European Commission Approves PADCEV™ (enfortumab vedotin) for Locally Advanced or Metastatic Urothelial Cancer

- Enfortumab vedotin is the first medicine approved in the EU for patients who received a prior platinum-containing chemotherapy and a PD-1/L1 inhibitor -

TOKYO and BOTHELL, Wash. – April 13, 2022 -- Astellas Pharma Inc. (TSE:4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and Seagen Inc. (Nasdaq:SGEN) today announced that the European Commission (EC) has approved PADCEV™ (enfortumab vedotin) as monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a PD-1/L1 inhibitor. The EC approval is supported by data from the global phase 3 EV-301 trial that demonstrated an overall survival (OS) benefit compared with chemotherapy.

"The approval of enfortumab vedotin in the European Union is a significant milestone for people living with advanced urothelial cancer who have had limited treatment options and poor survival rates," said Ahsan Arozullah, M.D., M.P.H., Senior Vice President, Head of Development Therapeutic Areas, Astellas. "We look forward to working with health authorities to ensure people living with advanced urothelial cancer can access this new treatment option as soon as possible."

The EV-301 trial compared enfortumab vedotin to chemotherapy in adult patients (n=608) with locally advanced or metastatic urothelial cancer who were previously treated with platinum-based chemotherapy and a PD-1/L1 inhibitor. At the time of the pre-specified interim analysis, patients who received enfortumab vedotin (n=301) in the trial lived a median of 3.9 months longer than those who received chemotherapy (n=307). Median OS was 12.9 vs. 9 months, respectively [Hazard Ratio=0.70 (95% Confidence Interval [CI]: 0.56, 0.89), p=0.001]. Across clinical trials, the most common adverse reactions with enfortumab vedotin were alopecia, fatigue, decreased appetite, peripheral sensory neuropathy, diarrhea, nausea, pruritus, dysgeusia, anemia, weight decreased, rash maculo-papular, dry skin, vomiting, aspartate aminotransferase increased, hyperglycemia, dry eye, alanine aminotransferase increased and rash.

"The EV-301 study is the first randomized trial to show improved overall survival in patients with advanced urothelial cancer who received a platinum-containing chemotherapy and an immunotherapy," said Professor Ignacio Durán, M.D., Ph.D., Hospital Universitario Marqués de Valdecilla, Spain. "This approval of enfortumab vedotin from the European Commission is an important moment for these patients and their physicians."

Results from the EV-301 trial are intended to support global registrations for enfortumab vedotin. The EC marketing authorization for enfortumab vedotin is applicable in the European Union (EU) Member States, as well as Iceland, Norway and Liechtenstein.[1]

Urothelial cancer is the most common type of bladder cancer.[2] In Europe, an estimated 204,000 people were diagnosed with urothelial cancer in 2020, and more than 67,000 died as a result of the disease.[3] Enfortumab vedotin is the first antibody-drug conjugate authorized in the EU for people living with urothelial cancer.

About Urothelial Cancer
Urothelial cancer is the most common type of bladder cancer (90 percent of cases) and can also be found in the renal pelvis (where urine collects inside the kidney), ureter (tube that connects the kidneys to the bladder) and urethra.[2] Globally, approximately 573,000 new cases of bladder cancer and 212,000 deaths are reported annually.[3]

About the EV-301 Trial
The EV-301 trial (NCT03474107) was 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 608 patients with locally advanced or metastatic urothelial cancer who were previously treated with a PD-1/L1 inhibitor and platinum-based therapies.[4] The primary endpoint was overall survival and secondary endpoints included 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. Results were published in the *New England Journal of Medicine.*

About PADCEV™ (enfortumab vedotin)
PADCEV is a first-in-class antibody-drug conjugate (ADC) that is directed against Nectin-4, a protein located on the surface of cells and highly expressed in bladder cancer.[5,6] Nonclinical data suggest the anticancer activity of PADCEV 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).[5] PADCEV is co-developed by Astellas and Seagen.

Important Safety Information
The full European Summary of Product Characteristics (SmPC) for PADCEV will be available from the European Medicines Agency website at www.ema.europa.eu.

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.

About Seagen
Seagen Inc. is a global biotechnology company that discovers, develops and commercializes transformative cancer medicines to make a meaningful difference in people's lives. Seagen is headquartered in the Seattle, Washington area, and has locations in California, Canada, Switzerland and the European Union. For more information on our marketed products and robust pipeline, visit www.seagen.com and follow @SeagenGlobal on Twitter.

About the Astellas and Seagen Collaboration
Astellas and Seagen 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. 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.

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.

Seagen Forward-Looking Statements
Certain statements made in this press release are forward-looking, such as those, among others, relating to the therapeutic potential of PADCEV, including its efficacy, safety and therapeutic uses, and the potential to make PADCEV available to patients in Europe. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include, without limitation, the possibilities that we may experience delays or setbacks in seeking pricing and reimbursement approvals or otherwise in commercializing PADCEV in Europe; that adverse events or safety signals may occur; and that adverse regulatory actions may occur. More information about the risks and uncertainties faced by Seagen is contained under the caption "Risk Factors" included in the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the Securities and Exchange Commission. Seagen disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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