

# PROJECT LIVIN' LABEL

LABELING UNFOLDED - KNOWLEDGE RELEASED

**AACR** American Association  
for Cancer Research\*

**FDA** U.S. FOOD & DRUG  
ADMINISTRATION



## Episode 7 – Pembrolizumab: The Backstory

### Project Livin' Label Speaker Biographies

#### Jennifer Gao, MD - Associate Director for Education, Oncology Center of Excellence, FDA



**Jennifer Gao, MD** is a medical oncologist and the Associate Director for Education in the Oncology Center of Excellence (OCE) at the U.S. Food & Drug Administration (FDA). She received her undergraduate degree from Harvard University and spent a year in Bonn, Germany, as a J. William Fulbright Fellow before completing her medical degree at the Alpert Medical School of Brown University. Dr. Gao pursued her internal medicine internship and residency training at Massachusetts General Hospital, followed by a fellowship in medical oncology at the National Cancer Institute (NCI), where she also served as Chief Fellow.

#### Mirat Shah, MD - Physician, Division of Oncology 1, FDA



**Mirat Shah, MD, MHS** is a medical oncologist on the Breast, Gynecologic, and Supportive Oncology team within the Division of Oncology 1, Office of Oncologic Diseases. She joined the FDA in 2019, after completing her internal medicine residency at Vanderbilt University, and her medical oncology and clinical pharmacology fellowships at Johns Hopkins, where she also served as the Chief Oncology Fellow. She has an interest in improving tolerability of oncology therapies through dose optimization and is the clinical lead for OCE's Project Optimus. She also has an interest in oncology regulatory education, serving as the co-lead for the 2021-2022 FDA-AACR Oncology Educational Fellowship. She maintains a supportive oncology clinic at Johns Hopkins, and she enjoys hiking and birding in her spare time.

#### Vassiliki Karantza, MD - Associate Vice President in Global Clinical Development, Merck



**Vassiliki Karantza, MD** is an Associate Vice President in Global Clinical Development at Merck and I lead the Breast Cancer Sub-Section of Women's Cancers. I joined Merck in 2014 and have been in the Breast Program since its inception 8 years ago, initially as a Clinical Director and as the Product Development Team Lead since mid-2017. The initial focus of the Breast Program was on the investigation of pembrolizumab for the treatment of triple-negative breast cancer; this goal was recently achieved with regulatory approvals in both the metastatic (KEYNOTE-355) and early (KEYNOTE-522) disease settings. In the meanwhile, the program has expanded to the hormone receptor-positive and the HER2-positive breast cancer subtypes and has as its mission the development of new and better treatment options for all patients with breast cancer world-wide.

## Heather Mc Arthur, MD - Clinical Director of Breast Cancer at University of Texas Southwestern Medical Center



**Heather McArthur, MD, MPH** is the Clinical Director of Breast Cancer at University of Texas Southwestern Medical Center (UTSW) and Komen Distinguished Chair in Clinical Breast Research. Dr. McArthur is a medical oncologist with a clinical practice dedicated to the care of patients with breast cancer. Her research activities are focused on innovations in the diagnosis and treatment of breast cancer, with a particular interest in novel immune therapy strategies. For example, she is currently evaluating the impact of tumor destruction with freezing (cryoablation) or radiation in combination with immune stimulation for the treatment of women with early-stage breast cancer. It is hoped that by augmenting one's immune response to the unique biologic features of one's tumor, that an affected individual may develop long-term immunity against their tumor, and thus, be cured.

## Demetria Lam - Patient



**Demetria Lam** is 45 years-old, a stay-at-home mom and mother of three. Demetria was diagnosed in 2018 with a stage 2 HR+ Breast cancer. In 2021, she had a recurrence that occurred in her sternum that came back as a triple-negative breast cancer.

## Sandra Cuellar Puri, PharmD - Clinical Associate Professor in the Department of Pharmacy Practice at the University of Illinois at Chicago, College of Pharmacy



**Sandra Cuellar, PharmD, BCOP, FHOPA, FASHP** is a Clinical Associate Professor in the Department of Pharmacy Practice at the University of Illinois at Chicago (UIC) College of Pharmacy and a clinical oncology pharmacist at UI Health. Dr. Cuellar received her Pharm.D. Degree from the University of Illinois at Chicago College of Pharmacy. She then completed a Pharmacy Practice Residency at University of Kentucky Chandler Medical Center. Following her residency, she completed a specialty oncology residency at MD Anderson Cancer Center in Houston, Texas. Dr. Cuellar is the director of the oncology residency program, member of the DSMC and co-chair of the IRB at UI Health. Dr. Cuellar is an editor at large for Journal of Hematology Oncology Pharmacy and an invited lecturer to national organizations including HOPA, ASHP, ACCP, ACCC, and AMCP. In addition, Dr. Cuellar serves as an ASHP oncology residency surveyor and past chair of the industry relation council for the Hematology Oncology Pharmacy Association.