

 Vico
 10390 Pacific Center Court, San Die

 858-646-1100, FAX: 858-646-1150
10390 Pacific Center Court, San Diego, CA 92121-4340 www.vical.com

FOR IMMEDIATE RELEASE June 25, 2013



Contacts: Vical Incorporated Alan R. Engbring +1-858-646-1127 www.vical.com

Astellas Pharma Inc. **Corporate Communications** +81-(3)-3244-3201 www.astellas.com/en

Vical and Astellas Announce Initiation of Phase 3 Trial of ASP0113 Cytomegalovirus Vaccine First Therapeutic CMV Vaccine to Reach Phase 3

SAN DIEGO & TOKYO—June 25, 2013—Vical Incorporated (Nasdaq: VICL) and Astellas Pharma Inc. (TOKYO: 4503) today announced the initiation of a multinational Phase 3 registration trial of ASP0113 (TransVaxTM), in approximately 500 hematopoietic cell transplant (HCT) recipients. Vical and Astellas entered into exclusive worldwide license agreements in 2011 to develop and commercialize ASP0113, Vical's investigational therapeutic vaccine designed to control cytomegalovirus (CMV) in transplant recipients. Astellas is conducting the trial, and Vical is providing development, regulatory and manufacturing support. The companies expect to begin a separate Phase 2 trial of ASP0113 in solid organ transplant (SOT) recipients later this year.

"There still remains high unmet medical needs to control CMV in transplant recipients. We are pleased to advance ASP0113 program in a highly challenging HCT recipient population." said Yoshihiko Hatanaka, President and Chief Executive Officer of Astellas.

"With the initiation of this trial, ASP0113 becomes the first investigational therapeutic CMV vaccine to reach Phase 3 testing," said Vijay Samant, President and Chief Executive Officer of Vical. "Therapeutic vaccines, designed to control disease in people with established and persistent infections, represent the highest hurdle in vaccinology. We are excited to achieve this important milestone as we continue advancing ASP0113 toward commercialization."

The Phase 3 trial protocol was designed to support full approval of ASP0113 for the HCT indication. The 1:1 randomized, double-blind, placebo-controlled trial will enroll CMV seropositive subjects undergoing HCT procedures. Randomization will be stratified by donor-recipient relatedness and donor CMV serostatus. The trial will use an adaptive design composed of two parts. The first part will enroll approximately 100 subjects

and the primary endpoint will be overall survival at one year. The second part will enroll approximately 400 subjects and the primary endpoint will be either survival or a composite endpoint including survival and other variables, depending on the statistical analysis of results from the first part. Enrollment will continue uninterrupted through both parts, and the endpoint for the second part will be determined by the time enrollment is complete. Treatment and follow-up for each subject will continue for one year following enrollment. The trial design was reviewed by regulatory agencies in the United States, Europe and Japan.

About ASP0113

ASP0113 is an investigational bivalent DNA vaccine containing plasmids (closed loops of DNA) encoding human CMV pp65 and gB antigens for induction of both cellular and humoral immune responses. ASP0113 is formulated with a proprietary poloxamer-based delivery system. ASP0113 has received orphan drug designation in the United States and Europe for HCT and SOT patients.

About CMV

CMV is a herpes virus that infects more than half of all adults in the United States by age 40, 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, and those 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 transplant patients and infants born to mothers who first become infected during pregnancy. Vical is pursuing two distinct vaccine approaches for these separate market segments: ASP0113 for the transplant market and CyMVectinTM for the congenital disease market.

About Astellas

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious diseases, Oncology, Neuroscience and DM Complications and Kidney diseases. For more information on Astellas Pharma Inc., please visit <u>www.astellas.com/en</u>.

About Vical

Vical researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. Potential applications of the company's DNA delivery technology include DNA vaccines for infectious diseases or cancer, in which the expressed protein is an immunogen; cancer immunotherapeutics, in which the expressed protein is an immune system stimulant; and cardiovascular therapies, in which the expressed protein is an angiogenic growth factor. The company is developing certain infectious disease vaccines and cancer therapeutics internally. In addition, the company collaborates with major pharmaceutical companies and biotechnology companies that give it access to complementary technologies or greater resources. These strategic partnerships provide the company with mutually beneficial opportunities to expand its product pipeline and address significant unmet medical needs. Additional information on Vical is available at <u>www.vical.com</u>.

This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements about Vical's technologies, the ASP0113 CMV vaccine, as well as the company's focus, licensees, and independent and partnered product candidates. Risks and uncertainties include whether Vical, Astellas or others will continue development of ASP0113 or any other product candidates; whether the companies will begin a Phase 2 trial of ASP0113 in SOT recipients later this year, if at all; whether the Phase 3 and Phase 2 trials of ASP0113 will be completed, and if so, whether results will support advancement to commercialization for HCT or SOT recipients; whether Astellas will successfully develop and commercialize ASP0113; whether Vical will provide assistance to Astellas with manufacturing, regulatory and development activities; whether Astellas will reimburse all, if any, of Vical's ASP0113-related costs; whether Vical or its licensees will seek or gain approval to market ASP0113 or any other DNA-based human vaccine or therapeutic product candidates; whether Vical or its licensees will succeed in marketing any product candidates; and additional risks set forth in the company's filings with the Securities and Exchange Commission. These forward-looking statements represent the companies' judgment as of the date of this release. The companies disclaim, however, any intent or obligation to update these forward-looking statements.