Category

Best Pharmaceutical Product

General Information

Company Name *

Pfizer Inc./Astellas

Product/Solution Name *

PADCEV®

Compound/Tech Name*

Enfortumab vedotin

Trade Name *

PADCEV®

Corporate Name *

PADCEV®

Date of Approval *

2023-12-15

Indications *

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

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Therapeutic Areas *

Oncology

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Attached Files:

- PADCEV_Pfizer_Astellas.docx

Background information and need for drug / device
(please be as specific as possible in your description; limit 500 words)

PADCEV® was approved as first line treatment in locally advanced or metastatic urothelial cancer (la/mUC) on December 15, 2023 when used in combination with pembrolizumab. Since this date, the combination has become standard of care in the US for these patients and has secured approval in 60 countries worldwide in both 1L and 2L la/mUC. Its rapid uptake indicates that PADCEV® plus pembrolizumab will continue to be adopted as 1L therapy in patients with la/mUC worldwide and has earned PADCEV® mega-blockbuster status. This achievement is the culmination of several firsts: PADCEV® is a first-in-class nectin-4-directed ADC, the first FDA approved combination of an ADC with an immune checkpoint inhibitor, and the first new treatment to significantly impact survival in over 3 decades in advanced urothelial cancer, where the overall survival was doubled in patients treated with the novel combination compared to subjects treated with the standard of care.

PADCEV® (enfortumab vedotin) has been developed to meet an unmet clinical need in treatment of locally advanced or metastatic urothelial cancer (la/mUC).

Bladder cancer is a common cancer type worldwide with over 600,000 new cases diagnosed annually. Advanced urothelial cancer has poor treatment outcomes and a low 5-year survival rate, resulting in approximately 200,000 deaths worldwide per year. For decades, platinum-based chemotherapy served as the first-line standard of care. Established guidelines recommended cisplatin or carboplatin combined with gemcitabine or other anti-cancer agents for first-line treatment in patients who could tolerate these regimens. Clinical trials with platinum-containing regimens showed a median survival of 12 to 14 months for patients with la/mUC. However, cisplatin-containing therapy, while preferred, was associated with significant toxicities such as nephrotoxicity, neuropathy, and ototoxicity. Due to advanced age and comorbidities, about half of patients with la/mUC could not tolerate cisplatin. For these patients, carboplatin plus gemcitabine served as the standard, though less effective than cisplatin. Other available treatments for la/mUC include checkpoint inhibitors such as avelumab for maintenance therapy, and monotherapy with PD-1/PD-L1 inhibitors like pembrolizumab for patients who are ineligible for platinum-containing chemotherapy. These treatments offer additional options for patients based on their specific medical conditions and treatment history, but these options did not improve survival leaving a significant unmet need for patients.

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History of the development of the solution/product *
(please be as specific as possible in your description; 500 words)

Enfortumab, an antibody that binds to Nectin-4 with high affinity, was discovered by Agensys ~15 years ago. First Seagen and Agensys, and later Seagen and Astellas, codeveloped the ADC enfortumab vedotin (EV) by combining enfortumab with the vedotin linker-payload. EV was tested in nonclinical pharmacology and toxicology studies, leading to a first-in-human Phase 1 study in 2014.

EV was then tested in clinical trials targeting several tumor-types as a monotherapy before focusing on advanced urothelial carcinoma. EV-201 Cohort 1 resulted in the first accelerated approval in 2L la/mUC in the US. EV-201 Cohort 2 had a positive readout for platinum-naïve and cisplatin ineligible patients, setting the stage for EV-301. EV-301 was a global, open-label, randomized phase 3 trial of EV

for the treatment of patients with la/mUC who had previously received platinum-containing chemotherapy and had disease progression during or after treatment with a PD-1/PD-L1 inhibitor. Compared to the chemotherapy comparator group, EV resulted in significantly longer overall survival (OS), significantly longer progression-free survival (PFS), and had similar total and grade 3 or higher treatment-related adverse events (TRAEs).

EV-301 resulted in the approval of EV, marketed as PADCEV®, in la/mUC as monotherapy for patients who have previously received a PD-1/PD-L1 inhibitor and platinum-containing chemotherapy.

Meanwhile, preclinical studies demonstrated that the combination of PADCEV® and checkpoint inhibitors (CPIs) enhanced anti-tumor activity with lasting antitumor immunity. These data suggested complimentary mechanisms of action and was pursued in EV-103, a Phase 1/2 trial that tested PADCEV® in combination with the CPI pembrolizumab. Data from EV-103 led to the accelerated FDA approval of PADCEV plus pembrolizumab in the US, paving the way for the practice changing phase 3 clinical trial, EV-302.

EV-302 is a global, open-label, randomized trial to compare the ef¬ficacy and safety of PADCEV® plus pembrolizumab to that of platinum-based chemotherapy in patients with previously untreated la/mUC. Study endpoints were:

• PFS was longer in the PADCEV® -pembrolizumab group than in the chemotherapy group (median, 12.5 months vs. 6.3 months; hazard ratio for disease progression or death, 0.45; 95% CI, 0.38 to 0.54; P<0.001).
• OS was longer in the PADCEV®-pembrolizumab group (median, 31.5 months vs. 16.1 months; hazard ratio for death, 0.47; 95% CI, 0.38 to 0.58; P<0.001).
• TRAEs of grade 3 or higher occurred in 55.9% of the patients in the PADCEV®-pembrolizumab group and in 69.5% of those in the chemotherapy group.

Presenting EV-302's results at ESMO in October 2023, speaker Thomas Powles identified PADCEV® plus pembrolizumab as a potential new standard of care for 1L la/mUC due to its "transformative" clinical benefit in bladder cancer. In December 2023, Pfizer acquired Seagen, and Pfizer and Astellas expanded PADCEV®'s approval to 60 countries worldwide in 1L and 2L la/mUC, highlighting the regulatory enthusiasm in making PADCEV® available to patients. PADCEV® plus pembrolizumab has become 1L in la/mUC in the US, and its rapid adoption has garnered mega-blockbuster status, demonstrating its acceptance as a new standard of care in a treatment landscape that had been unchanged for decades.

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Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition *

ADCs require each of their components to work together for clinical success. The tumor-associated target, antibody, drug linker, and payload play vital roles in an ADC's clinical performance. PADCEV® is the first approved ADC targeting Nectin-4, a tumor-associated antigen with consistently high expression in conventional urothelial carcinoma but limited expression on normal tissues. Once bound to Nectin-4 on tumor cells, PADCEV® internalizes to deliver its payload via cleavage of the valine-citrulline peptide linker by intracellular lysosomal proteases. This peptide linker, discovered and

developed by Seagen, was a massive improvement in conditional linker stability and has been clinically validated to maximize both safety and efficacy. The vedotin drug linker comprises the valine-citrulline linker connected to monomethyl auristatin E (MMAE). MMAE is PADCEV®'s payload, a potent and stable antimitotic agent that disrupts microtubule networks and causes cell cycle arrest followed by cell death. This is how PADCEV® begins to make an impact on patients, by targeting Nectin-4 positive tumor cells and killing them via delivery of MMAE, but PADCEV®'s mechanism of action likely extends beyond direct tumor-cell cytotoxicity.

PADCEV® is believed to impact tumors through at least two additional mechanisms: 1) a phenomenon termed "bystander effect" and by 2) driving anti-cancer immunity via a regulated form of cell death called immunogenic cell death (ICD). Bystander effect results from the permeability of MMAE, enabling it to readily cross cell membranes and diffuse into neighboring cells. This phenomenon likely allows PADCEV® to extend its reach and impact neighboring tumor cells with less Nectin-4 on the surface. ICD is a type of cell death that can train the immune system to recognize and eliminate cancer cells. Vedotin ADCs and MMAE appear to be particularly adept at inducing ICD compared to other common ADC payloads. Once the immune system has been induced to recognize tumor cells, it can search the body for cancerous cells and eliminate them, again, potentially extending PADCEV®'s reach.

Tumors often create and enforce a local environment designed to avoid immune detection. Nearly 15 years ago, immune CPIs were introduced and have subsequently demonstrated the ability to overcome tumor enforced immunosuppression for many patients. This is why we believe the combination of PADCEV® with the CPI pembrolizumab has significantly improved clinical outcomes relative to chemotherapy or checkpoint therapy alone: PADCEV® can directly kill tumor cells in a regulated manner to induce ICD, complementing the action of CPIs to overcome tumor enforced immunosuppression and enhance immune-mediated tumor cell killing.

PADCEV® and pembrolizumab are the first FDA approved demonstration of an ADC and CPI pairing. While PADCEV® alone made a substantial impact on la/mUC patients, its combination with pembrolizumab has been a massive success with further improved patient outcomes. These results made PADCEV® the first new medicine to impact survival in over 3 decades in advanced bladder cancer. The initiation of approximately 200 new clinical trials beyond bladder cancer pairing vedotin delivering ADCs with immune-oncology agents like CPIs demonstrate that learnings from PADCEV® will continue to impact cancer patients for decades to come.

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Please provide appropriate references (PubMed, Abstract, Website) *

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