Pfizer Logo

PADCEV™ Plus KEYTRUDA™, Given Before and After Surgery, Cuts the Risk of Recurrence, Progression or Death by 60% and the Risk of Death by 50% for Certain Patients with Bladder Cancer

Saturday, October 18, 2025 - 10:30am

- *First and only combination regimen to improve survival when used before and after surgical cystectomy in cisplatin-ineligible patients with muscle-invasive bladder cancer*
- *Unprecedented survival results from pivotal Phase 3 EV-303 trial show potential for PADCEV plus KEYTRUDA to redefine standard of care*

TOKYO AND NEW YORK, October 18, 2025 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Naoki Okamura, "Astellas") and Pfizer Inc. (NYSE: PFE) today announced positive results from the pivotal Phase 3 EV-303 clinical trial (also known as KEYNOTE-905) for PADCEV™ (enfortumab vedotin), a Nectin-4 directed antibody-drug conjugate, in combination with KEYTRUDA™ (pembrolizumab), a PD-1 inhibitor. The study evaluated the combination in patients with muscle-invasive bladder cancer (MIBC) who are ineligible for or declined cisplatin-based chemotherapy. PADCEV plus KEYTRUDA significantly improved event-free survival (EFS) and overall survival (OS) when used as a neoadjuvant and adjuvant treatment (before and after surgery) versus the current standard of care—surgery alone. Results from the EV-303 trial will be presented today in a Presidential Symposium (Abstract #LBA2) at the 2025 European Society of Medical Oncology (ESMO) Congress in Berlin, Germany.

At the first interim efficacy analysis, results from the primary endpoint of EFS showed a 60% reduction in the risk of tumor recurrence, progression or death for patients treated with neoadjuvant and adjuvant PADCEV plus KEYTRUDA as compared to surgery alone (Hazard Ratio (HR) of 0.40; 95% Confidence Interval (CI), 0.28-0.57; $p<0.0001$). The estimated median EFS has not yet been reached for the combination arm versus 15.7 months for the surgery alone arm. An estimated 74.7% of patients treated with the combination were event free at two years, relative to 39.4% of patients who received surgery only.

Results from the key secondary endpoint of OS showed a 50% reduction in the risk of death for neoadjuvant and adjuvant PADCEV plus KEYTRUDA as compared to surgery alone (HR of 0.50; 95% CI, 0.33-0.74; $p<0.0002$). The estimated median OS has not yet been reached for the combination arm versus 41.7 months for the surgery arm. An estimated 79.7% of patients were alive at two years relative to 63.1% of patients who received surgery only.

Consistent EFS and OS benefits were seen across all pre-defined subgroups, including age, gender, smoking status and PD-L1 status as well as protocol-defined stratification groups based on cisplatin ineligibility

(ineligible vs eligible but declined), clinical stage and geographic region.

The safety results in EV-303 were consistent with those previously reported for this combination. The most common (?30%) adverse events (AEs) reported in the neoadjuvant and adjuvant PADCEV plus KEYTRUDA arm were pruritus (itching), alopecia, diarrhea, fatigue and anemia. Grade ? 3 AEs due to any cause occurred in 71.3% of patients treated in the combination arm and 45.9% of patients who received surgery only.

Christof Vulsteke, M.D., Ph.D., Head of Integrated Cancer Center Ghent (IKG, Belgium) and Clinical Trial Unit Oncology Ghent and EV-303 Principal Investigator
"For decades, patients with muscle-invasive bladder cancer who are ineligible for cisplatin treatment have faced limited treatment options, often relying on surgery alone. The groundbreaking benefits seen in the KEYNOTE-905/EV-303 trial at this early interim analysis position the pembrolizumab and enfortumab vedotin combination to fundamentally change the way we approach the treatment of patients with this disease."

For the secondary endpoint of pathologic complete response (pCR), treatment with neoadjuvant PADCEV plus KEYTRUDA demonstrated a 57.1% pCR rate versus an 8.6% pCR rate for patients who received surgery only (estimated difference 48.3%; 95% CI 39.5-56.5; p<0.000001).

Moitreyee Chatterjee-Kishore, Ph.D., M.B.A., Head of Oncology Development, Astellas
"The compelling EV-303 results may establish a new efficacy benchmark in muscle-invasive bladder cancer. For the first time, a systemic treatment approach used before and after surgery has improved survival over standard surgery in cisplatin-ineligible patients. These data underscore the transformative potential of PADCEV plus KEYTRUDA as we continue to explore this combination in a broad population of patients with muscle-invasive bladder cancer."

Jeff Legos, Ph.D., M.B.A., Chief Oncology Officer, Pfizer
"The ability of PADCEV plus KEYTRUDA to reduce the risk of death by half in this setting is a remarkable advancement for patients who have seen limited treatment options and often face poor prognosis. These unprecedented results suggest that the transformational efficacy of this combination in advanced bladder cancer may extend into an earlier disease setting, potentially providing a life-changing impact for patients."

Bladder cancer is the ninth most common cancer worldwide, diagnosed in more than 614,000 patients each year globally.[i] MIBC represents approximately 30% of all bladder cancer cases.[ii] The standard treatment for patients with MIBC is neoadjuvant cisplatin-based chemotherapy followed by surgery, which has been shown to prolong survival.[iii] However, up to half of patients with MIBC are not eligible to receive cisplatin and face limited treatment options, typically undergoing surgery without any systemic treatment.[iii]

PADCEV plus KEYTRUDA is not currently approved for use as neoadjuvant and adjuvant treatment in cisplatin-ineligible patients with MIBC. These results will be discussed with global health authorities for potential regulatory filings. Neoadjuvant and adjuvant PADCEV plus KEYTRUDA is also being evaluated in cisplatin-eligible patients with MIBC in the EV-304 Phase 3 clinical trial (also known as KEYNOTE-B15).

The EV-303 trial is continuing to evaluate the secondary EFS, OS and pCR rate endpoints for neoadjuvant and adjuvant KEYTRUDA monotherapy versus surgery alone as they continue to mature.

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About the EV-303/KEYNOTE-905 Trial
The EV-303 trial (also known as KEYNOTE-905) is an ongoing, open-label, randomized, three-arm, controlled, Phase 3 study evaluating neoadjuvant and adjuvant PADCEV plus KEYTRUDA or neoadjuvant and adjuvant

KEYTRUDA versus surgery alone in patients with MIBC who are either not eligible for or declined cisplatin-based chemotherapy. Patients were randomized to receive either neoadjuvant and adjuvant KEYTRUDA (arm A), surgery alone (arm B) or neoadjuvant and adjuvant PADCEV plus KEYTRUDA (arm C).[iv]

The primary endpoint of this trial is EFS between arm C and arm B, defined as the time from randomization to the first occurrence of any of the following events: progression of disease that precludes radical cystectomy (RC) surgery or failure to undergo RC surgery in participants with residual disease, gross residual disease left behind at the time of surgery, local or distant recurrence as assessed by imaging and/or biopsy or death due to any cause. Key secondary endpoints include OS and pCR rate between arm C and arm B, as well as EFS, OS and pCR rate between arm A and arm B.[iv]

For more information on the global EV-303 trial, go to clinicaltrials.gov.

About PADCEV™ (enfortumab vedotin)
PADCEV™ (enfortumab vedotin) 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.[v] 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).[vi]

PADCEV plus KEYTRUDA is approved for the treatment of adult patients with locally advanced or metastatic urothelial cancer (la/mUC) regardless of cisplatin eligibility in the United States, Japan, and a number of other countries around the world. In the European Union, the combination is approved for the treatment of adult patients with la/mUC who are eligible for platinum-containing chemotherapy. PADCEV is also approved as a single agent for the treatment of adult patients with la/mUC who have previously received a PD-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.[vi]

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

PADCEV 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 70% (all grades) of the 564 patients treated with PADCEV in combination with pembrolizumab in clinical trials. When PADCEV was given in combination with pembrolizumab, the incidence of skin reactions, including severe events, occurred at a higher rate compared to PADCEV as a single agent. 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 17% of patients (Grade 3: 16%, Grade 4: 1%), 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 (0.2%). The median time to onset of severe skin reactions was 1.7 months (range: 0.1 to 17.2 months). Skin reactions led to discontinuation of PADCEV in 6% of patients.

Skin reactions occurred in 58% (all grades) of the 720 patients treated with PADCEV as a single agent in clinical trials. Twenty-three percent (23%) of patients had maculo-papular rash and 34% had pruritus. Grade 3-4 skin reactions occurred in 14% 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 0.6 months (range: 0.1 to 8 months). Among patients experiencing a skin reaction leading to dose interruption who then restarted PADCEV (n=75), 24% of patients restarting at the same dose and 24% of patients restarting at a reduced dose experienced recurrent severe skin reactions. Skin reactions led to discontinuation of PADCEV in 3.1% 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), 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, 17% of the 720 patients treated with PADCEV developed hyperglycemia of any grade; 7% of patients developed Grade 3-4 hyperglycemia (Grade 3: 6.5%, Grade 4: 0.6%). Fatal events of hyperglycemia and DKA 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. The median time to onset of hyperglycemia was 0.5 months (range: 0 to 20 months). Hyperglycemia led to discontinuation of PADCEV in 0.7% of patients. Five percent (5%) of patients required initiation of insulin therapy for treatment of hyperglycemia. Of the patients who initiated insulin therapy for treatment of hyperglycemia, 66% (23/35) discontinued insulin at the time of last evaluation. 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. When PADCEV was given in combination with pembrolizumab, 10% of the 564 patients treated with combination therapy had pneumonitis/ILD of any grade and 4% had Grade 3-4. A fatal event of pneumonitis/ILD occurred in two patients (0.4%). The incidence of pneumonitis/ILD, including severe events, occurred at a higher rate when PADCEV was given in combination with pembrolizumab compared to

PADCEV as a single agent. The median time to onset of any grade pneumonitis/ILD was 4 months (range: 0.3 to 26 months).

In clinical trials of PADCEV as a single agent, 3% of the 720 patients treated with PADCEV had pneumonitis/ILD of any grade and 0.8% had Grade 3-4. The median time to onset of any grade pneumonitis/ILD was 2.9 months (range: 0.6 to 6 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) When PADCEV was given in combination with pembrolizumab, 67% of the 564 patients treated with combination therapy had PN of any grade, 36% had Grade 2 neuropathy, and 7% had Grade 3 neuropathy. The incidence of PN occurred at a higher rate when PADCEV was given in combination with pembrolizumab compared to PADCEV as a single agent. The median time to onset of Grade ?2 PN was 6 months (range: 0.3 to 25 months).

PN occurred in 53% of the 720 patients treated with PADCEV as a single agent in clinical trials including 38% with sensory neuropathy, 8% with muscular weakness and 7% with motor neuropathy. Thirty percent of patients experienced Grade 2 reactions and 5% experienced Grade 3-4 reactions. PN occurred in patients treated with PADCEV with or without preexisting PN. The median time to onset of Grade ?2 PN was 4.9 months (range: 0.1 to 20 months). Neuropathy led to treatment discontinuation in 6% of patients.

Monitor patients for symptoms of new or worsening PN and consider dose interruption or dose reduction of PADCEV when PN occurs. Permanently discontinue PADCEV in patients who develop Grade ?3 PN.

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 30% of patients, and blurred vision occurred in 10% of patients, during treatment with PADCEV. The median time to onset to symptomatic ocular disorder was 1.7 months (range: 0 to 30.6 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 720 patients treated with PADCEV as a single agent in clinical trials, 1% 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 in combination with pembrolizumab)
Increased aspartate aminotransferase (AST), increased creatinine, rash, increased glucose, PN, increased lipase, decreased lymphocytes, increased alanine aminotransferase (ALT), decreased hemoglobin, fatigue, decreased sodium, decreased phosphate, decreased albumin, pruritus, diarrhea, alopecia, decreased weight, decreased appetite, increased urate, decreased neutrophils, decreased potassium, dry eye, nausea, constipation, increased potassium, dysgeusia, urinary tract infection and decreased platelets.

Most common adverse reactions, including laboratory abnormalities (?20%) (PADCEV monotherapy)
Increased glucose, increased AST, decreased lymphocytes, increased creatinine, rash, fatigue, PN, decreased albumin, decreased hemoglobin, alopecia, decreased appetite, decreased neutrophils, decreased sodium, increased ALT, decreased phosphate, diarrhea, nausea, pruritus, increased urate, dry eye, dysgeusia, constipation, increased lipase, decreased weight, decreased platelets, abdominal pain, dry skin.

EV-302 Study: 440 patients with previously untreated la/mUC (PADCEV in combination with pembrolizumab)
Serious adverse reactions occurred in 50% of patients treated with PADCEV in combination with pembrolizumab. The most common serious adverse reactions (?2%) were rash (6%), acute kidney injury (5%), pneumonitis/ILD (4.5%), urinary tract infection (3.6%), diarrhea (3.2%), pneumonia (2.3%), pyrexia (2%), and hyperglycemia (2%). **Fatal adverse reactions** occurred in 3.9% of patients treated with PADCEV in combination with pembrolizumab including acute respiratory failure (0.7%), pneumonia (0.5%), and pneumonitis/ILD (0.2%).

Adverse reactions leading to discontinuation of PADCEV occurred in 35% of patients. **The most common adverse reactions (?2%) leading to discontinuation** of PADCEV were PN (15%), rash (4.1%) and pneumonitis/ILD (2.3%). Adverse reactions leading to dose interruption of PADCEV occurred in 73% of patients. **The most common adverse reactions (?2%) leading to dose interruption** of PADCEV were PN (22%), rash (16%), COVID19 (10%), diarrhea (5%), pneumonitis/ILD (4.8%), fatigue (3.9%), hyperglycemia (3.6%), increased ALT (3%) and pruritus (2.5%). Adverse reactions leading to dose reduction of PADCEV occurred in 42% of patients. **The most common adverse reactions (?2%) leading to dose reduction** of PADCEV were rash (16%), PN (13%) and fatigue (2.7%).

EV-103 Study: 121 patients with previously untreated la/mUC who were not eligible for cisplatin-containing chemotherapy (PADCEV in combination with pembrolizumab)
Serious adverse reactions occurred in 50% of patients treated with PADCEV in combination with pembrolizumab; the most common (?2%) were acute kidney injury (7%), urinary tract infection (7%), urosepsis (5%), sepsis (3.3%), pneumonia (3.3%), hematuria (3.3%), pneumonitis/ILD (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 (?2%) were PN (20%) and rash (6%). **Adverse reactions leading to dose interruption** of PADCEV occurred in 69% of patients; the most common (?2%) were PN (18%), rash (12%), increased lipase (6%), pneumonitis/ILD (6%), diarrhea (4.1%), acute kidney injury (3.3%), increased ALT (3.3%), fatigue (3.3%), neutropenia (3.3%), urinary tract infection (3.3%), increased amylase (2.5%), anemia (2.5%), COVID19 (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 (?2%) were PN (17%), rash (12%), fatigue (5%), neutropenia (5%), and diarrhea (4.1%).

EV-301 Study: 296 patients previously treated with a PD-1/L1 inhibitor and platinum-based chemotherapy (PADCEV monotherapy)
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%), hepatic dysfunction, septic shock, hyperglycemia, pneumonitis/ILD, 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).

EV-201, Cohort 2 Study: 89 patients previously treated with a PD-1/L1 inhibitor and not eligible for cisplatin-based chemotherapy (PADCEV monotherapy)
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/ILD (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%), increased AST, 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%).

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 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 U.S. full Prescribing Information including BOXED WARNING for PADCEV here.

About Astellas
Astellas is a global life sciences company committed to turning innovative science into VALUE for patients. We provide transformative therapies in disease areas that include oncology, ophthalmology, urology, immunology and women's health. Through our research and development programs, we are pioneering new healthcare solutions for diseases with high unmet medical need. Learn more at www.astellas.com.

About Pfizer Oncology
At Pfizer Oncology, we are at the forefront of a new era in cancer care. Our industry-leading portfolio and

extensive pipeline includes three core mechanisms of action to attack cancer from multiple angles, including small molecules, antibody-drug conjugates (ADCs), and multispecific antibodies, including other immune-oncology biologics. We are focused on delivering transformative therapies in some of the world's most common cancers, including breast cancer, genitourinary cancer, hematology-oncology, and thoracic cancers, which includes lung cancer. Driven by science, we are committed to accelerating breakthroughs to help people with cancer live better and longer lives.

About the Pfizer, Astellas and Merck Collaboration

Seagen and Astellas previously entered a clinical collaboration agreement with Merck to evaluate the combination of Seagen's and Astellas' PADCEV™ (enfortumab vedotin) and Merck's KEYTRUDA™ (pembrolizumab) in patients with muscle-invasive bladder cancer (MIBC) who are not eligible for or declined cisplatin-based chemotherapy. Pfizer Inc. successfully completed its acquisition of Seagen on December 14, 2023. KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA (known as MSD outside of the United States and Canada).

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.

Pfizer Disclosure Notice

The information contained in this release is as of October 18, 2025. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer Oncology and PADCEV™ (enfortumab vedotin) in combination with pembrolizumab in cisplatin-ineligible patients with muscle-invasive bladder cancer, including their potential benefits and plans to present the Phase 3 EV-303 clinical trial results at the 2025 European Society of Medical Oncology Congress and discuss the Phase 3 EV-303 clinical trial results with global health authorities for potential regulatory filings that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risk and uncertainties include, among other things, uncertainties regarding the commercial success of enfortumab vedotin; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints (and continuing evaluation of endpoints), commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any applications may be filed with regulatory authorities in particular jurisdictions for any potential indication for enfortumab vedotin with pembrolizumab or as a single agent;

whether and when any applications that may be pending or filed for enfortumab vedotin with pembrolizumab or as a single agent may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether enfortumab vedotin with pembrolizumab or as a single agent will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of enfortumab vedotin with pembrolizumab or as a single agent; whether the collaboration between Pfizer, Astellas and Merck will be successful; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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[iii] Esteban-Villarrubia J, Torres-Jiménez J, Bueno-Bravo C, García-Mondaray R, Subiela JD, Gajate P. Current and Future Landscape of Perioperative Treatment for Muscle-Invasive Bladder Cancer. Cancers (Basel). 2023 Jan 17;15(3):566. doi: 10.3390/cancers15030566. PMID: 36765525; PMCID: PMC9913718.

[iv] National Institute of Health. National Library of Medicine. Perioperative Pembrolizumab (MK-3475) Plus Cystectomy or Perioperative Pembrolizumab Plus Enfortumab Vedotin Plus Cystectomy Versus Cystectomy Alone in Participants Who Are Cisplatin-ineligible or Decline Cisplatin With Muscle-invasive Bladder Cancer (MK-3475-905/KEYNOTE-905/EV-303. ClinicalTrials.gov identifier: NCT03924895. Published July 24, 2019. Updated June 17, 2025. Accessed October 16, 2025. Available at: https://clinicaltrials.gov/study/NCT03924895?term=AREA%5BBasicSearch%5D(myosarcoma)&rank=3

[v] 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.

[vi] PADCEV [package insert]. Northbrook, IL: Astellas Pharma US, Inc.

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