

Press Release

Astellas Establishes “Astellas Gene Therapies” as its Global Gene Therapy Center of Excellence

- *Astellas integrates its wholly owned subsidiary, Audentes Therapeutics, and expands the mission to further Astellas’ position as a global leader in the field of Gene Therapy -*

TOKYO, March 31, 2021 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) today announced that it will further integrate its wholly owned subsidiary, Audentes Therapeutics, and establish “Astellas Gene Therapies” within the organization. Genetic regulation is positioned as one of the Primary Focuses of the research and development strategy at Astellas. This will further advance our activities from research and development, manufacturing and commercialization of the associated programs with a foundation in adeno-associated virus (AAV)-based gene therapy. Further, the new center of excellence will enable us to achieve more effective and efficient operations, with a high-quality, safety and compliance standard.

Effective April 1, Astellas Gene Therapies will serve as the Gene Therapy Center of Excellence operated through three divisions specializing in gene therapy research including technical operations, medical and development, and future commercialization of gene therapy programs. The center of excellence will focus on the programs for neuromuscular diseases brought by Audentes including its lead program AT132 (for X-linked Myotubular Myopathy) and AT845 (for Pompe disease), in addition to advancing additional Astellas’ gene therapy programs toward clinical investigation.

“The field of gene therapy has made significant strides to date, and we believe the future holds even greater opportunity to bring new treatments to a wide range of diseases for patients in need,” said Kenji Yasukawa, President and CEO, Astellas. “With Astellas Gene Therapies as a Center of Excellence, we can continue to deepen our knowledge in this ever-evolving space with the expertise and talent from within Audentes to lead us to the forefront of creating next-generation treatments.”

In the future, instead of alternating between the Astellas and Audentes umbrella brands by program, the company comes together under one banner as Astellas Gene Therapies to advance our efforts in a way that provides the value of gene therapy to patients around the world.

About Astellas Gene therapies

Astellas Gene Therapies is an Astellas Center of Excellence developing genetic medicines with the potential to deliver transformative value for patients. Based on an innovative scientific approach and industry leading internal manufacturing capability and expertise, we are currently exploring three gene therapy modalities: gene replacement, exon skipping gene therapy, and vectorized RNA knockdown and will also advance additional Astellas gene therapy programs toward clinical investigation. We are based in San Francisco, with manufacturing and laboratory facilities in South San Francisco and Sanford, North Carolina.

About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+[®] healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands 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>.

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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