Astellas and Vical Announce Top-Line Results for Phase 3 Trial of Cytomegalovirus Vaccine ASP0113 in Hematopoietic Stem Cell Transplant Recipients

TOKYO and SAN DIEGO – Jan. 22, 2018 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, "Astellas") and Vical Incorporated (NASDAQ: VICL) announced today that ASP0113, an investigational DNA vaccine being developed for cytomegalovirus (CMV)-seropositive hematopoietic stem cell transplant (HSCT) recipients, did not meet its primary or secondary endpoints in the Phase 3 HELIOS clinical trial. The vaccine was generally well tolerated, with injection-site reactions being the most commonly reported adverse event.

"We are disappointed that the results did not demonstrate a significant improvement in overall survival and reduction in CMV end-organ disease," said Bernhardt G. Zeiher, president of Development, Astellas. "We would like to thank the patients and clinicians who participated in this important trial."

The Phase 3 trial was designed to evaluate the efficacy of ASP0113 compared with placebo in CMV-seropositive recipients undergoing an allogeneic stem cell transplant. Efficacy was assessed using a primary composite endpoint of overall mortality and CMV end-organ disease through the first year following the transplant, an endpoint which was not met. Secondary endpoints of time to first protocol-defined CMV viremia and time to first use of adjudicated CMV-specific antiviral therapy also were not met.

"The Phase 3 trial outcome is disappointing," said Vijay Samant, Vical's Chief Executive Officer. "Astellas and Vical employees, the investigators and study site personnel did an outstanding job conducting this study, but unfortunately, the vaccine was unable to provide protection against all-cause mortality in this very difficult-to-treat patient population."

The Phase 3 trial was a 1:1 randomized, double-blind, placebo-controlled study that enrolled a total of 514 CMV seropositive subjects undergoing hematopoietic stem cell transplantation. Randomization was stratified by donor-recipient relatedness and donor CMV serostatus. Subjects were followed for one year post-transplant. For more information about the ASP0113 clinical trial, please visit www.clinicaltrials.gov.

About Cytomegalovirus

CMV is a herpes virus that is estimated to infect more than half of all adults in the United States by age 50, and is even more widespread in developing countries. A healthy immune system typically protects an infected person against CMV disease, but does not prevent or clear latent infection. Individuals whose immune systems are not fully functional are at high risk of CMV reactivation, potentially leading to severe illness or death. Those at greatest risk include HCT and solid-organ transplant recipients, as well as infants born to mothers who first become infected during pregnancy.

About ASP0113
ASP0113 is an investigational vaccine candidate designed to prevent CMV disease and associated complications in CMV-seropositive HCT recipients. ASP0113 is a bivalent DNA vaccine encoding CMV phosphoprotein 65 and glycoprotein B antigens for induction of both cellular and humoral immune responses, formulated with a proprietary poloxamer-based delivery system. ASP0113 was initially developed by Vical which partnered with Astellas for further development and commercialization. ASP0113 received Orphan Drug Designation in the United States and Europe.

About Astellas
Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at https://www.astellas.com/en.

About Vical
Vical develops biopharmaceutical products for the prevention and treatment of chronic or life-threatening infectious diseases, based on its patented DNA delivery technologies and other therapeutic approaches. Additional information on Vical is available at www.vical.com

Astellas Cautionary Notes
In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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