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Astellas, Seagen announce positive results in Ph 2 pivotal trial of PADCEV

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Japan-based Astellas Pharma Inc. and Seagen Inc. in the US have announced positive topline results from the second cohort of patients in the pivotal phase 2 single-arm clinical trial known as EV-201. The cohort is evaluating the antibody-drug conjugate PADCEV (enfortumab vedotin-ejfv) for patients with locally advanced or metastatic urothelial cancer who have been previously treated with a PD-1/L1 inhibitor and have not received platinum-containing chemotherapy and are ineligible for cisplatin.

Results showed a 52 percent objective response rate (ORR) [95% Confidence Interval (CI): 40.8, 62.4] per blinded independent central review and a median duration of response of 10.9 months.

PADCEV 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.[1,2] The U.S. Food and Drug Administration (FDA) granted accelerated approval to PADCEV in 2019 based on results from the first cohort in this trial, which included patients whose disease had progressed during or following platinum-based chemotherapy and a PD-1/L1 inhibitor.

Urothelial cancer is the most common type of bladder cancer, and can also be found in the urothelial cells that line the renal pelvis, ureter and urethra.