



Press Release

Astellas and Dyno Therapeutics Announce Research Collaboration to Develop Next-Generation AAV Gene Therapy Vectors for Skeletal and Cardiac Muscle

- Dyno receives \$18 million upfront and is eligible for milestone and royalty payments potentially exceeding \$1.6 billion -

TOKYO and **CAMBRIDGE**, **Mass.**, **Dec. 2**, **2021** - Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and Dyno Therapeutics, Inc. (President and CEO: Eric Kelsic, Ph.D., "Dyno") today announced an option and license agreement was signed on November 23 to develop next-generation adenoassociated virus (AAV) vectors for gene therapy directed to skeletal and cardiac muscle using Dyno's CapsidMap™ platform.

Dyno's CapsidMap platform represents a transformative approach applying *in vivo* experimental data and machine learning to create novel AAV capsids – the cell-targeting protein shells of viral vectors – designed to optimize tissue targeting and immune-evading properties, in addition to improving packaging capacity and manufacturability. Unlike traditional approaches, CapsidMap is uniquely well-suited to simultaneously optimize capsids for delivery across multiple organs, with the goal of enabling more effective whole-body treatment for many diseases.

With the establishment of the Astellas Gene Therapies Center of Excellence following the 2020 acquisition of Audentes Therapeutics Inc., Astellas is a leader in genetic medicines, working alongside its world-renowned partners to build a portfolio of potentially life-changing gene therapies. This research collaboration combines Dyno's Al-powered AAV vector engineering capabilities with Astellas Gene Therapies global leadership in AAV-based pipeline assets.

"Through our efforts in gene therapy and the Astellas Gene Therapies Center of Excellence, Astellas strives to identify, develop and deliver transformative genebased therapies for patients with genetic diseases who currently have few or no effective treatment options. Our principal focus is on developing adeno-associated virus delivered therapies for the treatment of well-defined serious diseases," said Naoki Okamura, Chief Strategy Officer and Chief Financial Officer, Chief Business Officer at Astellas. "We are dedicated to delivering novel approaches and utilizing new technologies that can deliver transformational value for patients."

"We are so happy to be partnering with Astellas, a world leader in developing gene therapies. Dyno and Astellas each bring unique strengths to this collaboration, together enabling more rapid creation of new therapies for patients with great unmet need," said Dyno's CEO and co-founder Eric D. Kelsic, Ph.D. "This partnership demonstrates the flexibility of Dyno's platform to precisely design the delivery properties of gene therapy vectors towards multi-organ and disease-specific profiles, applying the scientific insights we are rapidly learning across all our partnered and internal vector engineering programs using CapsidMap."

Under the terms of the agreement, Dyno will design novel AAV capsids with improved functional properties for gene therapy, while Astellas will be responsible for conducting preclinical, clinical and commercialization activities, including manufacturing, of gene therapy product candidates using the novel capsids. Dyno will receive an \$18 million upfront payment and be eligible to receive additional payments during the research phase of the collaboration as well as clinical and sales milestone payments and royalties for any resulting products. The aggregate potential value of future milestone and royalty payments to Dyno exceeds \$235 million per product and over \$1.6 billion in total value.

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.

About Astellas Gene Therapies

Astellas integrated its wholly owned subsidiary, Audentes Therapeutics, Inc. as of April 1, 2021 and established "Astellas Gene Therapies" within the organization as an Astellas Center of Excellence to develop 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 hope to 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 Dyno Therapeutics

 $\underline{\text{Dyno Therapeutics}} \text{ is a pioneer in applying artificial intelligence (AI) and quantitative in vivo experiments to gene therapy. The company's proprietary <math display="block">\underline{\text{CapsidMap}}^{\text{TM}} \text{ platform} \text{ rapidly discovers and systematically}$

optimizes Adeno-Associated Virus (AAV) capsid vectors that significantly outperform current approaches for in vivo gene delivery, thereby expanding the range of diseases treatable with gene therapies. Dyno was founded in 2018 by experienced biotech entrepreneurs and leading scientists in the fields of gene therapy and machine learning. The company is located in Cambridge, Massachusetts. Visit www.dynotx.com for additional information.

About CapsidMap™ for Designing Optimized AAV Gene Therapies

Dyno's <u>CapsidMap™ platform</u> overcomes the limitations of gene therapies on the market and under development today by optimizing capsids, the cell-targeting protein shells of Adeno-Associated Virus (AAV) vectors. Current gene therapies primarily use a small number of naturally occurring capsids that are limited by delivery efficiency, pre-existing immunity, payload size, and manufacturing challenges. CapsidMap works in two stages, first by measuring capsid properties in high-throughput using next-generation DNA library synthesis and DNA sequencing. With these vast quantities of in vivo data, CapsidMap then generates improved capsid sequences by applying advanced search algorithms that leverage machine learning. Dyno's comprehensive map of capsid sequence space and AI-powered tools thereby accelerate the design of AAV gene therapies towards optimizing manufacturability and applicability for treating a broader range of diseases.

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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