PROJECT LIVIN' LABEL

LABELING UNFOLDED - KNOWLEDGE RELEASED

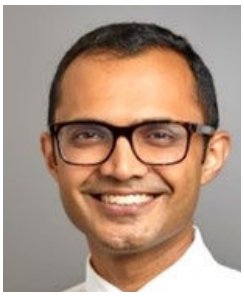
AACR American Association for Cancer Research

FDA U.S. FOOD & DRUG ADMINISTRATION

Episode 12 - Tebentafusp-tebn: The Backstory

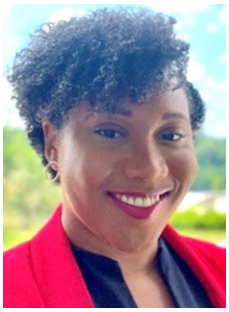
Project Livin' Label Speaker Biographies

Timil Patel, MD – Medical Oncologist, Division of Oncology 3, Oncology Center of Excellence, FDA



Timil Patel, MD, received his degree in Philosophy at the University of Illinois – Urbana Champaign and attended medical school at Wake Forest, graduating in 2014. He completed residency training in Internal Medicine at the University of Texas Southwestern Medical Center followed by fellowship training in hematology and oncology at the Yale School of Medicine, where he was selected for the FDA/AACR Educational Fellowship. His research interests are in drug development and modernizing evidence generation through decentralized and pragmatic trials.

Jamie Brewer, MD - Medical Oncologist and Acting Clinical Team Lead, Division of Oncology 3, Office of Oncologic Diseases, FDA



Jamie Brewer, MD, joined the FDA in 2018 and previously served as a clinical reviewer on the Genitourinary Cancer team. Dr. Brewer serves as the Oncology Center of Excellence (OCE) Scientific Liaison for Cancer Disparities for which she actively engages with FDA colleagues and external stakeholders to promote inclusion and representation of diverse patient populations in clinical trials.

Mark Moyer - Senior Vice President, Head of Regulatory Sciences, Immunocore

Mark Moyer joined Immunocore in March 2018 to lead the regulatory science functions. Mark was also the Project Leader for Kimmtrak (tebentafusp-tebn) leading the Phase 2/3 development, submission, and global approvals. He has 37 years of drug development experience. Prior to Immunocore, Mark was Vice President, Global Regulatory Sciences – Oncology at Bristol-Myers Squibb, where he led regulatory approval for oncology projects, including Opdivo, Empliciti, Yervoy, Erbitux, and Sprycel. Before joining BMS, Mark spent 22 years at Sanofi Pharmaceuticals where he oversaw the US regulatory development group and global Oncology, Anti-infectives, and Bone Products. Mark has provided oversight and been directly involved in 11 NME global submissions and approvals, including Jevtana, Zaltrap, Eloxatin, Elitek, Zoladex, Plavix, and Multaq. Mark earned his Master of Science degree in Immunology and Biochemistry from SUNY Buffalo's Jacobs School of Medicine and Biomedical Sciences at Roswell Park Cancer Institute, and his Bachelor of Science degree in biology/chemistry from Houghton University.

Richard D. Carvajal, MD - Deputy Physician-in-Chief, Director of Hematology/Oncology, Northwell Health Cancer Institute

Richard D. Carvajal, MD is recognized as a leader within the melanoma field, with expertise in rare melanoma subtypes such as uveal, mucosal and acral melanoma. His career has focused on utilizing cancer biology to develop hypothesis-driven clinical trials and investigate novel and promising therapeutic strategies for the treatment of melanoma and other treatment-refractory malignancies. He has been the principal investigator or co-investigator of over 500 clinical trials, including several Cancer Therapy Evaluation Program (CTEP) sponsored clinical trials, which have influenced treatment guidelines for melanoma in the National Comprehensive Cancer Network (NCCN). His research has been supported by the National Cancer Institute, the Food and Drug Administration, the Conquer Cancer Foundation, the Melanoma Research Alliance, the Melanoma Research Foundation and the Empire Clinical Research Investigator Program. He has authored or co-authored more than 200 peer-reviewed manuscripts, books, and book chapters.

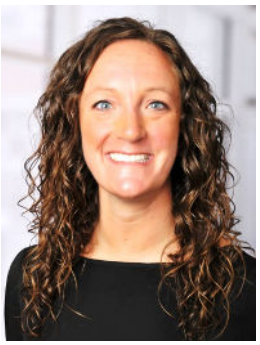
Jianan (Carlos) Sheng - Patient and Clinical Trial Participant

Jianan (Carlos) Sheng has been taking Tebentafusp for about a year now. So far, Carlos has been able to lead a normal life and plans to continue this treatment.

Carol Ann Wiggs - Clinical Research Nurse Manager, Duke Cancer Institute

Carol Ann Wiggs, RN, completed her RN from Watts College of Nursing in Durham NC and received her BSN at Appalachian State University in Boone, NC. She joined the DCI Melanoma Research program in September 2017 where she helped coordinate patient care on Phase I – III clinical trials. In 2019, Carol Ann took over as the Nurse Manager of the DCI Melanoma program overseeing both research nurse coordinators and data coordinators. In her current role, she ensures that the nurses provide patients with excellent research care and the data coordinators collect prompt and correct data.

Heather Armbruster, PharmD, BCOP – Outpatient Clinical Pharmacy Manager, James Cancer Hospital & Solove Research Institute



Heather Armbruster graduated with her PharmD from Ohio Northern University. She then completed PGY1 Pharmacy and PGY2 Oncology Specialty residencies at The Johns Hopkins Hospital. After residency, she practiced as their multiple myeloma specialist and collaborated to establish clinical, outpatient pharmacy services. Heather transitioned to Kaiser Permanente where she worked with general oncologists in Baltimore and Southern Maryland. Next, Heather returned to Ohio and began working at The James Cancer Hospital at The Ohio State University as a specialty practice pharmacist with the skin cancer and neuroendocrine teams. After holding a clinical lead position overseeing projects and committee management, Heather transitioned into her current role as the Outpatient Clinical Pharmacy Manager at The James Cancer Hospital.