Padcev® (enfortumab vedotin-ejfv) – Expanded indication

- On July 9, 2021, Seagen and Astellas Pharma announced the regular FDA approval and expanded indication for Padcev (enfortumab vedotin-ejfv), 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.

- Padcev was previously approved via accelerated approval for the treatment of adult patients with locally advanced or mUC who have previously received a PD-1 or PD-L1 inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting.

- The FDA decision to convert accelerated approval to regular approval was based on data from EV-301, an open-label, randomized study in 608 patients with locally advanced or mUC who received prior treatment with a PD-1 or PD-L1 inhibitor and platinum-based chemotherapy. Patients were randomized to receive Padcev on days 1, 8 and 15 of a 28-day cycle or investigator's choice of chemotherapy. The major efficacy measures were overall survival (OS), progression free survival (PFS), and overall response rate (ORR).
  - Median OS was 12.9 months and 9.0 months for Padcev and chemotherapy, respectfully (hazard ratio [HR] 0.70, 95% CI: 0.56, 0.89; p = 0.0014).
  - Median PFS was 5.6 months and 3.7 months for Padcev and chemotherapy, respectfully (HR 0.62, 95% CI: 0.51, 0.75; p < 0.0001).
  - ORR was 40.6% and 17.9% for Padcev and chemotherapy, respectfully (p < 0.0001).

- Additionally, the efficacy of Padcev was evaluated in Cohort 2 of EV-201, a single-arm, multi-cohort study in 89 patients with locally advanced or mUC who received prior treatment with a PD-1 or PD-L1 inhibitor, and were cisplatin ineligible and did not receive platinum in the locally advanced or metastatic setting.
  - ORR was 51% (95% CI: 39.8, 61.3). Median duration of response was 13.8 months (95% CI: 6.4, not estimable).

- The recommended dose of Padcev is 1.25 mg/kg (up to a maximum of 125 mg for patients ≥ 100 kg) administered as an intravenous infusion over 30 minutes on days 1, 8 and 15 of a 28-day cycle until disease progression or unacceptable toxicity.