PRESS RELEASE

Stockholm, Sweden, 23 September 2020

First patient randomised in the phase 3 DISSOLVE clinical programme of SEL-212 for Chronic Refractory Gout

STOCKHOLM, Sweden and WATERTOWN, Mass.-- Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) and Selecta Biosciences, Inc. (Nasdaq: SELB) today announced the commencement of the phase 3 clinical programme of SEL-212 for chronic refractory gout, with the randomisation of the first patient in the study.

"We are pleased to have commenced the phase 3 DISSOLVE programme evaluating SEL-212 in two phase 3 double-blind, placebo-controlled studies," said Carsten Brunn, Ph.D., President and CEO of Selecta. "SEL-212 serves as an important validation of Selecta's ImmTOR™ platform, and we are proud to have advanced it into late-stage clinical studies. In partnership with Sobi, we look forward to enrolling patients in the studies and continuing to evaluate SEL-212 as a new, once monthly treatment option for patients with chronic refractory gout."

Guido Oelkers, President and CEO of Sobi, added, "SEL-212 has the potential to significantly improve outcomes for patients with chronic refractory gout, and we are proud to have taken the next step towards making this therapy accessible to patients unable to maintain treatment with the currently available options."

Sobi has in-licensed SEL-212 from Selecta and will be 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. Topline data from the phase 3 clinical programme is expected in the second half of 2022. Biologics license application (BLA) filing to the US FDA for SEL-212 is expected in Q1, 2023.

On commencement of the phase 3 programme Sobi will pay a milestone of 5 MUSD to Selecta.

About the DISSOLVE Clinical Programme

The phase 3 DISSOLVE clinical programme consists of two double-blind, placebo-controlled trials of SEL-212 (NCT04513366), 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 study will aim to enrol 105 patients (35 at each dose level and 35 on placebo). In DISSOLVE I, safety and efficacy will be evaluated at six months and will have a six-month extension. 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 levels (SUA) at six months, 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.

About SEL-212

SEL-212 is a novel combination product candidate designed to sustain control of serum uric acid (SUA) levels[i] 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. 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, may reduce 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[ii] 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 refractory gout, a painful and debilitating condition in which patients are not able to get their 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. Elevated SUA levels have been associated with diseases of the heart, vascular system, metabolism, kidney and joints.[iii]

About Selecta Biosciences, Inc.
Selecta Biosciences, Inc. is a clinical-stage biotechnology company focused on unlocking the full potential of biologic therapies based on its immune tolerance technology (ImmTOR) platform. Selecta plans to combine ImmTOR with a range of biologic therapies for rare and serious diseases that require new treatment options due to high immunogenicity. The company's current proprietary pipeline includes ImmTOR-powered therapeutic enzyme and gene therapy product candidates. SEL-212, the company's lead product candidate, is being developed to treat chronic refractory gout patients and resolve their debilitating symptoms, including flares and gouty arthritis. Selecta's proprietary gene therapy product candidates are in preclinical development for certain rare inborn errors of metabolism and incorporate ImmTOR with the goal of addressing barriers to repeat administration. Selecta is based in Watertown, Massachusetts. 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. Today, Sobi employs approximately 1,400 people across Europe, North America, the Middle East, Russia and North Africa. In 2019, Sobi's revenues amounted to SEK 14.2 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at www.sobi.com.

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[i] https://www.sec.gov/ix?doc=/Archives/edgar/data/1453687/000145368720000096/selectabiosciences10-q.htm
[ii] https://www.sec.gov/ix?doc=/Archives/edgar/data/1453687/000145368720000096/selectabiosciences10-q.htm.

[iii] Takashi Kei Kishimoto*: Development of ImmTOR Tolerogenic Nanoparticles for the Mitigation of Anti-drug Antibodies. Published: 20 May 2020 doi:10.3389/fimmu.2020.00969