

Press Release

Astellas Executes License Agreement with Auration Biotech for the Development and Commercialization of AU-935 - Addressing Unmet Medical Needs -

Tokyo, January 31, 2017 – Astellas Pharma Inc. (“Astellas”; Head Office: Tokyo, President and CEO: Yoshihiko Hatanaka) today announced that it executed a license agreement with respect to an exclusive worldwide license for an AU-935 program with Auration Biotech, Inc. (“Auration”, Head Office: San Mateo, California, President and CEO: Benjamin F. McGraw, III, PharmD).

Astellas and Auration executed an evaluation agreement with an option for Astellas to enter into the license agreement with Auration for AU-935 in October 2015. Astellas concluded to exercise the option as the efficacy of AU-935 was confirmed with pre-clinical studies for chronic tympanic membrane perforation conducted by Astellas under the agreement.

Tympanic membrane perforation can result from middle ear infections, pressure equalization, tube implantation or injury. Most perforation heal spontaneously within a few months but in some cases the perforation becomes chronic. In these cases, the only currently available treatment is an invasive surgical procedure.

AU-935 is a program, based on a discovery from Stanford University, that includes the active substance heparin-binding epidermal growth factor-like growth factor (HB-EGF). HB-EGF is a member of the EGF family and has been shown to play a critical role in the process of tympanic membrane regeneration. AU-935 is being developed as a simple ear topical application that would be an alternative to the surgical procedure.

Going forward Astellas will, at its cost and expense, develop and commercialize AU-935. Astellas will make an up-front payment at the time of the execution of the agreement and milestone payments upon the achievement of certain development milestones. Moreover, Astellas will make royalty payments at certain rate for net sales of the product.

For the purpose of enhancing the capability to create new drugs, Astellas is looking for challenges in new therapeutic areas and novel technology platforms as well as new drug discovery opportunities that address unmet medical needs through collaboration with external partners. The agreement with Auration is one of these initiatives, and Astellas continues strengthening these efforts.

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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 Auration

Auration Biotech, Inc., based in San Mateo, California, is a privately held biotechnology company dedicated to the development of novel therapeutics that restore or maintain hearing.

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.

Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Communications
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473