Food and Drug Administration
Center for Drug Evaluation and Research

Final Summary Minutes of the Oncologic Drugs Advisory Committee Meeting

February 10, 2022

Location: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform.

Topic: The committee discussed 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.

These summary minutes for the February 10, 2022 meeting of the Oncologic Drugs Advisory Committee (ODAC) meeting of the Food and Drug Administration were approved on March 17, 2022 .

I certify that I attended the February 10, 2022 meeting of the Oncologic Drugs Advisory Committee (ODAC) of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
LaToya Bonner, PharmD
Acting Designated Federal Officer, ODAC

/s/
Pamela L. Kunz, MD
Acting Chairperson, ODAC

Final Summary Minutes of the Oncologic Drugs Advisory Committee Meeting
February 10, 2022

The Oncologic Drugs Advisory Committee (ODAC) of the Food and Drug Administration, Center for Drug Evaluation and Research, met on February 10, 2022. The meeting presentations were heard, viewed, captioned, and recorded through an online teleconferencing platform. The meeting was called to order by Pamela L. Kunz, MD (Chairperson). The conflict-of-interest statement was read into the record by LaToya Bonner, PharmD (Acting Designated Federal Officer). There were approximately 2,123 people online. There was one Open Public Hearing (OPH) presentation.

A verbatim transcript will be available, in most instances, at approximately ten to twelve weeks following the meeting date.

Agenda: The committee discussed 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.

Attendance:
Oncologic Drugs Advisory Committee Members Present (Voting): Ranjana H. Advani, MD; Mark R. Conaway, PhD; Massimo Cristofanilli, MD, FACP; Jorge A. Garcia, MD, FACP; Pamela L. Kunz, MD (*Acting Chairperson*); Christopher H. Lieu, MD; Ravi A. Madan, MD; David E. Mitchell (*Consumer Representative*); Jorge J. Nieva, MD; Ashley Rosko, MD; Anthony D. Sung, MD

Oncologic Drugs Advisory Committee Members Not Present (Voting): Jaffer A. Ajani, MD; Alberto S. Pappo, MD

Oncologic Drugs Advisory Committee Member Present (Non-Voting): Jonathan D. Cheng, MD *(Industry Representative)*

Temporary Members (Voting): Karen E. Arscott, DO, MSc (*Patient Representative*); Ibiayi Dagogo-Jack, MD; John Deeken, MD; Antoinette J. Wozniak, MD

FDA Participants (Non-Voting): Julia Beaver, MD; Nicole Drezner, MD; Richard Pazdur, MD; Harpreet Singh, MD; Paz J. Vellanki, MD, PhD

Acting Designated Federal Officer (Non-Voting): LaToya Bonner, PharmD

Open Public Hearing Speaker: Diana Zuckerman (National Center for Health Research)

The agenda was as follows:

Call to Order	**Pamela L. Kunz, MD** Acting Chairperson, ODAC
Introduction of Committee and Conflict of Interest Statement	**LaToya Bonner, PharmD** Acting Designated Federal Officer, ODAC
FDA Introductory Remarks	**Harpreet Singh, MD** Division Director Division of Oncology 2 (DO2) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
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
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
Clarifying Questions Presenters	
LUNCH	

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

ADJOURNMENT

Questions to the Committee:

1. **DISCUSSION:** Discuss the generalizability of ORIENT-11 to a U.S. population and U.S. medical practice.

   Committee Discussion: *Most of the Committee agreed that ORIENT-11 is not generalizable to the U.S. population or U.S. medical practice due to its current single region design. Although the Committee were convinced in the efficacy and safety profile presented, they noted that the applicability of the results to a U.S population was not proven. Collectively, the Committee encouraged a multi-regional clinical trial (MRCT) approach as it could enable generalizability of the safety and efficacy profile, increase new investigators and improve access to the product. The committee members commented that consideration of a single region clinical trial, like ORIENT-11, would undermine the current rigorous process and regulatory framework already established in U.S. clinical trials. Please see the transcript for details of the Committee's discussion.*

2. **DISCUSSION:** Discuss potential clinical trials (if any) which may address issues of applicability of ORIENT-11 to a U.S. population.

   Committee Discussion: *The Committee collectively prefer a randomized multi-regional trial with a diverse population to address issues of applicability of ORIENT-11 to a U.S. population, but lack the consensus as to the type of study design needed to examine the safety and efficacy of the product in a U.S. population. Some committee members suggested a noninferiority trial while others recommended a standard trial that would examine the efficacy of one arm over another. Altogether, the Committee recognized that there is a potential class effect with this drug product if given an opportunity for a progression-free survival study in a U.S. population with similar parameters as in ORIENT-11. Please see the transcript for details of the Committee's discussion.*

3. **VOTE:** Should additional clinical trial(s) demonstrating applicability to U.S. patients and U.S. medical care be required prior to a final regulatory decision?

   Vote Results: Yes: 14 No: 1 Abstain: 0

   Committee Discussion: *The majority of the committee members voted "Yes", agreeing that additional clinical trials demonstrating applicability to U.S. patients and U.S. medical care should be required prior to a final regulatory decision. The committee members who voted "Yes" noted the lack of diversity in the study population and stated that MRCTs are needed in single country trials to promote inclusion and clinical integrity. The same members cited their concerns with the Applicant not getting input from the FDA early in the trial but also noted that the original intent for the trial was to get regulatory approval in China only. Also,*

the Committee was concerned that the participant informed consent form was not updated when the standard of care changed during the study. The member who voted "No" agreed that MRCTs are ideal but noted that it should not be a fixed criterion for regulatory approval. This member recognized that the Applicant failed to include diversity in their clinical trial but did demonstrate product safety and efficacy. Overall, the committee members agreed with their colleague, noting that the product's mechanism of action and the data shown would not be extraordinarily different in a U.S. population, but the same data (safety and efficacy profile) was not proven to be applicable to a multidimensional population similar to that in the U.S. Please see the transcript for details of the Committee's discussion.

The meeting was adjourned at approximately 3:00 p.m. Eastern Time.