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ASIA EDITION

FDA grants accelerated approval to Astellas' and Seattle Genetics' PADCEV

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PADCEV is the First Treatment approved for locally Advanced or Metastatic Urothelial Cancer Following Treatment with Platinum-based Chemotherapy and a PD-1 or PD-L1 Inhibitor

Astellas Pharma Inc. and Seattle Genetics, Inc. have announced that the U.S. Food and Drug Administration (FDA) granted accelerated approval to PADCEV™ for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1/L1 inhibitor and a platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery or in a locally advanced or metastatic setting. PADCEV is approved under the FDA's Accelerated Approval Program based on tumor response rate. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. PADCEV is the first FDA approved treatment in the U.S. for these patients. It 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.

"Metastatic urothelial cancer is an aggressive and devastating disease with limited treatment options, and the approval of PADCEV is a significant advance for these patients who previously had limited options after initial therapies failed," said Jonathan E. Rosenberg, M.D., Medical Oncologist, Chief, Genitourinary Medical Oncology Service, Memorial Sloan Kettering Cancer Center in New York. "The PADCEV clinical trial enrolled a range of patients whose cancer was difficult to treat, including those whose disease had spread to the liver."

"The FDA approval of PADCEV is welcome news for patients with bladder cancer," said Andrea Maddox-Smith, Chief Executive Officer, Bladder Cancer Advocacy Network. "Though new medicines for bladder cancer have been approved in recent years, most people living with advanced stages of this disease face a difficult journey with few treatment options."

"This approval underscores our commitment to develop novel medicines that address unmet patient needs, and we're grateful to the patients and physicians whose participation led to this outcome," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Oncology Therapeutic Area Head, Astellas.

"PADCEV is the first antibody-drug conjugate approved for patients facing this aggressive disease, and it is the culmination of

years of innovative work on this technology," said Roger Dansey, M.D., Chief Medical Officer, Seattle Genetics.

The FDA's Accelerated Approval Program allows approval of a medicine based on a surrogate endpoint if the medicine fills an unmet medical need for a serious condition. A global, randomized phase 3 confirmatory clinical trial (EV-301) is underway and is also intended to support global registrations.