

PRESS RELEASE

Stockholm, Sweden, 1 December 2021

Sobi and Selecta Biosciences announce completion of enrolment in DISSOLVE Phase 3 study evaluating SEL-212 for chronic refractory gout

Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO: SOBI) and Selecta Biosciences, Inc. (NASDAQ: SELB), today announced the completion of enrolment for DISSOLVE I, the first of two clinical studies of the phase 3 DISSOLVE development programme of SEL-212 for chronic refractory gout. SEL-212 is a combination of Selecta's ImmTOR™ immune tolerance platform and a therapeutic uricase enzyme (pegadricase).

Guido Oelkers, President and Chief Executive Officer of Sobi, said "We are pleased that the DISSOLVE programme is progressing and we believe that the less burdensome treatment regimen of the potential new medicine SEL-212 will improve the lives of those suffering from chronic refractory gout. We are proud to collaborate with Selecta as we continue to deliver on our shared vision to advance innovative therapies and improve the lives of patients with rare diseases."

"The completion of enrolment for the DISSOLVE I study of our phase 3 DISSOLVE programme is an important step forward in advancing SEL-212 as a potential new, once-monthly treatment option for people suffering from chronic refractory gout," added Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta. "We are continuing enrolment in the DISSOLVE II study and we remain on track to share topline results from the DISSOLVE clinical program in H2 2022. Our pipeline builds on the learnings from this programme and shows the potential of ImmTOR to overcome unwanted immunogenicity, mitigate detrimental immune responses against enzyme or gene therapies, and provide real change for people with autoimmune diseases."

Sobi has in-licensed SEL-212 from Selecta and is responsible for development, regulatory and commercial activities in all markets outside of China. The phase 3 programme for SEL-212 is being run by Selecta and funded by Sobi.

About the DISSOLVE clinical programme

The Phase 3 DISSOLVE clinical programme consists of two double-blind, placebo-controlled studies of SEL-212, titled "A Randomized Double-Blind, Placebo-Controlled Study of SEL-212 in Patients with Gout Refractory to Conventional Therapy," in which SEL-212 will be evaluated at two doses of ImmTOR (0.1 mg/kg and 0.15 mg/kg), and one dose of pegadricase (0.2 mg/kg) in both studies. Each trial will enrol up to 120 patients (with up to 40 patients at each dose level and 40 patients on placebo). In DISSOLVE I, safety and efficacy will be evaluated at six months and will have a six-month extension to evaluate safety. DISSOLVE II will assess safety and efficacy at only the six-month time point, with no extension. The primary endpoint in both studies is serum uric acid (SUA) control during month six, a well-validated measure of disease severity in chronic refractory gout. Secondary endpoints include tender and swollen joint counts, tophus burden, patient reported outcomes of activity limitation and quality of life and gout flare incidence. For more details about the study, visit [clinicaltrials.gov \(NCT04513366\)](https://clinicaltrials.gov/NCT04513366).

About SEL-212

SEL-212 is a novel combination product candidate designed to sustain control of serum uric acid (SUA) levels in patients with chronic refractory gout, potentially reducing harmful tissue urate deposits which when left

untreated can lead to debilitating gout flares and joint deformity.¹ SEL-212 consists of pegadricase, Selecta's proprietary pegylated uricase, co-administered with ImmTOR, designed to mitigate the formation of anti-drug antibodies (ADAs). ADAs develop due to unwanted immune responses to biologic medicines, reducing their efficacy and tolerability, which remains an issue across multiple therapeutic modalities and disease states including chronic refractory gout.

About Chronic Refractory Gout

Gout is the most common form of inflammatory arthritis with more than 8.3 million patients in the United States having been diagnosed with gout, which is caused by high levels of uric acid in the body that accumulate around the joints and other tissues and can result in flares that cause intense pain. Approximately 160,000 patients in the United States suffer from chronic gout refractory to conventional treatments, a painful and debilitating condition in which patients SUA levels below 6 mg/dL and therefore have several flares per year and can develop nodular masses of uric acid crystals known as tophi.¹ Elevated SUA levels have been associated with diseases of the heart, vascular system, metabolism, kidney and joints.²

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 programmes 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 Sobi

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Sobi is providing sustainable access to innovative therapies in the areas of haematology, immunology and specialty indications. Sobi employs approximately 1,500 people across Europe, North America, the Middle East, Russia and Asia. In 2020, Sobi's revenues amounted to SEK 15.3 billion. Sobi's share (STO: SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at sobi.com.

¹ <https://www.sec.gov/ix?doc=/Archives/edgar/data/1453687/000145368720000096/selectabiosciences10-q.htm>

² Lee, S.J., Oh, B.K. & Sung, K. Uric acid and cardiometabolic diseases. Clin Hypertens 26, 13 (2020). <https://doi.org/10.1186/s40885-020-00146-y>

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