

PRESS RELEASE

Stockholm, Sweden, 30 September 2020

Sobi and Selecta Biosciences announce topline data of SEL-212 from the phase 2 COMPARE study supporting the potential for important clinical improvement in patients with Chronic Refractory Gout

- *All data consistent with stronger performance of SEL-212 versus pegloticase*
- *Numerically higher response rate for SEL-212 versus pegloticase during primary endpoint of months 3 and 6 combined; statistically significant higher response rate for SEL-212 versus pegloticase during month 3*
- *Statistically significant greater overall reduction in mean serum uric acid (SUA) levels in SEL-212 versus pegloticase*
- *Patients with tophi showed a substantially higher overall response rate for SEL-212 versus pegloticase and a statistically significant overall reduction in mean SUA levels for SEL-212 versus pegloticase*
- *Data demonstrate both SEL-212 and pegloticase were well-tolerated*
- *Data support commenced phase 3 DISSOLVE programme*

Stockholm, Sweden and Watertown, Massachusetts, US.-- Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) and Selecta Biosciences, Inc. (NASDAQ: SELB), today announced topline data for the phase 2 COMPARE study comparing the efficacy of SEL-212, a combination of Selecta's tolerogenic ImmTOR™ immune tolerance platform and a therapeutic uricase enzyme (pegadricase), to pegloticase (KRYSTEXXA®), the currently approved uricase in the US, for the treatment of chronic refractory gout.

Per FDA guidance on Statistical Considerations for Clinical Trials during the COVID-19 Public Health Emergency, the statistical analysis plan was modified and submitted to FDA prior to database lock to address the potential impact of the COVID-19 pandemic on the statistical analysis of the study endpoints. This was necessary due to increased protocol deviations in the intention-to-treat (ITT) population observed during the ongoing COVID-19 pandemic. Data are therefore presented per protocol (PP*) and ITT.

Topline results from the phase 2 COMPARE study are as follows:

- **SEL-212 showed a numerically higher response rate on the primary endpoint during months 3 and 6 combined, but did not meet the primary endpoint of statistical superiority:** SUA < 6 mg/dL for at least 80% of the time during months 3 and 6 combined: 59% SEL-212 versus 46% pegloticase, PP, p=0.056, 53% SEL-212 versus 46% pegloticase, ITT, p=0.181.

- **Statistically significant higher response rate of SEL-212 during month 3:** SUA < 6 mg/dL for at least 80% of the time during month 3: PP: 70% SEL-212 versus 51% pegloticase, p=0.019, ITT: 70% SEL-212 versus 54% pegloticase, p=0.017.
- **Numerically higher response rate of SEL-212 during month 6:** SUA < 6 mg/dL for at least 80% of the time during month 6: PP: 61% SEL-212 versus 47% pegloticase, p=0.053, ITT: 54% SEL-212 versus 47% pegloticase, p=0.179.
- **Statistically significant greater overall reduction in mean SUA levels in SEL-212 versus pegloticase:** Serum uric acid levels were reduced by an average of 6.68 mg/dL (computed by subtracting baseline SUA from mean SUA during the treatment period) for patients treated with SEL-212 versus 4.51 mg/dL for patients treated with pegloticase, p=0.003, during months 3 and 6 combined, PP; ITT: 6.79 mg/dL SEL-212 versus 4.85 mg/dL pegloticase, p=0.003.
- **In patients with tophi at baseline, substantially higher responder rates for SEL-212 compared to pegloticase on the primary endpoint, and statistically significant reduction in mean SUA:** Approximately 41% of patients in the phase 2 COMPARE study had visible tophi at baseline. A greater differential on the primary endpoint between SEL-212 versus pegloticase on patients with tophi was observed: PP: 58% SEL-212 versus 39% pegloticase; ITT: 57% SEL-212 versus 41% pegloticase. In these patients, the mean SUA levels were reduced by an average of 7.42 mg/dL for patients treated with SEL-212 versus 4.64 mg/dL for patients treated with pegloticase, p=0.016, during months 3 and 6 combined, PP; ITT: 7.32 mg/dL for SEL-212 versus 4.89 mg/dL for pegloticase, p=0.019.
- **SEL-212 and pegloticase showed favorable safety results and were well-tolerated:** There were no deaths during the study. There were no notable differences in serious Treatment Emergent Adverse Events (TEAEs), treatment-related serious TEAEs, or infusion reactions between the two groups. A full analysis of safety signals, including gout flare incidence and severity, awaits evaluation of the full data set and will be reported together with the full efficacy analysis at a later medical meeting.

“There is a clear need for a next-generation treatment for chronic refractory gout, and the phase 2 COMPARE study demonstrated that SEL-212 led to a statistically significant reduction of serum uric acid levels versus standard of care in patients suffering from this painful, debilitating disease,” said Robert T. Keenan, MD, MBA, MPH, board certified rheumatologist at Duke University School of Medicine and Principal Investigator of the COMPARE study. “I believe that SEL-212 could meaningfully impact the lives of patients and provide a much-needed alternative in the treatment paradigm for patients with chronic refractory gout.”

“We believe SEL-212, if approved, could improve the lives of patients with chronic refractory gout, as data suggest that SEL-212 addresses several key unmet needs, including the potential to provide a persistent and significant reduction in SUA levels with a convenient monthly treatment,” said Carsten Brunn, Ph.D., President and CEO of Selecta. “The topline data from our COMPARE study demonstrate the promise of our ImmTOR platform to allow sustained therapeutic activity when combined with a highly immunogenic enzymatic therapy, such as our proprietary pegadricase. We look forward to evaluating SEL-212 in partnership with Sobi



in our ongoing double blinded, placebo-controlled phase 3 DISSOLVE programme and continuing to advance our ImmTOR platform in gene therapy.”

Guido Oelkers, Ph.D., President and CEO of Sobi, added, “SEL-212 is a highly differentiated product candidate for the treatment of chronic refractory gout, and these data reinforce our excitement about its potential. We are proud to collaborate with Selecta for the ongoing phase 3 programme which has already enrolled the first patient.”

SEL-212 has been licensed to Sobi, with Sobi undertaking development, regulatory and commercial activities in all markets outside of China. Sobi and Selecta recently announced the initiation of two double-blinded, placebo-controlled phase 3 clinical studies (DISSOLVE I and DISSOLVE II) of SEL-212 for the treatment of chronic refractory gout. Topline data from the DISSOLVE programme is expected in the second half of 2022, and a Biologics License Application (BLA) filing is expected in the first quarter of 2023.

About the phase 2 COMPARE study

The phase 2 COMPARE study evaluated 170 patients with chronic refractory gout, with 83 receiving an infusion of SEL-212 once monthly for six months and 87 receiving an infusion of pegloticase twice monthly for six months. The primary endpoint measure was a comparison of the percentage of patients on SEL-212 versus pegloticase who achieved and maintained a reduction of serum uric acid (SUA) < 6 mg/dL for at least 80% of the time during months three and six combined. Key secondary endpoint measures included a comparison of the percentage of patients on SEL-212 versus pegloticase who achieved and maintained a reduction of serum uric acid (SUA) < 6 mg/dL for at least 80% of the time during month 3 and during month 6, separately, and reduction of mean SUA assessed at the three- and six-month time points.

*The PP population is defined as patients who were administered any amount of study medication and have completed at least 65% of the study dosing visits unless early termination from the study occurred after study drug withdrawal due to meeting stopping rules or due to an adverse event, or due to investigator discretion and who have no major protocol deviations affecting the primary efficacy assessments.

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. 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, rendering these therapies less potent, 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 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.

About Selecta Biosciences, Inc.

Selecta Biosciences Inc. (NASDAQ: SELB) is leveraging its clinically validated 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. The company’s first program aimed at addressing immunogenicity to AAV gene



therapies is expected to enter clinical trials in early 2021 in partnership with AskBio for the treatment of methylmalonic acidemia (MMA), a rare metabolic disorder. A wholly-owned program focused on addressing IgA nephropathy driven by ImmTOR and a therapeutic enzyme is also in development among additional product candidates. Selecta recently licensed its Phase 3 clinical program in chronic refractory gout to Sobi. 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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