Press Release

Japan's Ministry of Health, Labour and Welfare Grants Priority Review for Enfortumab Vedotin New Drug Application

NDA, submitted in March, is for locally advanced or metastatic urothelial cancer that has progressed after anti-cancer medication

TOKYO, May 14, 2021 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced Japan's Ministry of Health, Labour and Welfare (MHLW) has granted priority review for the company's New Drug Application (NDA), which was submitted in March. If approved, enfortumab vedotin would be the first antibody-drug conjugate (ADC) available in Japan for the treatment of patients with locally advanced or metastatic urothelial cancer that has progressed after anti-cancer medication.

Priority reviews are granted by MHLW for applications based on their clinical usefulness and the seriousness of the diseases for which they are indicated.[1] The NDA includes data from the phase 3 EV-301 trial and the phase 2 EV-201 trial, both global clinical trials with investigational sites in Japan.

"The decision by the Ministry of Health, Labour and Welfare to evaluate enfortumab vedotin under priority review reflects the urgent need for new medicines to treat advanced urothelial cancer in Japan, where an estimated 9,500 people die from urothelial cancer each year," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Oncology Therapeutic Area Head, Astellas.[2]

Urothelial cancer makes up approximately 90 percent of cases of bladder cancer.[3] Locally advanced or metastatic urothelial cancer is an aggressive disease that is associated with poor survival and high healthcare costs.[4]

About the EV-301 Trial
The EV-301 trial (NCT03474107) is a global, multicenter, open-label, randomized phase 3 trial designed to evaluate enfortumab vedotin versus physician's choice of chemotherapy (docetaxel, paclitaxel or vinflunine) in approximately 600 patients with locally advanced or metastatic urothelial cancer who were previously treated with a PD-1/L1 inhibitor and platinum-based therapy.[5] The primary endpoint is overall survival and secondary endpoints include progression-free survival, overall response rate, duration of response and disease control rate, as well as assessment of safety/tolerability and quality-of-life parameters.

About the EV-201 Trial
The EV-201 trial (NCT03219333) is a single-arm, dual-cohort, pivotal phase 2 clinical trial of enfortumab vedotin for patients with locally advanced or metastatic urothelial cancer who have been previously treated with a PD-1 or PD-L1 inhibitor, including those who have also been treated with a platinum-containing chemotherapy (cohort 1) and those who have not received a platinum-containing chemotherapy in this setting and who are ineligible for cisplatin (cohort 2). The trial enrolled 128 patients in cohort 1 and 91 patients in cohort 2 at multiple centers internationally.[6] The primary endpoint is confirmed objective response rate per blinded independent central review. Secondary endpoints include assessments of duration of response, disease control rate, progression-free survival, overall survival, safety and tolerability.

About Enfortumab Vedotin
Enfortumab vedotin is an antibody-drug conjugate (ADC) that is directed against Nectin-4, a protein located on the surface of cells and highly expressed in bladder cancer.[7,8] Nonclinical data suggest the anticancer activity of enfortumab vedotin is due to its binding to Nectin-4 expressing cells followed by the internalization and release of the anti-tumor agent monomethyl auristatin E (MMAE) into the cell, which result in the cell not reproducing (cell cycle arrest) and in programmed cell death (apoptosis).[7]

About the Astellas and Seagen Collaboration
Astellas and Seagen Inc. are co-developing enfortumab vedotin under a 50:50 worldwide development and commercialization collaboration. In the United States, Astellas and Seagen co-promote enfortumab vedotin under the brand name PADCEV® (enfortumab vedotin-ejfv). In the Americas outside the US, Seagen holds responsibility for commercialization activities and regulatory filings. Outside of the Americas, Astellas holds responsibility for commercialization activities and regulatory filings.

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.

Astellas 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.

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