Press Release

Astellas Executes License Agreement with an Option to Acquire JVS-100 Gene Therapy Program from Juventas

TOKYO and CLEVELAND, Ohio, November 22, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and Juventas Therapeutics (President & CEO: Rahul Aras, "Juventas") today announced that they have entered into an exclusive, worldwide (excluding China) option and license agreement for Juventas' lead product candidate, JVS-100. JVS-100 is a non-viral gene therapy that expresses stromal cell-derived factor-1 (SDF-1), a naturally occurring signaling protein that activates the endogenous tissue repair pathways. The agreement grants to Astellas a license to conduct research and to develop JVS-100 through Phase 2a clinical studies with an option to acquire JVS-100 from Juventas for further development and commercialization. Astellas currently plans to focus development efforts on the treatment of fecal incontinence (FI).

FI is the accidental passing of bowel movements including liquid or solid stools, which can result in quality of life issues (both social and hygienic) for those that suffer with this disorder. FI may result from a variety of factors including aging, damage to muscles or nerves and childbirth. At present, there is no standard of care for FI and there is no effective therapy to cure FI.

JVS-100 is a DNA plasmid designed to be delivered directly to the site of injured tissue and is non-immunogenic. Clinical trials have demonstrated its safety profile and the ability to allow for repeat administrations. It has been shown that intramuscular injection of JVS-100 in FI animal models promotes functional/histological improvement in anal sphincter muscle.

"Astellas is committed to exploring all types of partnership opportunities to turn cutting-edge science and technological advances into VALUE for patients," said Naoki Okamura, Chief Strategy Officer, Astellas. "We look forward to further investigating the promise of JVS-100 as a potential regenerative treatment for patients around the world."

"JVS-100 has been well tolerated in multiple clinical studies and has demonstrated the potential to revive intrinsic regenerative processes and restore tissue function," said Rahul Aras, Ph.D., President & CEO, Juventas. "We are excited to partner with Astellas to advance the program for treatment of patients with FI".

Under the agreement, Astellas will pay undisclosed up-front and consideration for the option right. Astellas will fund preclinical and clinical studies and be responsible for conducting development efforts directed toward the use of JVS-100 for the treatment of FI in a collaboration with Juventas.

Summit Pharmaceuticals International Corporation, a subsidiary of Sumitomo Corporation, served as advisor to Juventas in connection with this transaction.

The impact of this transaction on Astellas' financial results for the fiscal year ending March 31, 2019, is not material.

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. For more information, please visit our website at https://www.astellas.com/en

About Juventas Therapeutics
Juventas Therapeutics is a private, clinical-stage biotechnology company developing novel non-viral gene therapies that activate natural processes to repair the body. Product candidate JVS-100 is a DNA plasmid therapy that expresses stromal cell-derived factor-1, or SDF-1, a naturally occurring signaling protein that has been shown to recruit the body's own stem cells and promote tissue repair. This therapeutic approach is based on research originating at the Cleveland Clinic.

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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