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Astellas submits biologics license application for Urothelial Cancer drug

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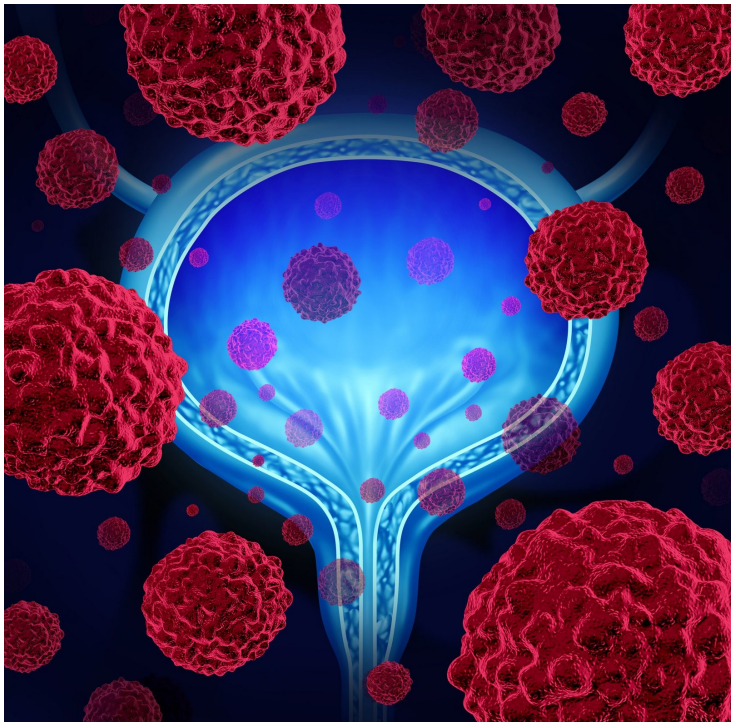
Submission Based on Pivotal Phase 2 Trial Results Recently Presented at Annual Meeting of American Society of Clinical Oncology



Japan based Astellas Pharma Inc. and US headquartered Seattle Genetics, Inc. have announced submission of a Biologics License Application for accelerated approval to the U.S. Food and Drug Administration for the investigational agent enfortumab vedotin for the treatment of patients with locally advanced or metastatic urothelial cancer who have received a PD-1/L1 inhibitor and who have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting.

The submission is based on results from the first cohort of patients in the EV-201 pivotal phase 2 clinical trial that were presented as a late-breaking abstract at the annual meeting of the American Society of Clinical Oncology (ASCO) in June. Enfortumab vedotin is an investigational antibody-drug conjugate (ADC) that targets Nectin-4, a protein that is highly expressed in urothelial cancers.

Based on preliminary results from a phase 1 trial (EV-101), the FDA granted enfortumab vedotin Breakthrough Therapy designation for patients with locally advanced or metastatic urothelial cancer whose disease has progressed during or following checkpoint inhibitor therapy.

A global, randomized phase 3 confirmatory clinical trial (EV-301) is ongoing and is intended to support global registrations. Another ongoing trial, EV-103, is evaluating enfortumab vedotin in earlier lines of treatment for patients with locally advanced or metastatic urothelial cancer, including in combination with pembrolizumab and/or platinum chemotherapy in newly

diagnosed patients as well as patients whose cancer progressed from earlier-stage disease.