



Selecta Biosciences and Astellas Announce Exclusive Licensing and Development Agreement for Xork IgG Protease

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Next-generation IgG protease candidate Xork to be licensed for development with AT845, an investigational Astellas Gene Therapies' product, for the treatment of Pompe Disease

Selecta to receive a \$10M upfront payment and eligible to receive up to \$340M for certain additional development and commercial milestones plus royalties on commercial sales

WATERTOWN, Mass. and TOKYO, Jan. 9, 2023 /PRNewswire/ -- Selecta Biosciences, Inc. (NASDAQ: SELB, President and CEO: Carsten Brunn, Ph.D., "Selecta"), and Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas" or "Astellas Gene Therapies") today announced an exclusive licensing and development agreement for IdeXork (Xork). Xork is being studied as a potential next generation immunoglobulin G (IgG) protease that will be developed by Astellas for use with AT845, an investigational, adeno-associated virus (AAV)-based treatment for Late-Onset Pompe disease (LOPD) in adults.



"Currently many patients are ineligible for clinical trials with investigational AAV gene therapy products due to the presence of naturally occurring antibodies against AAV gene therapy capsids," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta. "Xork has the potential to expand access to life-changing gene therapies by addressing pre-existing immunity to AAV. Most other IgG proteases in development are derived from common human pathogens, and as a result there is a high prevalence of pre-existing antibodies against these proteases that can restrict their use. Xork is differentiated by its low cross-reactivity to pre-existing antibodies in human serum. We are thrilled to partner with Astellas as they advance their robust gene therapy portfolio through the clinic."

Naoki Okamura, Chief Strategy Officer of Astellas added, "We are looking forward to partnering with Selecta as we strive to expand our therapies to a broader range of patients living with debilitating diseases, who have limited treatment options. This agreement provides an opportunity to deliver potentially transformative gene therapy treatments to a specific population of LOPD adult patients who might otherwise be ineligible for clinical trials or treatment with Astellas' investigational product."

Under the terms of the agreement, Selecta will receive a \$10M upfront payment and is eligible to receive up to \$340M for certain additional development and commercial milestones plus royalties on any potential commercial sales where Xork is used as a pre-treatment for AT845. Selecta is responsible for the development and manufacturing of Xork and will maintain the rights for the development of additional indications beyond Pompe disease. Astellas would have the sole and exclusive right to commercialize Xork for use in Pompe disease with an Astellas gene therapy investigational or authorized product, with a current focus on AT845.

About Selecta Biosciences, Inc.

Selecta Biosciences Inc. (NASDAQ: SELB) is a clinical stage biotechnology company leveraging its ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses. With a proven ability to induce tolerance to highly immunogenic proteins, ImmTOR has the potential to amplify the efficacy of biologic therapies, including redosing of life-saving gene therapies, as well as restore the body's natural self-tolerance in autoimmune diseases. Selecta has several proprietary and partnered programs in its pipeline focused on enzyme therapies, gene therapies, and autoimmune diseases. Selecta Biosciences is headquartered in the Greater Boston area. For more information, please visit www.selectabio.com.

About AT845 for the treatment of Late-Onset Pompe Disease (LOPD)

Astellas is developing AT845, a novel gene replacement therapy using an AAV8 vector under a muscle-specific promoter to deliver a functional copy of the GAA gene, for the treatment of adult LOPD. AT845 is being investigated to determine whether it can deliver a functional GAA gene that is efficiently transduced to express GAA directly in tissues affected by the disease, including skeletal and cardiac muscle.

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 Gene Therapies is an Astellas Center of Excellence developing genetic medicines with the potential to deliver transformative value for patients. Our gene therapy drug discovery engine is built around innovative science, a validated AAV platform, and industry leading internal manufacturing capability with a particular focus on rare diseases of the eye, CNS and neuromuscular system. Astellas Gene Therapies will also be advancing additional Astellas gene therapy programs toward clinical investigation. Astellas Gene Therapies is based in San Francisco, with manufacturing and laboratory facilities in South San Francisco, Calif., Sanford, N.C. and Tsukuba, Japan.

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.

Selecta Forward-Looking Statements

Any statements in this press release about the future expectations, plans and prospects of Selecta Biosciences, Inc. (the "Company"), including without limitation, statements regarding the unique proprietary technology platform of the Company and its partners, the anticipated benefits of the Company's licensing and development agreement with Astellas related to Xork, the potential of ImmTOR to enable re-dosing of AAV gene therapy and to mitigate immunogenicity, the potential of ImmTOR and the Company's product pipeline to treat chronic refractory gout, MMA, IgAN, other autoimmune diseases, lysosomal storage disorders, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's and its partners' ability to conduct its and their clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, gout and autoimmune disease, the ability of the Company and its partners where applicable to develop gene therapy products using ImmTOR, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human study subjects will translate to studies performed with human beings, the potential of any therapies developed by the Company to fulfill unmet medical needs, the Company's plan to apply its ImmTOR technology platform to a range of biologics for rare and orphan genetic diseases, the potential of the Company's technology to enable repeat administration in gene therapy product candidates and products, the ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, the potential to safely re-dose AAV, the ability to restore transgene expression, the potential of the ImmTOR technology platform generally and the Company's ability to grow its strategic partnerships and enrollment in the Company's clinical trials and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including proof of concept trials, including the uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's ImmTOR technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, its reliance on third parties to manufacture its product candidates and to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the Company's recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any intention to update any forward-looking statements included in this press release, except as required by law.

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