

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)**

Oncologic Drugs Advisory Committee (ODAC) Meeting
February 10, 2022

AGENDA

The committee will discuss biologics license application (BLA) 761222, for sintilimab injection, submitted by Innovent Biologics (Suzhou) Co., Ltd. The proposed indication (use) for this product is in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of patients with Stage IIIB, IIIC, or Stage IV non-squamous non-small cell lung cancer with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.

10:00 a.m.	Call to Order	Pamela L. Kunz, MD Acting Chairperson, ODAC
10:05 a.m.	Introduction of Committee and Conflict of Interest Statement	LaToya Bonner, PharmD Acting Designated Federal Officer, ODAC
10:10 a.m.	FDA Opening Remarks	Harpreet Singh, MD Division Director Division of Oncology 2 (DO2) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
10:25 a.m.	APPLICANT PRESENTATIONS	Innovent Biologics (Suzhou) Co., Ltd.
	Introduction	Lana Shiu, MD Senior Vice President, Global Regulatory Affairs Innovent Biologics USA, Inc.
	Treatment Landscape in Non-small Cell Lung Cancer (NSCLC)	Mark A. Socinski, MD Executive Medical Director Advent Health Cancer Institute Member, Thoracic Oncology Program Orlando, Florida
	ORIENT-11 Efficacy and Conduct	Eduard Gasal, MD President Innovent Biologics USA, Inc.
	Safety	Maria Fernandes, MD Senior Medical Advisor, Global Patient Safety Eli Lilly and Company
	Applicability to U.S. Population	David Ferry, MD, PhD Vice President, Oncology Medical Strategy Eli Lilly and Company

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AGENDA (cont.)

11:15 a.m. **FDA PRESENTATION**

Sintilimab for Locally Advanced or
Metastatic Nonsquamous NSCLC

Paz J. Vellanki, MD, PhD
Clinical Reviewer
Thoracic and Head and Neck Cancer
DO2, OOD, OND, CDER, FDA

11:55 a.m. Clarifying Questions to Presenters

12:25 p.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Questions to the Committee/Committee
Discussion

3:00 p.m. **ADJOURNMENT**