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Japan approves first and only antibody-drug conjugate (ADC) to treat Urothelial Cancer

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MHLW approves PADCEV® (enfortumab vedotin)

Astellas Pharma Inc. and Seagen Inc. 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 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 PD1/L1 inhibitor.

Each year in Japan, more than 24,300 people are diagnosed with bladder cancer and an estimated 9,500 die from the disease. 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.