FDA Grants Accelerated Approval for PADCEV® (enfortumab vedotin-ejfv) with KEYTRUDA® (pembrolizumab) for First-Line Treatment of Locally Advanced or Metastatic Urothelial Cancer

– First treatment option combining an antibody-drug conjugate plus a PD-1 inhibitor in this patient population –

TOKYO and BOTHELL, Wash. – April 3, 2023 -- Astellas Pharma Inc. (TSE:4503, President and CEO: Naoki Okamura, "Astellas") and Seagen Inc. (Nasdaq: SGEN) today announced the U.S. Food and Drug Administration (FDA) has granted PADCEV® (enfortumab vedotin-ejfv) with KEYTRUDA® (pembrolizumab) accelerated approval in the U.S. as a combination therapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer (la/mUC) who are not eligible to receive cisplatin-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication is contingent upon verification and description of clinical benefit in the EV-302 confirmatory trial.

"The accelerated approval for the combination of PADCEV and pembrolizumab marks an important milestone for the approximately 8,000 to 9,000 patients in the United States with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy," said Ahsan Arozullah, M.D., M.P.H., Senior Vice President, Head of Oncology Development, Astellas. "This patient population now has an additional treatment option to treat advanced bladder cancer at first diagnosis of metastatic disease."

"Advanced-stage urothelial cancer is aggressive and associated with devastating outcomes," said David R. Epstein, Chief Executive Officer, Seagen. "In the EV-103 clinical trial, the use of PADCEV in combination with pembrolizumab resulted in confirmed and durable tumor responses in over two-thirds of patients with advanced bladder cancer. Global enrollment in the confirmatory trial, EV-302, is complete. With this approval, we look forward to providing a new treatment option that helps address a high unmet need for these patients."

The U.S. Prescribing Information for PADCEV includes a **BOXED WARNING** for **Serious Skin Reactions** as well as the following Warnings and Precautions: hyperglycemia, pneumonitis/interstitial lung disease, peripheral neuropathy, ocular disorders, infusion site extravasation, and embryo-fetal toxicity. **Please see below for additional Important Safety Information.**

The approval is based on objective response rates (ORR) and median duration of response (DOR) in combined Dose Escalation/Cohort A and Cohort K of the phase 1b/2 EV-103 trial (NCT03288545, also known as KEYNOTE-869). In these EV-103 cohorts, patients treated with PADCEV in combination with pembrolizumab (n=121) obtained a 68% confirmed ORR (95% CI: 58.7 to 76.0) per RECIST v1.1 by blinded independent central review (BICR), with 12% of patients experiencing a complete response and 55% of patients experiencing a partial response. The median DOR per BICR for Dose Escalation/Cohort A was 22.1 months (range: 1.0+ to 46.3+) and was not reached (range: 1.2 to 24.1+) for Cohort K.[1] The median number of treatment cycles (per 21-day treatment cycle) was nine in Dose Escalation/Cohort A and 11 in Cohort K.[2,3]

The most common adverse reactions (≥20%), including laboratory abnormalities, in patients treated with PADCEV in combination with pembrolizumab were glucose increased (74%), aspartate aminotransferase increased (73%), rash (71%), hemoglobin decreased (69%), creatinine increased (69%), peripheral neuropathy (65%), lymphocytes decreased (64%), fatigue (60%), alanine aminotransferase increased (60%), sodium decreased (60%), lipase increased (59%), albumin decreased (59%), alopecia (52%), phosphate decreased (51%), decreased weight (48%), diarrhea (45%), pruritus (40%), decreased appetite (38%), nausea (36%), dysgeusia (35%), potassium decreased (35%), neutrophils decreased (32%), urinary tract infection (30%), constipation (27%), potassium increased (27%), calcium increased (27%), peripheral edema (26%), dry eye (25%), dizziness (23%), arthralgia (23%), and dry skin (21%).[1]

Results from Cohort K were presented in a late-breaking session at the 2022 European Society for Medical Oncology (ESMO) Congress. Additionally, results from Dose Escalation/Cohort A were published in the *Journal of Clinical Oncology* in August 2022.

The combination therapy was granted Breakthrough Therapy designation by the FDA in February 2020 based on Dose Escalation/Cohort A data. The combination therapy was also granted Priority Review in December 2022. The accelerated approval granted to the combination therapy today is part of the FDA's Accelerated Approval Program, which allows approval of a medicine based on a surrogate endpoint if the medicine fills an unmet medical need for a serious condition.

The ongoing phase 3 EV-302 trial (NCT04223856, also known as KEYNOTE-A39) evaluating the clinical benefit of PADCEV in combination with pembrolizumab in patients with previously untreated advanced urothelial cancer is intended to serve as the pivotal confirmatory trial for the U.S. accelerated approval. It is also intended to serve as the basis for global registrations. The trial has completed global enrollment, with the China extension of the study currently enrolling patients.

About Bladder and Urothelial Cancer
It is estimated that approximately 82,290 people in the U.S. will be diagnosed with bladder cancer in 2023.[4] Urothelial cancer accounts for 90% of all bladder cancers and can also be found in the renal pelvis, ureter and urethra.[5] Approximately 12% of cases are locally advanced or metastatic urothelial cancer at diagnosis.[6] Globally, approximately 573,000 new cases of bladder cancer and 212,000 deaths are reported annually.[7]

Ongoing Investigational Trials
The EV-103 trial (NCT03288545) is an ongoing, multi-cohort, open-label, multicenter phase 1b/2 study investigating enfortumab vedotin alone or in combination with pembrolizumab and/or chemotherapy in first- or second-line settings in patients with locally advanced or metastatic urothelial cancer (la/mUC) and in patients with muscle-invasive bladder cancer (MIBC). The use of enfortumab vedotin in combination with pembrolizumab in second-line urothelial cancer and in MIBC has not been proven safe or effective.

Enfortumab vedotin in combination with pembrolizumab is being investigated in an extensive program in multiple stages of urothelial cancer, including two phase 3 clinical trials in MIBC in EV-304 (NCT04700124, also known as KEYNOTE-B15) and EV-303 (NCT03924895, also known as KEYNOTE-905). The use of enfortumab vedotin in combination with pembrolizumab in second-line urothelial cancer and in MIBC has not been proven safe or effective.

About PADCEV® (enfortumab vedotin-ejfv)
PADCEV (enfortumab vedotin-ejfv) 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.[8] 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).[1]

PADCEV (enfortumab vedotin-ejfv) U.S. Indication & Important Safety Information

BOXED WARNING: SERIOUS SKIN REACTIONS

- PADCEV can cause severe and fatal cutaneous adverse reactions including Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), which occurred predominantly during the first cycle of treatment, but may occur later.
- Closely monitor patients for skin reactions.
- Immediately withhold PADCEV and consider referral for specialized care for suspected SJS or TEN or severe skin reactions.
- Permanently discontinue PADCEV in patients with confirmed SJS or TEN; or Grade 4 or recurrent Grade 3 skin reactions.

Indication

PADCEV®, as a single agent, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who:

- have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy, or
- are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.[1]

PADCEV, in combination with pembrolizumab, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who are not eligible for cisplatin-containing chemotherapy.[1]

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Important Safety Information

Warnings and Precautions

Skin reactions Severe cutaneous adverse reactions, including fatal cases of SJS or TEN occurred in patients treated with PADCEV. SJS and TEN occurred predominantly during the first cycle of treatment but may occur later. Skin reactions occurred in 56% (all grades) of the 753 patients treated with PADCEV as a single agent in clinical trials. Twenty-four percent (24%) of patients had maculo-papular rash and 33% had pruritus. Grade 3-4 skin reactions occurred in 12% of patients, including maculo-papular rash, erythematous rash, rash or drug eruption, symmetrical drug-related intertriginous and flexural exanthema (SDRIFE), bullous dermatitis, exfoliative dermatitis, and palmar-plantar erythrodysesthesia. The median time to onset of severe skin reactions was 0.7 months (range: 0.1 to 6 months). Among patients experiencing a skin reaction leading to dose interruption who then restarted PADCEV (n=59), 24% of

patients restarting at the same dose and 16% of patients restarting at a reduced dose experienced recurrent severe skin reactions. Skin reactions led to discontinuation of PADCEV in 2.6% of patients.
When PADCEV was given in combination with pembrolizumab, the incidence of skin reactions, including severe events, occurred at a higher rate. Skin reactions occurred in 72% (all grades) of the 121 patients treated with PADCEV in combination with pembrolizumab in clinical trials. The majority of the skin reactions that occurred with combination therapy included maculo-papular rash, macular rash and papular rash. Grade 3-4 skin reactions occurred in 20% of patients (Grade 3: 19%, Grade 4: 0.8%), including maculo-papular rash, bullous dermatitis, dermatitis, exfoliative dermatitis, pemphigoid, rash, erythematous rash, macular rash, and papular rash. A fatal reaction of bullous dermatitis occurred in one patient (0.8%). The median time to onset of severe skin reactions was 2.6 months (range: 0.3 to 16 months). Skin reactions led to discontinuation of PADCEV in 6% of patients. Monitor patients closely throughout treatment for skin reactions. Consider topical corticosteroids and antihistamines, as clinically indicated. For persistent or recurrent Grade 2 skin reactions, consider withholding PADCEV until Grade ≤1. Withhold PADCEV and refer for specialized care for suspected SJS, TEN or for Grade 3 skin reactions. Permanently discontinue PADCEV in patients with confirmed SJS or TEN; or Grade 4 or recurrent Grade 3 skin reactions.

Hyperglycemia and diabetic ketoacidosis (DKA). Hyperglycemia and diabetic ketoacidosis (DKA), including fatal events, occurred in patients with and without pre-existing diabetes mellitus, treated with PADCEV. Patients with baseline hemoglobin A1C ≥8% were excluded from clinical trials. In clinical trials of PADCEV as a single agent, 14% of the 753 patients treated with PADCEV developed hyperglycemia; 7% of patients developed Grade 3-4 hyperglycemia. Fatal events of hyperglycemia and diabetic ketoacidosis occurred in one patient each (0.1%). The incidence of Grade 3-4 hyperglycemia increased consistently in patients with higher body mass index and in patients with higher baseline A1C. Five percent (5%) of patients required initiation of insulin therapy for treatment of hyperglycemia. The median time to onset of hyperglycemia was 0.6 months (range: 0.1 to 20 months). Hyperglycemia led to discontinuation of PADCEV in 0.4% of patients. Closely monitor blood glucose levels in patients with, or at risk for, diabetes mellitus or hyperglycemia. If blood glucose is elevated (>250 mg/dL), withhold PADCEV.

Pneumonitis/Interstitial Lung Disease (ILD) Severe, life-threatening or fatal pneumonitis/ILD occurred in patients treated with PADCEV. In clinical trials of PADCEV as a single agent, 2.9% of the 753 patients treated with PADCEV had pneumonitis/ILD of any grade and 0.8% had Grade 3-4. The median time to onset of pneumonitis/ILD was 2.7 months (range: 0.6 to 6 months). The incidence of pneumonitis/ILD, including severe events occurred at a higher rate when PADCEV was given in combination with pembrolizumab. When PADCEV was given in combination with pembrolizumab, 9% of the 121 patients treated with combination therapy had pneumonitis/ILD of any grade and 3.3% had Grade 3. A fatal event of pneumonitis occurred in one patient (0.8%). The median time to onset of pneumonitis/ILD was 6 months (range: 0.6 to 26 months). Monitor patients for signs and symptoms indicative of pneumonitis/ILD such as hypoxia, cough, dyspnea or interstitial infiltrates on radiologic exams. Evaluate and exclude infectious, neoplastic and other causes for such signs and symptoms through appropriate investigations. Withhold PADCEV for patients who develop Grade 2 pneumonitis/ILD and consider dose reduction. Permanently discontinue PADCEV in all patients with Grade 3 or 4 pneumonitis/ILD.

Peripheral neuropathy (PN) Peripheral neuropathy occurred in 53% of the 753 patients treated with PADCEV as a single agent in clinical trials including 40% with sensory neuropathy, 7% with muscular weakness and 7% with motor neuropathy. Thirty percent of patients experienced Grade 2 reactions and 5% experienced Grade 3-4 reactions. Peripheral neuropathy occurred in patients treated with PADCEV with or without preexisting peripheral neuropathy. The median time to onset of Grade ≥2 peripheral neuropathy was 4.9 months (range: 0.1 to 20 months). Neuropathy led to treatment discontinuation in 7% of patients. Of the patients who experienced neuropathy who had data regarding resolution (N = 319), 14% had complete resolution, 46% had partial improvement, and 40% had no improvement at the time of their last evaluation. Of the 86% of patients with residual neuropathy at last evaluation, 51% had Grade 2 or greater neuropathy at the time of their last evaluation. The incidence of peripheral neuropathy occurred at a higher rate when PADCEV was given in combination with pembrolizumab. When PADCEV was given in combination with pembrolizumab, 65% of the 121 patients treated with combination therapy had peripheral neuropathy of any grade, 45% had Grade 2 neuropathy, and 3.3% had Grade 3 neuropathy. The median time to onset of Grade ≥2 peripheral neuropathy was 6 months (range: 0.3 to 25 months). Monitor patients for symptoms of new or worsening peripheral neuropathy and consider dose interruption or dose reduction of PADCEV when peripheral neuropathy occurs. Permanently discontinue PADCEV in patients who develop Grade ≥3 peripheral neuropathy.

Ocular disorders were reported in 40% of the 384 patients treated with PADCEV as a single agent in clinical trials in which ophthalmologic exams were scheduled. The majority of these events involved the cornea and included events associated with dry eye such as keratitis, blurred vision, increased lacrimation, conjunctivitis, limbal stem cell deficiency, and keratopathy. Dry eye symptoms occurred in 34% of patients, and blurred vision occurred in 13% of patients, during treatment with PADCEV. The median time to onset to symptomatic ocular disorder was 1.6 months (range: 0 to 19 months). Monitor patients for ocular disorders. Consider artificial tears for prophylaxis of dry eyes and ophthalmologic evaluation if ocular symptoms occur or do not resolve. Consider treatment with ophthalmic topical steroids, if indicated after an ophthalmic exam. Consider dose interruption or dose reduction of PADCEV for symptomatic ocular disorders.

Infusion site extravasation Skin and soft tissue reactions secondary to extravasation have been observed after administration of PADCEV. Of the 753 patients treated with PADCEV as a single agent in clinical trials, 1.5% of patients experienced skin and soft tissue reactions, including 0.3% who experienced Grade 3-4 reactions. Reactions may be delayed. Erythema, swelling, increased temperature, and pain worsened until 2-7 days after extravasation and resolved within 1-4 weeks of peak. Two patients (0.3%) developed extravasation reactions with secondary cellulitis, bullae, or exfoliation. Ensure adequate venous access prior to starting PADCEV and monitor for possible extravasation during administration. If extravasation occurs, stop the infusion and monitor for adverse reactions.

Embryo-fetal toxicity PADCEV can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during PADCEV treatment and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with PADCEV and for 4 months after the last dose.

Adverse Reactions

Most common adverse reactions, including laboratory abnormalities (≥20%) (PADCEV monotherapy)

Rash, aspartate aminotransferase increased, glucose increased, creatinine increased, fatigue, peripheral neuropathy, lymphocytes decreased, alopecia, decreased appetite, hemoglobin decreased, diarrhea, sodium decreased, nausea, pruritus, phosphate decreased, dysgeusia, alanine aminotransferase increased, anemia, albumin decreased, neutrophils decreased, urate increased, lipase increased, platelets decreased, weight decreased and dry skin.

EV-301 Study: 296 patients previously treated with a PD-1/L1 inhibitor and platinum-based chemotherapy.

Serious adverse reactions occurred in 47% of patients treated with PADCEV; the most common (≥2%) were urinary tract infection, acute kidney injury (7% each) and pneumonia (5%). Fatal adverse reactions occurred in 3% of patients, including multiorgan dysfunction (1.0%), hepatic dysfunction, septic shock, hyperglycemia, pneumonitis and pelvic abscess (0.3% each). Adverse reactions leading to discontinuation occurred in 17% of patients; the most common (≥2%) were PN (5%) and rash (4%). Adverse reactions leading to dose interruption occurred in 61% of patients; the most common (≥4%) were PN (23%), rash (11%) and fatigue (9%). Adverse reactions leading to dose reduction occurred in 34% of patients; the most common (≥2%) were PN (10%), rash (8%), decreased appetite and fatigue (3% each). Clinically relevant adverse reactions (<15%) include vomiting (14%), AST increased (12%), hyperglycemia (10%), ALT increased (9%), pneumonitis (3%) and infusion site extravasation (0.7%).

EV-201, Cohort 2 Study: 89 patients previously treated with a PD-1/L1 inhibitor and not eligible for cisplatin-based chemotherapy.

Serious adverse reactions occurred in 39% of patients treated with PADCEV; the most common (≥3%) were pneumonia, sepsis and diarrhea (5% each). Fatal adverse reactions occurred in 8% of patients, including acute kidney injury (2.2%), metabolic acidosis, sepsis, multiorgan dysfunction, pneumonia and pneumonitis (1.1% each). Adverse reactions leading to discontinuation occurred in 20% of patients; the most common (≥2%) was PN (7%). Adverse reactions leading to dose interruption occurred in 60% of patients; the most common (≥3%) were PN (19%), rash (9%), fatigue (8%), diarrhea (5%), AST increased and hyperglycemia (3% each). Adverse reactions leading to dose reduction occurred in 49% of patients; the most common (≥3%) were PN (19%), rash (11%) and fatigue (7%). Clinically relevant adverse reactions (<15%) include vomiting (13%), AST increased (12%), lipase increased (11%), ALT increased (10%), pneumonitis (4%) and infusion site extravasation (1%).

EV-103 Study: 121 patients with previously untreated locally advanced or metastatic urothelial cancer who were not eligible for cisplatin-containing chemotherapy (PADCEV in combination with pembrolizumab)

The **most common adverse reactions**, including laboratory abnormalities (≥20%), of PADCEV in combination with pembrolizumab were glucose increased, aspartate aminotransferase increased, rash, hemoglobin decreased, creatinine increased, peripheral neuropathy, lymphocytes decreased, fatigue, alanine aminotransferase increased, sodium decreased, lipase increased, albumin decreased, alopecia, phosphate decreased, decreased weight, diarrhea, pruritus, decreased appetite, nausea, dysgeusia,

potassium decreased, neutrophils decreased, urinary tract infection, constipation, potassium increased, calcium increased, peripheral edema, dry eye, dizziness, arthralgia, and dry skin.
Serious adverse reactions occurred in 50% of patients treated with PADCEV in combination with pembrolizumab. The **most common serious adverse reactions** (≥2%) were acute kidney injury (7%), urinary tract infection (7%), urosepsis (5%), sepsis (3.3%), pneumonia (3.3%), hematuria (3.3%), pneumonitis (3.3%), urinary retention (2.5%), diarrhea (2.5%), myasthenia gravis (2.5%), myositis (2.5%), anemia (2.5%), and hypotension (2.5%). **Fatal adverse reactions** occurred in 5% of patients treated with PADCEV in combination with pembrolizumab including sepsis (1.6%), bullous dermatitis (0.8%), myasthenia gravis (0.8%), and pneumonitis/ILD (0.8%). Adverse reactions leading to discontinuation of PADCEV occurred in 36% of patients. The **most common adverse reactions (≥2%) leading to discontinuation** of PADCEV were peripheral neuropathy (20%) and rash (6%). Adverse reactions leading to dose interruption of PADCEV occurred in 69% of patients. The **most common adverse reactions (≥2%) leading to dose interruption** of PADCEV were peripheral neuropathy (18%), rash (12%), lipase increased (6%), pneumonitis (6%), diarrhea (4.1%), acute kidney injury (3.3%), alanine aminotransferase increased (3.3%), fatigue (3.3%), neutropenia (3.3%), urinary tract infection (3.3%), amylase increased (2.5%), anemia (2.5%), COVID-19 (2.5%), hyperglycemia (2.5%), and hypotension (2.5%). Adverse reactions leading to dose reduction of PADCEV occurred in 45% of patients. The **most common adverse reactions (≥2%) leading to dose reduction** of PADCEV were peripheral neuropathy (17%), rash (12%), fatigue (5%), neutropenia (5%), and diarrhea (4.1%).

Drug Interactions
Effects of other drugs on PADCEV (*Dual P-gp and Strong CYP3A4 Inhibitors*)
Concomitant use with dual P-gp and strong CYP3A4 inhibitors may increase unconjugated monomethyl auristatin E exposure, which may increase the incidence or severity of PADCEV toxicities. Closely monitor patients for signs of toxicity when PADCEV is given concomitantly with dual P-gp and strong CYP3A4 inhibitors.

Specific Populations
Lactation Advise lactating women not to breastfeed during treatment with PADCEV and for at least 3 weeks after the last dose.

Hepatic impairment Avoid the use of PADCEV in patients with moderate or severe hepatic impairment.

For more information, please see the full Prescribing Information including BOXED WARNING for PADCEV here.

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 the company's marketed products and robust pipeline, visit www.seagen.com and follow @SeagenGlobal on Twitter.

About the Astellas, Seagen and Merck Collaboration
Astellas and Seagen entered a clinical collaboration agreement with Merck to evaluate the combination of Astellas' and Seagen's PADCEV® (enfortumab vedotin-ejfv) and Merck's KEYTRUDA® (pembrolizumab) in patients with previously untreated metastatic urothelial cancer. KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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 continued FDA approval in the referenced indication; the potential for the EV-302 trial to serve as the confirmatory trial for accelerated approval in the U.S. or as the basis for global registrations; the therapeutic potential of PADCEV, alone or in combination, and its possible efficacy, safety and therapeutic uses; the development program for PADCEV in combination with pembrolizumab; and planned and ongoing clinical trials. 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 EV-302 and other clinical trials may fail to establish sufficient efficacy; that adverse events or safety signals may occur; that utilization and adoption of PADCEV by prescribing physicians in the referenced indication may be limited by the availability and extent of reimbursement and other factors; that adverse regulatory actions may occur; and that delays, setbacks or failures in clinical development and regulatory activities for a variety of reasons, including without limitation the inherent difficulty and uncertainty of pharmaceutical product development. More information about the risks and uncertainties faced by Seagen is contained under the caption "Risk Factors" included in the company's Annual Report on Form 10-K for the year ended December 31, 2022 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.

###

Astellas Contacts:
For Media
Elysia Wood
(703) 722-4656
elysia.wood@astellas.com

For Investors
Astellas Pharma Inc.
Corporate Advocacy & Relations
+81-3-3244-3202

Seagen Contacts:
For Media
David Caouette
(310) 430-3476
dcaouette@seagen.com

For Investors
Douglas Maffei, Ph.D.
(425) 527-4881
dmaffei@seagen.com

---

[1] PADCEV [package insert]. Northbrook, IL: Astellas Pharma US, Inc.
[2] Rosenberg JE, Milowsky MI, Ramamurthy C, et al. Study EV-103 cohort K: antitumor activity of enfortumab vedotin monotherapy or in combination with pembrolizumab in previously untreated cisplatin-ineligible patients with locally advanced or metastatic urothelial cancer (la/mUC). Presented at: European Society for Medical Oncology Congress; September 9-13, 2022; Paris, France.
[3] Hoimes CJ, Flaig TW, Milowsky MI, et al. Enfortumab vedotin plus pembrolizumab in previously untreated advanced urothelial cancer. J Clin Oncol 2023;41(1):22-31.
[4] Siegel RL, Miller KD, Wagle NS, Jemal A. Cancer statistics, 2023. CA Cancer J Clin 2023;73(1):17-48.
[5] American Society of Clinical Oncology. Bladder cancer: introduction (12-2021). https://www.cancer.net/cancer-types/bladder-cancer/introduction. Accessed 09-14-2022.
[6]National Cancer Institute. Cancer stat facts: bladder cancer. https://seer.cancer.gov/statfacts/html/urinb.html. Accessed 05-05-2022.
[7] International Agency for Research on Cancer. Cancer Today: bladder globocan 2020 fact sheet (12-2020). https://gco.iarc.fr/today/data/factsheets/cancers/30-Bladder-fact-sheet.pdf. Accessed 03-01-2023.
[8] Challita-Eid PM, 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.