PROJECT LIVIN' LABEL

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AACR American Association for Cancer Research

FDA U.S. FOOD & DRUG ADMINISTRATION

Project Livin' Label Speaker Biographies

Episode 6 – Tivozanib: The Backstory

Chana Weinstock, MD

Chana Weinstock, MD is a medical oncologist who has been a genitourinary oncology team lead at the U.S. Food and Drug Administration since 2017. She graduated with high distinction from the University of Toronto before completing her medical degree at the Albert Einstein College of Medicine. She completed her medical oncology and hematology fellowship at the University of Maryland Medical System (UMMS), then practiced thoracic and genitourinary oncology at the UMMS and at the Baltimore Veterans' Affairs Medical Center, where she remains on staff.

Her original research has been published in peer-reviewed journals such as the Journal of Clinical Oncology, Journal of Urology, and Clinical Cancer Research, and she has presented at national meetings including ASCO, ASTRO, RSNA, SABCS, and CAMO, including oral presentations at ASCO, ASCO GU symposium, and at ASTRO workshops. She served as the track leader for ASCO 2021's GU oncology kidney and bladder cancer educational committee, on the Bladder Cancer Advocacy Network (BCAN) Annual Meeting planning committee, as an FDA observer on the National Cancer Institute NCTN Scientific Steering Committee in Genitourinary Oncology. She has been involved in organizing several workshops and minisymposia on clinical trial design and endpoint definition in genitourinary oncology.

Elaine Chang, MD

Dr. Elaine Chang is a medical oncologist serving as a clinical reviewer in the FDA's Division of Oncology 1 in the Office of Oncologic Diseases. She completed residency and hematology/oncology fellowship at Baylor College of Medicine and subsequently joined FDA in 2018. She is a part of a team of 10 oncologists who review trial protocols, drug development proposals, expedited designation requests, and marketing applications for genitourinary malignancies. Her research has focused on novel endpoints in renal and bladder cancer.

Michael N. Needle, MD

Michael N. Needle, MD, serves as chief medical officer and leads the medical affairs group at AVEO, and brings more than 20 years of pharmaceutical industry experience in drug development and regulatory affairs. This includes central roles in the development of oncology and hematology drugs, including Erbitux® (cetuximab), Revlimid® (lenalidomide) and Pomalyst® (Pomalidomide). He most recently served as the Chief Medical Officer of Array BioPharma. Prior to Array, Dr. Needle was Chief Medical Officer of the Multiple Myeloma Research Foundation and Consortium (MMRF). Prior to MMRF, he held multiple Vice President level positions at Celgene in Clinical Research and Development in Oncology, Strategic Medical Business Development, and Pediatric Strategy. Dr. Needle also served as the Vice President of Clinical Affairs at ImClone Systems Incorporated. Dr. Needle did his fellowship in Pediatric Hematology / Oncology at the Children's Hospital Medical Center and the Fred Hutchinson Cancer Research Center of the University of Washington in Seattle and the University of Texas MD Anderson Cancer Center in Houston. Dr. Needle has held faculty positions at the University of Pennsylvania and Columbia University. Dr. Needle graduated from Binghamton University with a Bachelor of Arts in Physics and received his medical degree from SUNY Downstate Medical Center, in Brooklyn, New York.

Brian I. Rini, MD, FASCO

Brian I. Rini, MD, FASCO, is the Chief of Clinical Trials at Vanderbilt-Ingram Cancer Center (VICC) and Ingram Professor of Medicine at Vanderbilt University, where he leads kidney cancer clinical research efforts and the expansion of cancer clinical research operations. His research activities include over 300 publications extensively covering genitourinary cancer, most notably renal cell carcinoma. Dr. Rini has been lead investigator of several phase 3 clinical trials which have led to FDA approval. He has spoken at numerous seminars and invited lectureships, locally, nationally, and internationally, on genitourinary cancers and their treatments. He is a member of ASCO, KCA (Kidney Cancer Association) and SITC (Society for Immunotherapy of Cancer) with leadership positions in these organizations. He recently completed a term as a member and immediate past Chair of the Oncologic Drugs Advisory Committee (ODAC).

B. George Bufkin, PhD

B. George Bufkin, PhD is President and CEO of Davro, Inc., Mansfield Paint Company and Alchem Corporation, all located in Ohio. He is in overall good health even today. Regular exercise regimen for 40+ years, including jogging, push-ups, sit-ups. Ran two marathons. June 2015, kidney cancer discovered, clear cell tumor removed in July 2015. Cancer metastasis to lungs found in November 2015. Joined Clinical trial with Sutent, December 2015. Cancer worsened, side effects were numerous, removed from trial February 2016. Clinical trial with Axitinib and Dalantercept (or placebo) began, March 2016. Cancer improved slightly, but side effects forced end of trial in July 2016. Clinical trial with Nivolumab began in July 2016. Trial abandoned in September 2016 due to disease progression and side effects. Tivozanib clinical trial began September 2016. Cancer shrank dramatically, side effects did not affect quality of life. August 2018, drug held due to protein in urine. Restarted twice, at lower dosage, but had to be stopped due to protein in urine. Last dose of Tivozanib was February 2019. CT scans done every 8 weeks from February 2019 through March 2021. Cancer has been stable, no progression. Last CT scan done March 2021. He gives thanks Aveo, Cleveland Clinic, Dr. Rini, Dr. Ornstein, Laura Wood and The Lord and Savior Jesus Christ every day for the gift of life and health.