Press Release

Astellas Announces FDA Fast Track Designation for ASP0892, DNA Vaccine for Mitigation of Severe Hypersensitivity Reactions due to Peanut Allergy

Tokyo, December 20, 2016 - Astellas Pharma Inc. (President and CEO: Yoshihiko Hatanaka, "Astellas") and Immunomic Therapeutics, Inc. (Founder & CEO: William Hearl, Ph.D., "Immunomic Therapeutics") today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the drug candidate ASP0892 for the mitigation of severe hypersensitivity reactions due to peanut allergy. ASP0892 is a new DNA vaccine program based on the investigational LAMP-Vax platform. A Phase I clinical trial to evaluate the safety, tolerability and immune response of ASP0892 in adults allergic to peanuts has been initiated.

"We are pleased that the FDA granted a Fast Track designation for ASP0892," said Bernhardt Zeiher, M.D., President, Development of Astellas. "Such designations reinforce the urgency of accelerating development programs for new treatments in these types of potentially life-threatening allergies. This milestone also reflects our commitment to addressing diseases and conditions with the highest of unmet medical needs."

"In the United States alone, over three million people are affected by peanut allergy. We are glad that the FDA made this decision regarding the early LAMP-Vax research as applied to peanut allergy and look forward to further work from Astellas on this important effort," said William Hearl, Ph.D., the founder and CEO of Immunomic Therapeutics.

Peanut allergy can be a fatal food-related allergy with potential of life-threatening anaphylaxis induced by trace exposure. The estimated prevalence in the US for peanut allergy is reported as 1.3% overall, 1.4% in children, and 0.6% in adults[1]. There is no currently approved treatment for preventing peanut-induced allergic reactions in the event of accidental ingestion. Currently patients manage their condition by strict allergen avoidance and carrying epinephrine auto-injectors for use in case of

[1] Sicherer, 2011

accidental exposure. In the case of children, this vigilance must also be maintained by parents, schools, and other guardians.

In January 2015, Astellas and Immunomic Therapeutics entered into an agreement to grant Astellas the exclusive license for the Japan territory to develop and commercialize ASP4070, currently under investigation and designed to treat allergies induced by Japanese red cedar pollen. Thereafter, in October 2015, both companies entered into an exclusive worldwide license agreement to the LAMP-Vax products for the treatment or prevention of any and all human allergic diseases. The LAMP-Vax technology may be able to enhance the effectiveness of DNA vaccines. Its purpose is to utilize the body's natural biochemistry to develop a more complete immune response, which could potentially enable effective vaccinations for a wide spectrum of diseases with unmet need. The Phase I clinical trial of ASP4070 in Japan was completed.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs and vaccines intended to treat or prevent serious conditions and that demonstrate the potential to address an unmet medical need.

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About LAMP-Vax platform

The LAMP-Vax platform is a breakthrough technology that has the potential to fundamentally improve the use of vaccines across a wide variety of diseases. LAMP-Vax is a next-generation DNA vaccine designed to stimulate an immune response against a particular protein, injecting the DNA encoding the protein rather than the protein itself. However, unlike conventional DNA vaccines, the LAMP-Vax includes a short DNA sequence encoding the Lysosomal Associated Membrane Protein (LAMP). This allows DNA vaccines developed based on the LAMP-Vax platform to utilize the body's natural biochemistry to develop a more complete immune response compared to conventional DNA vaccines. Unlike conventional DNA vaccines that primarily elicit a cytotoxic T cell immune response, vaccines developed using LAMP-Vax may initiate a more complete immune response, including antibody production, cytokine release and critical immunological memory. The ability to activate a complete immune response gives LAMP-Vax technology potential across a number of diseases, including allergic disease and cancer immunotherapy.

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 www.astellas.com/en.

About Immunomic Therapeutics

Immunomic Therapeutics, Inc. is a privately-held, clinical stage biotech company on a mission to pioneer vaccines that transform lives. The company, based in Rockville, MD, is developing nucleic acid vaccines

based on the patented Lysosomal Associated Membrane Protein (LAMP) Technology. Termed LAMP-Vax™, the exclusive immunotherapy technology works with the body's natural biochemistry system and has the potential to improve a broad range of vaccines. ITI entered into a licensing agreement with Astellas Pharma Inc. in 2015 to explore the use of LAMP-Vax in the prevention and treatment of allergic diseases, and is now focused on cancer immunotherapy. The LAMP platform has been tested in Phase I and II clinical studies. For more information, please visit www.immunomix.com.

Cautionary Notes

The safety and efficacy of the agent discussed herein are under investigation and have not been established. There is no guarantee that the agent will receive regulatory approval and become commercially available for uses being investigated. 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.

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.

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