and as a Certified Clinical Research Professional, (CCRP). Debbie's most passionate as a patient advocate and educator to her patients. Debbie's passion has been a key factor in screening patients for clinical trials. Watching many of the patients have a complete response (CR) from their disease after being treated with an investigational medication has increased her love for research and her wish to offer research to every possible patient. Debbie has worked in many areas as a nurse including, in patient bedside nursing, radiation oncology, alcohol and drug detoxification, chemotherapy infusion unit, and as a manager, but her love for oncology continues to bring her back to this specialty. She has specialized in breast cancer for the last 20 years, and her expertise is highly regarded by her peers. Debbie has been married for 32 years now, with 4 children and 7 grandchildren and she is excited to have 4 new grandbabies to be born this year. She enjoys reading, traveling and "out of the box" adventures, with her last adventure, ice fishing in Minnesota. Even though retirement is in the future (not so near), she still loves being a nurse each day.

Neha Mangini, PharmD, BCOP - Clinical Oncology Pharmacist, Breast Oncology, Huntsman Cancer Institute



Neha Mangini, PharmD, BCOP, is a clinical oncology pharmacist at the Huntsman Cancer Institute. Dr. Mangini received her PharmD from Rutgers University. She then completed her PGY1 pharmacy practice and PGY2 oncology practice residency at Yale-New Haven Hospital. Dr. Mangini helped launch the pharmacist-run oral oncolytic management program at Johns Hopkins and has been practicing in breast oncology for over 8 years.