Press Release

Astellas Provides Update on Zolbetuximab Biologics License Application in U.S.

TOKYO, January 8, 2024 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") today announced the U.S. Food and Drug Administration (FDA) issued a complete response letter on January 4, 2024, regarding the Biologics License Application (BLA) for zolbetuximab, an investigational agent for the treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive.

The FDA stated that the agency cannot approve the BLA by the Prescription Drug User Fee Act (PDUFA) action date of January 12, 2024, due to unresolved deficiencies following its pre-license inspection of a third-party manufacturing facility for zolbetuximab. The FDA has not raised any concerns related to the clinical data, including efficacy or safety, of zolbetuximab, and is not requesting additional clinical studies. Astellas is working closely with the FDA and the third-party manufacturer to establish a timeline to quickly resolve the agency's feedback. No other Astellas products are affected.

Moitreyee Chatterjee-Kishore, Ph.D., M.B.A., Senior Vice President and Head of Immuno-Oncology Development, Astellas
"We remain confident in zolbetuximab's clinical profile and potential to fill a significant therapeutic gap for those diagnosed with advanced gastric or GEJ cancer whose tumors are CLDN18.2 positive. Astellas is committed to working with the FDA and the third-party manufacturer to address the agency's feedback, and to bringing zolbetuximab to U.S. patients in need, as soon as possible."

Regulatory applications for zolbetuximab are also under review in several other countries and regions, including Japan, Europe, and China.

The impact of this matter on Astellas' financial results in the fiscal year ending March 31, 2024, will be limited.

For more information, please see the press release "Astellas Announces U.S. FDA Grants Priority Review for Zolbetuximab Biologics License Application" issued on July 6, 2023.

About Zolbetuximab
Zolbetuximab is an investigational, first-in-class chimeric IgG1 monoclonal antibody (mAb) that targets and binds to claudin 18.2 (CLDN18.2), a transmembrane protein. Zolbetuximab acts by binding to CLDN18.2 on the cancer cell surface of gastric epithelial cells. In pre-clinical studies, this binding interaction then induces cancer cell death by activating two distinct immune system pathways — antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC).[1] Zolbetuximab has not been approved by any regulatory bodies for the treatment of patients with gastric and GEJ cancers, and there is no guarantee the agent will receive regulatory approval or become commercially available for the uses being investigated.

About Astellas
Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality.

Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into VALUE for patients. For more information, please visit our website at https://www.astellas.com/en.

Cautionary Notes
In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

###

Contacts for inquiries or additional information:

Astellas Portfolio Communications
Elysia Wood
+1-703-722-4656
elysia.wood@astellas.com

Astellas Pharma Inc.
Corporate Communications
+81-3-3244-3201

Reference

[1] Sahin U, et al. FAST: a randomised phase II study of zolbetuximab (IMAB362) plus EOX versus EOX alone for first-line treatment of advanced CLDN18.2-positive gastric and gastro-oesophageal adenocarcinoma. Ann Oncol. 2021;32(5):609-19.