PROJECT LIVIN' LABEL

LABELING UNFOLDED - KNOWLEDGE RELEASED

AACR American Association for Cancer Research

FDA U.S. FOOD & DRUG ADMINISTRATION

Episode 10 – Ivosidenib: The Backstory

Project Livin' Label Speaker Biographies

Kelly Norsworthy, MD - Deputy Division Director, Division of Hematologic Malignancies 1, Office of Oncologic Diseases, FDA Center for Drug Evaluation and Research

Kelly Norsworthy, MD, is a medical oncologist and hematologist who serves as Scientific Liaison for AML in the Division of Hematologic Malignancies I (DHMI) at the FDA. She is a Clinical Team Leader on one of the leukemia, MDS, and CML teams in DHMI. Her interests include development of novel therapeutics for myeloid malignancies and assessment of clinical trial endpoints for AML and MDS. Dr. Norsworthy attended the University of Maryland School of Medicine where she received her MD, completed residency training, and served as Chief Resident of the Internal Medicine training program. She completed her fellowship in Hematology and Medical Oncology at Johns Hopkins Hospital, where she continues to serve on the leukemia faculty part-time as an Adjunct Assistant Professor of Oncology.

Ashley Woods, MD - Hematologist, Division of Hematologic Malignancies 1, Office of Oncologic Diseases, FDA Center for Drug Evaluation and Research

Ashley Woods, MD, is a hematologist who has been a clinical reviewer in the Division of Hematological Malignancies I at the FDA since 2020. She graduated with a BA in Psychology from Spelman College and completed her M.D. at the University of Chicago, Pritzker School of Medicine. She then completed her internal medicine residency at Yale-New Haven Hospital. She then completed her hematology/medical oncology fellowship at Emory University. During her fellowship she participated in the AACR Vail Workshop in 2019 and won numerous grants for her research in AML. At the FDA, she moderated a panel on discussion on health disparities and hematological malignancies in 2021 and is a member of Project Equity and Project Endpoint.

Susan Pandya, MD – Vice President, Clinical Development, Head of Cancer Metabolism Global Division, Servier Pharmaceuticals

Susan Pandya, MD, is Vice President of Clinical Development/Head of Cancer Metabolism Global Development at Servier Pharmaceuticals and has over a decade of drug development experience. Dr. Pandya has designed and developed pivotal programs starting from Phase 1 through global Phase 3 development yielding FDA approvals for ivosidenib in IDH1 mutated cholangiocarcinoma and in IDH1 mutated acute myeloid leukemia. She developed the first dual IDH1/IDH2 mutant inhibitor in Glioma from Phase 1 to Phase 3 in an ongoing global study. She has led clinical teams across a variety of hard to treat, orphan disease cancer settings and currently oversees 3 late-stage programs in 5 Hematology/Oncology indications at Servier. Prior to joining industry, Dr. Pandya earned her Doctor of Medicine from Tufts University School of Medicine and completed her residency in internal medicine and fellowship in Hematology/Oncology at the Beth Israel Deaconess Medical Center (BIDMC), a Harvard University teaching hospital. She continued her career as a board-certified Hematologist/Oncologist practicing at BIDMC with a focus on early phase clinical development as the Associate Director of the Phase 1 experimental therapeutics program, while maintaining a clinical practice in GI and Breast Oncology.

Stéphane de Botton, MD, PhD - Physician, Clinical Investigator, Head of Hematology, Gustave Roussy Cancer Center

Stéphane de Botton, MD, PhD, is a physician, clinical investigator in acute leukemias and the head of the department of hematology at Gustave Roussy Cancer Center. He conducts phase I to III clinical trials. He also belongs to the research unit UMR 117 for novel preclinical research. He is associated with the discovery of AG-120 (Ivosidenib) and AG-221 (Enasidenib) (anti mutant IDH1 and IDH2 drugs, respectively), the discovery of the mechanism of action and AG-221 (Enasidenib), and registration of both drugs in R/R AML but also frontline for AG-120 (Ivosidenib).He is associated with development and registration of another anti- mutant IDH1 (Olutasidenib) He is a member of the executive board of the Acute Leukemia French Association (ALFA) That focuses on the clinical and translational research in adult acute myeloid leukemia (AML).

Amir Fathi, MD - Director of Leukemia Program, Massachusetts General Hospital

Amir Fathi, MD, is the Program Director of the Center for Leukemia at the Massachusetts General Hospital Cancer Center; he is also an Associate Professor in Medicine at Harvard Medical School. Dr. Fathi is a clinician-scientist with a deep interest in developing novel therapies for acute myeloid leukemia (AML).

As faculty at the MGH Cancer Center and Harvard Medical School, he provides clinical care, supervises trainees, administers a busy clinic, and as the director of clinical research in leukemia, is the lead investigator on numerous clinical trials investigating novel treatments in acute leukemias. His other interests focus on developing translational projects to discover new targets for therapy. He has presented at national meetings of the American Society of Clinical Oncology (ASCO) and the American Society of Hematology (ASH), spoken at national academic and educational meetings, and has served on national committees that establish guidelines for the management of acute and chronic leukemias. Dr. Fathi endeavors to provide outstanding clinical care, teaching and mentoring, while also

conducting translational projects, retrospective research, and clinical trials, with the overarching goal improving the health and outcomes of patients with bone marrow malignancies.

Aura Ramos, RN, BSN - Research Nurse, Massachusetts General Hospital

Aura Ramos, RN, BSN, has been a leukemia research nurse at the Massachusetts General Hospital Cancer Center in Boston for the past 8 1/2 years. Aura has over 18 years of nursing experience caring for oncology patients in the ambulatory and inpatient setting. Prior to becoming a research nurse, she worked as a staff nurse on the leukemia and bone marrow transplant unit. She had the opportunity to travel to Dhaka, Bangladesh and educate nurses on caring for bone marrow transplant and leukemia patients. As a research nurse, she continues to educate staff on the administration of new research oral and intravenous drugs. Her experience includes coordination, implementation, and care of patients on phase 1, 2 and 3 trials in myelofibrosis, acute myeloid leukemia, acute lymphoblastic leukemia and myelodysplastic syndrome.

Matthew Newman, Pharm D - Oncology Pharmacist, Johns Hopkins University

Matthew Newman, Pharm D, is the lead clinical pharmacy specialist for acute care oncology at The Johns Hopkins Hospital in Baltimore, MD. His practice area is hematologic malignancies, and he is part of the inpatient leukemia service at The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. Dr. Newman is also the Director of the PGY-2 Oncology Pharmacy residency program at Johns Hopkins, and adjunct faculty member at Notre Dame of Maryland University. Dr. Newman is a graduate of Northeastern University and completed PGY1 Pharmacy Practice and PGY2 Oncology Pharmacy residencies at The Johns Hopkins Hospital.

Lucille Giunta - Patient and Clinical Trial Participant

Lucille Giunta has been taking Ivosidenib for about 5 years. So far, feels that she's been able to lead a normal life and plans to continue this treatment.