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Seattle Genetics, Astellas gets USFDA priority review for Enfortumab Vedotin

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US FDA Grants Priority Review for Enfortumab Vedotin Biologics License Application in Locally Advanced or Metastatic Urothelial Cancer

Seattle Genetics, Inc. and Astellas Pharma Inc. have announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for the investigational agent enfortumab vedotin and granted Priority Review 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 filing 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 oral presentation at the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2019. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of March 15, 2020. Enfortumab vedotin is a novel investigational antibody-drug conjugate (ADC) that targets Nectin-4, a protein that is highly expressed in urothelial cancers.

The FDA granted enfortumab vedotin Breakthrough Therapy designation in March 2018, for patients with locally advanced or metastatic urothelial cancer whose disease has progressed during or following checkpoint inhibitor therapy.

"The FDA's filing of the application for enfortumab vedotin and granting of Priority Review is a significant milestone toward offering a new treatment to patients with advanced urothelial cancer who have a clear unmet need," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics.

"If approved, enfortumab vedotin will likely play an important role in the treatment of advanced urothelial cancer, and we look forward to working with the FDA as the review process advances," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Oncology Therapeutic Area Head at Astellas.