Taiwanese American Association of Pharmaceutical Sciences

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Speaker Introduction

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FDA:
FDA Regulatory Review Process for Oncology Drugs

Bio

Hsiao-Ling is currently Global Regulatory Strategy Lead for OPDIVO Lung Cancer Program at Bristol-Myers Squibb. Prior to joining BMS in May 2019, Hsiao-Ling spent 10 years at Janssen Pharmaceutical Companies of Johnson & Johnson, first as an Asia Pacific Latin America Regulatory Leader, then as a North America Regulatory Leader for Oncology products. Hsiao-Ling led the regulatory strategy, execution, and FDA interactions for a first in class FGFR inhibitor BALVERSA indicated for bladder cancer from first in human study through NDA approval.

Prior to a career in regulatory affairs, Hsiao-Ling was a scientist for over 20 years. At Genaera Corporation, a biopharmaceutical company, she led the discovery and preclinical research programs of compounds across multiple therapeutic areas including oncology, ophthalmology, metabolic disease and respiratory disease. Before industry, she was a post-doctoral fellow at the University of Pennsylvania, investigating chromatin modification in hematopoiesis.

Hsiao-Ling received a B.S. in Medical Technology from the National Taiwan University and a PhD in Pathology and Molecular Biology from the University of Pennsylvania.

Abstract

FDA Regulatory Review Process for Oncology Drugs

For this presentation, Hsiao-Ling will introduce the FDA regulatory review process, from IND to NDA/BLA, with a focus on Oncology drugs and the programs available to expedite development and approval.