PROJECT LIVIN' LABEL

LABELING UNFOLDED - KNOWLEDGE RELEASED







Project Livin' Label Speaker Biographies Episode 4 – DARA SC + CyBorD: The Backstory

B Amore, Patient



B Amore is an artist, writer and founder of the Carving Studio and Sculpture Center. She has spent her life between Italy and America. Her awards include Fulbright and Mellon Fellowships, public art commissions in the US and Japan, and the Lifeline exhibit at Ellis Island. Her books include *Journeys on the Wheel* published by Bordighera Press, *An Italian American Odyssey: Through Ellis Island and Beyond, Art by Mexican Farmworkers in Vermont*, and *Carving Out a Dream*. Her art and poetry reviews appear in *Sculpture* magazine, *Art New England*, and various journals. Her art and writing reflect her interest in migration, transnationalism, and globalization.

Raymond Comenzo, MD, Tufts Medical Center



Dr. Comenzo directs the John C. Davis Program in Myeloma and Amyloidosis in the Tufts Cancer Center and attends on the Bone Marrow Transplant Service. He also directs the blood bank and transfusion service, as well as stem cell processing services at Tufts Medical Center. Dr. Comenzo is an internationally recognized expert in plasma cell disorders. Over the past three decades he has been the principal investigator of many trials in myeloma and AL amyloidosis, including two large trials funded by the FDA Orphan Products Division, and the landmark ANDROMEDA trial that led to the approval of daratumumab faspro with bortezomib-based therapy for AL — the first FDA-approved medications for AL.

Dr. Comenzo has an active research program focused on the biology of clonal plasma cells and with NIH-funding on the identification of patients at risk for AL due to MGUS and smoldering myeloma. His lab has focused on therapeutic applications of RNA interference and of monoclonal antibodies on clonal plasma cell diseases, and on understanding the kidney damage caused by monoclonal gammopathies. Dr. Comenzo is a member of the International Myeloma Foundation (IMF) Working Group and of the IMF scientific board and sits on the board of directors of the Amyloidosis Research Consortium (ARC).

Jessica Vermeulen, MD, PhD, Janssen



Jessica Vermeulen, MD, PhD, earned her degrees at the University of Amsterdam in the Netherlands. Jessica has more than 20 years of industry experience, including substantial expertise across multiple oncology indications and products. She led the clinical development program and global submission activities of siltuximab for patients with multicentric Castleman's disease, after which she joined as Clinical Leader in the ibrutinib clinical team, overseeing the ibrutinib non-Hodgkin lymphoma and Waldenstrom's macroglobulinemia development programs. Since 2019, Jessica has been leading the

daratumumab program, focusing on the development of daratumumab as initial treatment for transplant eligible multiple myeloma and AL amyloidosis, resulting in the recent approval for daratumumab in AL amyloidosis. She has co-authored numerous publications and presentations at key oncology congresses and in top international peer-reviewed journals. Jessica currently holds the position of Vice President, Clinical R&D, overseeing the global clinical development of

daratumumab as well as other emerging assets for the treatment of patients with AL amyloidosis and is part of the late development team for new treatment developments in non-Hodgkin lymphoma.

Bindu Kanapuru, MD, U.S. Food and Drug Administration



Dr. Bindu Kanapuru is a board-certified hematologist-oncologist and the Multiple Myeloma Team Lead in the Division of Hematologic Malignancies 2 (DHM2) in the Office of Oncologic Diseases (OOD). She also serves as a Cross Center Team Lead for Multiple Myeloma at the US Food and Drug Administration. Dr. Kanapuru joined the FDA in 2015. Her areas of interest include disparities in clinical trials and novel trial designs. She serves as the scientific liaison for geriatric hematologic malignancies. Dr. Kanapuru completed her fellowship in hematology and oncology at the University of Maryland

Medical Center in Baltimore. During her fellowship she did her research at the National Institute on Aging on mechanisms of unexplained anemia and cancer in older adults, and co-authored book chapters and publications.

Nicole Gormley, MD, U.S. Food and Drug Administration



Nicole Gormley, MD, is the Division Director for the Division of Hematologic Malignancies II at the U.S. Food and Drug Administration. Dr. Gormley joined the FDA in 2011 and previously served as a clinical reviewer and the Multiple Myeloma Clinical Team Lead. While in these roles, Dr. Gormley has actively engaged with the multiple myeloma community on the development of novel endpoints, including minimal residual disease, and methods to address racial disparities. Dr. Gormley completed fellowship training in hematology and critical care at the National Institutes of Health and served as the Deputy Clinical Director at the National Heart, Lung and Blood Institute prior to joining the Food and Drug Administration.