Selecta Biosciences Announces Dosing of First Patient in Phase 1b Clinical Trial of SEL-212, Designed to be the First Non-Immunogenic Biologic Treatment for Gout

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SEL-212 aims to address the high unmet needs of refractory and tophaceous gout patients

Phase 1b trial study follows successful completion of Phase 1a clinical trial in SEL-212 clinical development program

Watertown, Mass. – December 23, 2015 – Selecta Biosciences, Inc., a clinical-stage biopharmaceutical company developing a novel class of targeted antigen-specific immune therapies, today announced the dosing of the first patient in the Company's Phase 1b clinical trial to assess the safety, pharmacodynamic profile and efficacy of SEL-212, Selecta's proprietary biologic treatment for refractory and tophaceous gout. Patients suffering from these severe gout indications accumulate uric acid deposits in joints and tissues, which can cause debilitating pain and damage to joints and organs. SEL-212, the lead immunotherapeutic product 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 demonstrated the ability to significantly reduce uric acid levels and dissolve uric acid deposits that cause refractory or tophaceous gout, their utility is limited by undesired immune responses such as anti-drug antibodies (ADAs), which compromise both efficacy and safety. Results from this Phase 1b clinical trial, which follows the successful completion of the Phase 1a clinical trial in the SEL-212 clinical program, are expected in the first half of 2016.

"In gout, tissue deposits of the sodium salt of uric acid cause excruciatingly painful and incapacitating attacks of gouty arthritis and ultimately can lead to impaired health related quality of life, hospital admissions, high medical care costs and joint damage. Furthermore, our options to treat gout and high body uric acid burden, in particular, are currently limited, and especially so in those with the most severe forms of the disease" said Dr. Robert A Terkeltaub, MD, Professor of Medicine at the University of California San Diego, and scientific advisor to Selecta. "We know that uricase has unique, and remarkably rapid efficacy in removing tissue deposits of crystalline uric acid. However, uricase is a foreign protein to humans, and undesired immune responses frequently occur and this has greatly limited our ability to effectively employ uricase treatment use in clinical practice for gout. SEL-212 could be a significant addition to our treatment options for gout."

SEL-212 combines Selecta's proprietary SVP-Rapamcyin, a product developed with Selecta's proprietary SVP platform that encapsulates the immunomodulator rapamycin for the induction of immune tolerance, with pegsiticase, a pegylated uricase enzyme, with the goal of developing the first non-immunogenic biologic treatment for refractory and tophaceous gout. This Phase 1b clinical trial will be conducted in approximately 53 patients with elevated uric acid levels, who will receive single ascending doses of SVP-Rapamycin, fixed doses of pegsiticase alone or SEL-212. This Phase 1b clinical trial follows a single ascending dose Phase 1a clinical trial of pegsiticase as a monotherapy in 22 patients with elevated uric acid levels. Selecta completed the patient treatment portion of the Phase 1a clinical trial in November 2015. In the Phase 1a clinical trial, pegsiticase was observed to be safe and was shown to reduce uric acid levels. However, as expected, all patients in the Phase 1a clinical trial developed undesired immune responses in the form of ADAs to pegsiticase as a monotherapy. The Phase 1b clinical trial of SEL-212 is designed to demonstrate that the addition of Selecta's proprietary SVP-Rapamcyin to pegsiticase mitigates the formation of ADAs compared to pegsiticase alone and therefore would have the potential to substantially improve the efficacy and safety of repeated dose administrations of pegsiticase.

"SVP-Rapamycin is a product platform designed to mitigate the harmful effect of anti-drug antibodies," said Werner Cautreels, PhD, CEO and President of Selecta. "This Phase 1b clinical trial has the potential to further advance Selecta's plan to expand the use of uricase in the treatment of gout. At the same time, the data from this trial may pave the way for applying SVP-Rapamycin to other biologic drugs that currently induce undesired immune responses, including novel biologic technologies, such as gene therapies or also enzyme replacement therapies for the treatment of lysosomal storage diseases."

Results from this Phase 1b clinical trial of SEL-212 in patients with gout are expected in the first half of 2016.Additionally, after the successful completion of this Phase 1b clinical trial, Selecta plans to initiate a Phase 2 clinical trial of multiple doses of SEL-212.

About Refractory and Tophaceous Gout

Approximately 8.3 million patients in the United States suffer from gout, which is caused by elevated levels of serum uric acid. Excessive uric acid levels result in harmful uric acid deposits in joints and tissues, causing joint damage and painful inflammation. Refractory and tophaceous gout are each a painful and debilitating disease with unmet medical need. Approximately 50,000 patients in the United States have been diagnosed with chronic refractory gout, an orphan indication defined as uric acid levels that cannot be controlled by available oral therapies. In addition, it is estimated that around 200,000 patients in the United States suffer from chronic tophaceous gout, in which patients develop palpable nodular masses of uric acid crystals referred to as tophi, typically in the joints or their surrounding soft tissue bursae at the fingers, toes or elbows. Tophi are a source of inflammation and pain and can cause joint and organ damage. Current options for chronic tophaceous gout are limited, since highly effective serum uric acid lowering is indicated for this condition.

About SEL-212 and Pegsiticase

SEL-212 is our proprietary product candidate for the treatment of refractory and tophaceous gout. SEL-212 consists of SVP-Rapamycin co-administered with pegsiticase, a pegylated uricase. We believe that SEL-212 has the potential to offer an effective treatment for patients with refractory or tophaceous gout, while also demonstrating the clinical effectiveness of our SVP technology.

In an initial Phase 1a clinical trial, pegsiticase was observed to be safe and effective in lowering uric acid levels. As expected, all patients in this study developed antibodies to pegsiticase. The ongoing Phase 1b clinical trial of SEL-212 is designed to demonstrate that SVP-Rapamycin co-administered with pegsiticase reduces uric acid levels and mitigates the formation of antibodies that can neutralize the efficacy of pegsiticase and cause allergic reactions, compared to pegsiticase alone.

About Selecta

Selecta Biosciences, Inc. is a clinical-stage biopharmaceuticalcompany developing novel drugs that use immunomodulators encapsulated in nanoparticles to induce targeted antigen-specific immune responses to prevent and treat disease. Selecta's proprietary Synthetic Vaccine Particle (SVP) technology is a highly flexible nanoparticle platform, capable of incorporating a wide range of antigens and immunomodulators, allowing the SVP products to either induce antigen-specific tolerance or activate the immune system.

Selecta's focus is on developing and commercializing differentiated therapies that are designed to modulate the immune system to effectively and safely treat rare diseases by mitigating the formation of anti-drug antibodies (ADAs) in response to life-sustaining biologic drugs. Tolerance inducing SVP products also have potential applications in the treatment of allergies and autoimmune diseases.

Selecta is also developing SVP products that activate the immune system to prevent and treat cancer, infections and other diseases.

Selecta is based in Watertown, Massachusetts, USA.

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