

PROJECT LIVIN' LABEL

LABELING UNFOLDED - KNOWLEDGE RELEASED

AACR American Association
for Cancer Research*

FDA U.S. FOOD & DRUG
ADMINISTRATION



Episode 8 – Sotorasib: The Backstory

Project Livin' Label Speaker Biographies

Nicole Drezner, MD – Team Leader, Division Oncology 2, FDA



Nicole Drezner, MD, completed her medical degree at St. George's University School of Medicine. She completed a pediatrics residency at Cohen Children's Medical Center of NY and then completed 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. She joined the thoracic and head and neck oncology team (Division of Oncology 2) as a medical officer at the FDA in July 2016 and became team lead of the thoracic and head and neck team in August 2020.

Erica Nakajima, MD – Physician, Division Oncology 2, FDA



Erica Nakajima, MD, completed her medical degree at the University of Pittsburgh as a member of their Physician Scientist Training Program. She completed her Internal Medicine residency at Vanderbilt University Medical Center, where she participated in imaging-based research of early lung cancers. She then completed her medical oncology fellowship at Johns Hopkins Medical Institute. She joined the thoracic oncology division (Division of Oncology 2) as a medical officer at the FDA in September 2020. She served as the primary clinical reviewer for the new drug application of sotorasib for the treatment of patients with locally advanced or metastatic NSCLC with KRAS p.G12C mutation following at least one prior systemic therapy.

Stacy Shord, PharmD - Deputy Division Director, Division of Cancer Pharmacology II · FDA



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. Karantza joined Merck in 2014 and has 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.

Greg Friberg, MD - Vice President, Medical Affairs for Europe, Latin America, Middle East, Africa and Canada, Amgen, Inc.



Greg Friberg, MD, currently serves as Vice President, Medical Affairs for Europe, Latin America, Middle East, Africa, and Canada (the ELMAC Region), having taken on the role in the Summer of 2021. Greg joined Amgen in Medical Sciences in 2006, first serving as an Early Development Lead and then as Oncology Therapeutic Area (TA) head for the early pipeline. Starting in 2014, Greg served as the interim Global Development co-TA Head for Oncology, overseeing the initial regulatory approvals for blinatumomab in ALL and talimogene laherparepvec in melanoma. He then served for two years as Global Product General Manager for the early hematology BiTE portfolio, including blinatumomab. Starting in 2018, Greg became the Global Development TA Head for Hematology/Oncology and then Bone in 2019. Over the next 4 years he helped to usher romosozumab for osteoporosis, blinatumomab for MRD+ ALL, and sotorasib for KRAS G12C lung cancer to approval.

Grace K. Dy, MD - Chief, Division of Thoracic Oncology, Department of Medicine, Roswell Park Center Institute



Grace K. Dy, MD, is Professor of Oncology, Section Chief of Thoracic Medicine at Roswell Park Comprehensive Cancer Center in Buffalo, NY. She earned her B.S. and M.D. degrees from University of Santo Tomas in the Philippines, graduating summa cum laude for both degrees. She subsequently completed her internal medicine residency and hematology-oncology fellowship training at Mayo Clinic (Rochester, MN) where she was a recipient of the Oncology Outstanding Achievement Award and the William H.J. Summerskill Award. She also received the International Association for the Study of Lung Cancer (IASLC) Lung Cancer Fellowship award as a junior faculty

John A. Szczesny – Patient



John A. Szczesny was a patient at Roswell Park Comprehensive Cancer Center in Buffalo, New York since 2016 and underwent various treatments for non-small cell lung cancer. John participated in an Amgen Clinical Trial receiving AMG 510. Mr. Szczesny retired after completing a 45-year career in Operational and Executive Management of Automobile Parking companies with primary focus on on-site and off-site airport parking facilities.

Mr. Szczesny passed away in October 2022. We offer our deepest condolences to Mr. Szczesny's family and are grateful to Mr. Szczesny for participating in the discussion and sharing his insights.

Askia Dozier, RN - Clinical Research Nurse Coordinator III, Roswell Park Center Institute



Askia Dozier, RN, is currently working in the field of clinical research as a Clinical Research Nurse Coordinator III, in the Early Phase Clinical Trial Program. Askia works with end stage oncology patients via solid tumor medical and surgical ambulatory clinics. She operates closely with the medical oncologist to facilitate accrual to clinical research studies using investigational pharmaceuticals; most of which are first in humans. Nurse Dozier examines medical records to confirm eligibility according to protocol driven instructions. Askia regularly monitors and records patients' outcomes and adverse events related to investigational chemotherapy. Additionally, Nurse Dozier enters and monitors all clinical research data for the phase 1 clinical trials she oversees. Askia coordinates the continuum of care for research subjects in compliance with protocol driven clinical research studies. Lastly, she troubleshoots and resolve unanticipated issues related to the assigned studies as they arise.