

PROJECT LIVIN' LABEL

LABELING UNFOLDED - KNOWLEDGE RELEASED

AACR American Association
for Cancer Research*

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Project Livin' Label Speaker Biographies

Episode 3 – Osimertinib: The Backstory

Jill Feldman, *Patient*



Jill Feldman is a lung cancer patient and advocate. When Jill was 13 years old, she lost her dad and two grandparents to lung cancer and then her mom and close aunt died of lung cancer when she was in her 20's. She became a volunteer, an advocate and past president of LUNGevity Foundation before the unthinkable happened. In 2009, at 39 years old with four small children, Jill herself was diagnosed with EGFR-positive lung cancer.

Jill continues to be involved with LUNGevity. She is also Deputy Chair of IASLC's patient advisory board and a member of The Chicago Institute of Translational Medicine's patient advisory board. Jill is committed to understanding and promoting patient-centered research as a member of the programmatic panel for the Department of Defense Lung Cancer Research Program, as a planning committee member on IASLC's North America Conference on Lung Cancer and as a member of the ECOG-ACRIN Research Group's patient advocate committee and thoracic committee. She is the patient advocate on the National Lung Cancer Round Table steering committee. She is a co-author of the ASTRO Guidelines for SBRT in early stage lung cancer that was published in an ASCO special article in the Journal of Clinical Oncology.

In 2017, Jill co-founded the EGFR Resisters, a grassroots, patient-driven community committed to accelerating research that will prolong and better the lives of people diagnosed with EGFRm lung cancer. Jill also continues to share her story in the media and at various events and participates in countless advocacy opportunities to shine a light on lung cancer and end the stigma associated with it.

Roy S. Herbst, MD, PhD, *Yale Comprehensive Cancer Center | Yale School of Medicine | Smilow Cancer Hospital*



Roy S. Herbst, MD, PhD is Ensign Professor of Medicine, Professor of Pharmacology, Chief of Medical Oncology, and Associate Director for Translational Research at Yale Cancer Center (YCC) and Yale School of Medicine, New Haven, CT.

Dr. Herbst has worked over several decades as a pioneer of personalized medicine and immunotherapy to identify biomarkers and bring novel targeted treatments and immunotherapies to patients, serving as principal investigator for numerous clinical trials testing these agents in advanced stage lung cancers. This work led to the approval of several therapies (such as gefitinib, cetuximab, bevacizumab, axitinib, atezolizumab, and pembrolizumab), which have revolutionized the field and greatly enhanced patient survival. His leadership in targeted therapeutics resulted in a 2020 ASCO plenary talk and publication of results of the third-generation EGFR-inhibitor osimertinib for the treatment of resected EGFR-mutant NSCLC in the New England Journal of Medicine. He and his Yale colleagues were among the first to describe the PD-1/PD-L1 adaptive immune response in early phase trials and to offer trials of PD-L1 inhibitors atezolizumab and pembrolizumab to lung cancer patients. In 2015 and again in 2020, his team at Yale was awarded a Lung Cancer SPORE (P50 grant) by the NCI, which has identified new immunotherapies and mechanisms of sensitivity and resistance to EGFR targeted therapies.

His work on "umbrella" trials has galvanized the field of targeted therapy and cancer drug approvals at the FDA. Nationally, he works closely with public-private partnerships to develop large master protocol clinical studies, such as Lung-MAP. He testified on the subject of modernizing clinical trials during the 21st Century Cures hearing before the US House of Representatives Subcommittee on Health and has served as a prominent figure in the public policy arena, for nine years having served as a member of the National Academy of Medicine's Cancer Policy Forum, for which he organized several meetings focused on policy issues in personalized medicine and tobacco control.

Dr. Herbst is a highly respected clinician-scientist who has been a champion of translational medicine for decades, recently authoring a high-profile review of the 20-year progress in lung cancer. He has authored or co-authored more than 350 publications, including peer-reviewed journal articles, abstracts, and book chapters. His work has appeared in many prominent journals, such as the Journal of Clinical Oncology, Clinical Cancer Research, Lancet, and the New England Journal of Medicine. Work published in Nature was awarded the 2015 Herbert Pardes Clinical Research Excellence Award by the Clinical Research Forum.

He is a Fellow of the American Society of Clinical Oncology and a member of the American Association of Cancer Research (AACR), where he serves as an elected member of its board of directors and chairs the Tobacco Task Force. He has been a major proponent of efforts to promote tobacco control and regulation (including e-cigarettes), authoring multiple policy statements and leading frequent Capitol Hill briefings. In 2019 he was elected to the International Association for the Study of Lung Cancer (IASLC) board of directors. He is a fellow of the American College of Physicians and an elected member of the Association of American Physicians. He is vice chair of the Southwestern Oncology Group's (SWOG) Lung Committee.

For his lifetime achievement in scientific contributions to thoracic cancer research, Dr. Herbst was awarded the 2016 Paul A. Bunn, Jr. Scientific Award by the IASLC at their 17th World Conference on Lung Cancer in Vienna, Austria. A team of Yale Cancer Center investigators led by Roy S. Herbst, MD, PhD, was awarded the 2018 Team Science Award from the Association for Clinical and Translational Science (ACTS) for its pioneering work in advancing our understanding of Immunotherapy. In 2020, Dr. Herbst was awarded the AACR Distinguished Public Service Award for Exceptional Leadership in Cancer Science Policy.

Yuri Rukazenzov, MD, PhD *AstraZeneca*



Dr. Rukazenzov earned his medical degree with distinction from Moscow State University for Medicine and Dentistry and a PhD in Pharmacology from the same University. He received post graduate training in both Internal diseases and Medical Oncology.

Prior to joining the industry, he worked as an assistant professor at the Department of Clinical Pharmacology of the Moscow State University for Medicine and Dentistry.

In 2005 he joined Global Research and Development of AstraZeneca in the UK as a senior research physician and worked across early and late clinical development programmes in breast and lung cancer.

Dr. Rukazenzov led AstraZeneca clinical teams on several pivotal Phase III studies in lung cancer for Iressa and Tagrisso such as IPASS, FLAURA and ADAURA. He has co-authored numerous publications and presentations at key oncology congresses and in top international peer reviewed journals. He has more than 25 years of experience in pharmaceutical industry and has worked across different functions and geographies at AstraZeneca.

Dr. Rukazenzov currently holds the position of the Global Clinical Head for Tagrisso at AstraZeneca Oncology R&D Unit and oversees the clinical development programme of this product.

Harpreet Singh, MD, U.S. Food and Drug Administration



Harpreet Singh, M.D., is director of the Division of Oncology 2 in the Office of Oncology Diseases, as well as the Acting Associate Director for Cancer in Older Adults and Special Populations in the Oncology Center of Excellence at the FDA. Dr. Singh received her M.D. degree from the University of Southern California. She completed her Internal Medicine residency and Geriatrics fellowship at USC, followed by a Medical Oncology fellowship at the National Cancer Institute. As Director of the Division of Oncology 2, Dr. Singh oversees drug development for lung cancer, head and neck cancer, neurologic tumors, pediatric solid tumors, and rare cancers. Her scope of expertise includes precision medicine and targeted therapy, novel trial design, innovative regulatory initiatives designed to expedite drug approvals, and use of real-world data in regulatory decision making. Recent notable approvals in lung cancer include targeted therapies for MET exon 14 skipping mutations and RET fusions. In her role as Associate Director for Cancer in Older Adults, Dr. Singh leads multiple OCE efforts to advance drug development and regulatory science for older adults with cancer and special populations. Dr. Singh has expertly engaged with the greater scientific community, to increase the evidence base for treating older adults with cancer. She has consistently presented her FDA research on this topic at major academic conferences and published in peer reviewed journals such as the *Journal of Clinical Oncology*. She serves as the lead for OCE's Project Silver, a global regulatory effort to increase the evidence base for older adults with cancer. Under Project Silver, global regulatory agencies will discuss key applications and development programs with indications affecting older adults with cancer, consider more detailed labeling information that reflects the clinical experience of older adults, and conduct educational programs with global stakeholders. Dr. Singh maintains her clinical credentials at the National Cancer Institute.

Richard Pazdur, MD, U.S. Food and Drug Administration



Richard Pazdur, MD, is director of the FDA Oncology Center of Excellence, which leverages the combined skills of FDA's scientists and reviewers with expertise in drugs, biologics, and devices to expedite the development of novel cancer products.

Prior to joining FDA in 1999, Dr. Pazdur was professor of medicine at The University of Texas M.D. Anderson Cancer Center. From 1982 to 1988, he served on the faculty of Wayne State University. He received his bachelor's degree from Northwestern University, his MD from Loyola Stritch School of Medicine, and completed clinical training at Rush-Presbyterian St. Luke's Medical Center and University of Chicago Hospitals and Clinics.

Dr. Pazdur has published more than 600 articles, book chapters, and abstracts, and received many awards, including recognition in *Fortune* magazine's 2015 list of "50 World's Greatest Leaders," the Massachusetts General Hospital Cancer Center's "The One Hundred" list in 2016, and one of "The Bloomberg 50" in 2017.