Selecta Biosciences Initiates Phase 1 Clinical Program of SEL-212, Designed As the First Non-Immunogenic Biologic Treatment for Gout

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The first immunotherapeutic candidate from Selecta's proprietary Synthetic Vaccine Particle (SVP) Platform, SEL-212 aims at addressing the high unmet needs of refractory and tophaceous gout patients

Selecta's SVP immunotherapeutic platform has broad applications, including inhibition of immunogenicity for biologic therapies and antigen-specific treatment of allergies and autoimmune diseases

Watertown, Mass. – June 10, 2015 – Selecta Biosciences, Inc., a clinical stage biotechnology company developing a novel class of targeted antigen-specific immune therapies, today announced that it has initiated a Phase 1 clinical study to assess the safety, pharmacodynamic profile, and immunogenicity of pegsiticase, a component of SEL-212. The product candidate is developed for the indications of refractory and tophaceous gout, which result from elevated levels of uric acid within the body that cause debilitating pain and damage to joints and organs. SEL-212, the lead immunotherapeutic candidate from Selecta's proprietary Synthetic Vaccine Particle (SVP™) Platform, is designed to be the first non-immunogenic version of uricase, an enzyme that metabolizes uric acid. While uricase therapeutics have been demonstrated to be very effective in breaking down uric acid deposits that cause refractory or tophaceous gout, their utility is limited by undesired immune responses in patients, which compromise both efficacy and safety. This Phase 1 clinical study is a single ascending dose multi-center study of pegsiticase in subjects with elevated uric acid levels in order to define safe and effective dose levels for SEL-212.

"Gout remains an underestimated disease, as persistent elevated uric acid levels can cause joint and kidney damage and are associated with cardiac disease. Once uric acid deposits have built up, only uricase treatment is truly effective at dissolving them," said Werner Cautreels, PhD, CEO and President of Selecta. "We have positioned SEL-212 to become the first non-immunogenic uricase, designed to dramatically improve treatment of patients with refractory and tophaceous gout. The success of this clinical program will also pave the way for our SVP platform to unlock the full therapeutic potential of many other biologic therapies adversely affected by immunogenicity."

SEL-212 exemplifies Selecta's approach for deploying its SVP platform to prevent the formation of Anti-Drug Antibodies (ADAs) following repeated treatments with biologics, such as with uricase treatment in severe gout. ADAs are a common problem with other biologic therapies such as enzyme therapy, hemophilia medicines, and novel technologies such as gene therapies and antibody drug conjugates. Application of the SVP platform will yield a pipeline of products with improved therapeutic benefit related to the reduction of unwanted immune responses. Selecta is advancing a series of research and development programs, including a novel Hemophilia A product and novel gene therapy products that enable repeat dosing. By modulating antigen-specific immune responses, the SVP platform can enhance existing therapies and enable novel treatment approaches.

About Refractory and Tophaceous Gout

A painful inflammatory disease caused by elevated plasma uric acid levels, gout affects 4.7 million patients in the United States[1] and more than 2 million patients in Europe[2]. Approximately 3 percent of gout patients are not effectively treated[3], leading to painful deposits of uric acid crystals in joints, tendons and surrounding tissue and potential damage to heart and kidneys. Oral therapies are not indicated to dissolve uric acid deposits, because the mechanism of these oral therapies interferes with the synthesis of uric acid but is ineffective in the breakdown of existing uric acid deposits.

Approved uricase enzymes are highly effective in keeping plasma uric acid levels at target and dissolving tophi, but can rapidly lose efficacy due to the formation of anti-drug antibodies. Their clinical use is further restricted due to risks of allergic reactions.

About SEL-212 and Pegsiticase

SEL-212 applies Selecta's Synthetic Vaccine Particle (SVP) products for immune tolerance to pegsiticase under exclusive license from 3SBio outside Greater China and Japan. The product is designed to durably and specifically prevent undesired immune responses that can appear after multiple dosages of uricase.

Pegsiticase is a pegylated urate oxidase or uricase, an enzyme not present in humans that is highly effective in catalyzing the oxidation of uric acid. Phase 1 studies completed in the United States with a single dose of pegsiticase confirmed safety and efficacy in reducing plasma uric acid levels.

The avoidance of anti-drug antibodies and severe allergic reactions is a key unmet need for biologic gout therapies. SEL-212 is designed to address this important requirement to become the first non-immunogenic version of uricase.

About Selecta
Selecta Biosciences, Inc. is a clinical-stage biotechnology company developing novel drugs that use immune modulating nanomedicines to generate targeted antigen-specific immune responses to prevent and treat disease. Selecta's proprietary Synthetic Vaccine Particle (SVP) platform creates a novel paradigm in immunotherapeutics and vaccines, enabling completely new applications while offering the potential of improved efficacy and safety profiles.

Selecta's immunomodulatory SVPs can induce antigen-specific immune tolerance, enabling them to be applied in a variety of therapeutic areas with large unmet medical need. The company is focused on three key near-term applications: inhibition of immunogenicity of biologic therapies, treatment of allergies, and treatment of autoimmune diseases. Immunogenicity adversely affects the safety and efficacy profile for many biological therapies, and is known to have caused the termination of a number of promising biological therapies in clinical development. Selecta's SVP is a product engine that has the potential to unlock the full therapeutic value of biologic therapies.

Through proprietary products and collaborations with leading pharmaceutical companies and research organizations, Selecta is building a pipeline of product candidates to address unmet medical needs in serious and chronic diseases. Selecta Biosciences, Inc. is based in Watertown, Massachusetts, USA. For more information, please visit www.selectabio.com.

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