Japan's MHLW Approves PADCEV® (enfortumab vedotin) for Advanced Urothelial Cancer

- Enfortumab vedotin is the first and only antibody-drug conjugate (ADC) approved in Japan for patients with advanced urothelial cancer -

TOKYO and BOTHELL, Wash. – Sept. 27, 2021 -- Astellas Pharma Inc. (TSE:4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and Seagen Inc. (Nasdaq:SGEN) today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved PADCEV® (enfortumab vedotin) for radically unresectable urothelial carcinoma that has progressed after anti-cancer chemotherapy. The New Drug Application received priority review.

Radically unresectable urothelial carcinoma is urothelial cancer that cannot be treated by surgical removal of the urinary bladder or the kidney and the ureter due to tumor growth.

"Unfortunately, advanced urothelial cancer has a relatively poor prognosis and can be challenging to treat with currently available therapies," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Head of Development Therapeutic Areas, Astellas. "The MHLW's review of enfortumab vedotin in just six months, supported by overall survival data from a pivotal Phase 3 clinical trial, reflects the seriousness of this condition and the potential benefit of enfortumab vedotin for patients in Japan."

The approval is primarily based on the global Phase 3 EV-301 clinical trial, which included sites in Japan. The trial evaluated enfortumab vedotin versus chemotherapy in adult patients 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 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 overall survival was 12.9 vs. 9.0 months, respectively [Hazard Ratio=0.70 (95% Confidence Interval [CI]: 0.56, 0.89), p=0.001]. The most common (≥20%) adverse reactions included alopecia, peripheral sensory neuropathy, pruritus, fatigue, decreased appetite, diarrhea, dysgeusia and nausea.

Each year in Japan, more than 24,300 people are diagnosed with bladder cancer and an estimated 9,500 die from the disease.[1] Enfortumab vedotin is the subject of a robust clinical development program aimed at addressing unmet needs across the continuum of urothelial cancer and in other solid tumors.

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. Globally, approximately 573,000 new cases of bladder cancer and 212,000 deaths are reported annually.[2]

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. 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 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.[3,4] 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).[4] PADCEV is co-developed by Astellas and Seagen.

Important Safety Information
For important Safety Information for PADCEV, please see the Package Insert.

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, including in Japan, 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 clinical development program for PADCEV, including its efficacy, safety and therapeutic uses. 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 possibility that delays or setbacks in the commercialization of PADCEV, adverse events or safety signals, and 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 June 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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[1] Cancer Information Service, Projected cancer statistics. Published 2021. https://ganjoho.jp/en/public/statistics/short_pred.html. Accessed September 22, 2021

[2] American Society of Clinical Oncology. Bladder cancer: introduction (9-2020). https://www.cancer.net/cancer-types/bladder-cancer/introduction Accessed September 22, 2021.

[3] PADCEV [package insert]. Northbrook, Ill.: Astellas Pharma US, Inc.

[4] Challita-Eid P, Satpayev D, Yang P, et al. Enfortumab Vedotin Antibody-Drug Conjugate Targeting Nectin-4 Is a Highly Potent Therapeutic Agent in Multiple Preclinical Cancer Models. *Cancer Res* 2016;76(10):3003-13.