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ASIA EDITION

Seattle Genetics, Astellas announce Clinical Trial collaboration with Merck

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Companies to Evaluate Enfortumab Vedotin in Combination with KEYTRUDA® (pembrolizumab) in Patients with Metastatic Urothelial Cancer

Seattle Genetics, Inc. and Astellas Pharma Inc.have announced a clinical collaboration agreement with Merck, known as MSD outside the United States and Canada through a subsidiary, to evaluate the combination of Seattle Genetics' and Astellas' antibody-drug conjugate (ADC) enfortumab vedotin and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with previously untreated metastatic urothelial cancer.

Under the terms of the agreement, the three companies will conduct and fund a global, registrational phase 3 clinical trial to be led by Seattle Genetics. The trial will be designed to evaluate the efficacy of the combination of enfortumab vedotin and pembrolizumab in patients with previously untreated locally advanced or metastatic urothelial cancer. The companies are working in consultation with regulatory authorities to finalize the trial design and currently plan to initiate the trial in the first half of 2020.

"We look forward to initiating a randomized phase 3 trial in patients with previously untreated locally advanced or metastatic urothelial cancer," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics. "Recent data from a phase 1b trial of enfortumab vedotin in combination with pembrolizumab showed evidence of clinical activity leading to the development of this phase 3 trial."

"An unmet medical need exists for previously untreated patients with metastatic urothelial cancer, and we are committed to studying enfortumab vedotin in combination with other agents in different stages of urothelial cancer," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Oncology Therapeutic Area Head at Astellas. "We look forward to further evaluating enfortumab vedotin and pembrolizumab in this high unmet need patient population."

Enfortumab vedotin is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of adult 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.