**Phase 3 DISSOLVE Program of SEL-212 in Chronic Refractory Gout Meets Primary Endpoint**

--Response rate of 56% in patients treated monthly with high dose SEL-212 in DISSOLVE I and 47% in DISSOLVE II

--In patients 50 years and older, response rate with high dose SEL-212 was 65% in DISSOLVE I and 48% in DISSOLVE II

--75% of subjects in the DISSOLVE I extension phase on active treatment were responders through 12 months of therapy with no infusion reactions or new safety signals

--Favorable safety profile with 3.4% of patients with infusion reactions at high dose

WATERTOWN, Mass./STOCHOLM SWEDEN March 21, 2023 -- Selecta Biosciences, Inc. (NASDAQ: SELB) and Sobi®, today announced positive topline results from the Phase 3 DISSOLVE I & II placebo controlled randomized clinical trials to determine safety and efficacy of two different dose levels of SEL-212 in adult patients with chronic refractory gout. The DISSOLVE I (the "US Study") met its primary endpoint, with 56% of patients receiving monthly doses of SEL-212 at 0.15 mg/kg achieving a response (defined as achievement and maintenance of reduction in serum urate (SU) <6mg/dL for at least 80% of the time during month six). The DISSOLVE II (the "Global Study") also met its primary endpoint, with 47% receiving monthly doses of SEL-212 at 0.15 mg/kg achieving a response. SEL-212 is a combination of Selecta's ImmTOR immune tolerance platform and a therapeutic uricase enzyme (pegadricase).

Herbert S. B. Baraf, MD, FACP, MACR, Clinical Professor of Medicine, George Washington University School of Medicine and Health Sciences; Principal Investigator of the DISSOLVE Program said, "Based on these data, I believe SEL-212 has the potential to provide an important new uricase-based treatment option for patients with chronic refractory gout. These patients suffer from chronic pain and endure debilitating functional impairment. The demonstrated profound lowering of the serum uric acid in the DISSOLVE program should meaningfully impact the quality of the lives of these severely afflicted patients. SEL-212's favorable safety profile, coupled with the convenient once monthly treatment regimen, will be welcomed by patients with this challenging form of gout and the physicians who treat them."

Topline results from the Phase 3 DISSOLVE program are as follows:

- **DISSOLVE I had a statistically significant higher response rate of SEL-212 during month six**: 56% and 48% of patients randomized to receive SEL-212 at the high dose of 0.15 mg/kg ($p<0.0001$) and the low dose of 0.1 mg/kg ($p<0.0001$) of ImmTOR, respectively, versus 4% of patients randomized to receive the placebo reached the primary endpoint

- **DISSOLVE II also had a statistically significant higher response rate of SEL-212 during month six**: 47% and 41% of patients randomized to receive SEL-212 at high

dose (p=0.0002) and low dose (p=0.0015) of ImmTOR, respectively, versus 12% of patients randomized to receive the placebo reached the primary endpoint

- **Statistically significant higher response rate in patients 50 years and older at the high dose in DISSOLVE I and II:** 65% and 47% of DISSOLVE I patients randomized to receive SEL-212 at the high dose (p<0.0001) and the low dose (p<0.0001) of ImmTOR, respectively, versus 5% of patients randomized to receive the placebo reached the primary endpoint; 48% and 45% of DISSOLVE II patients randomized to receive SEL-212 the high dose (p=0.0017) and low dose (p=0.0044) of ImmTOR, respectively, versus 14% of patients randomized to receive the placebo reached the primary endpoint

- **Significant and clinically meaningful overall reduction of 69% in mean SU levels in patients randomized to receive SEL-212 at 0.15mg/kg in DISSOLVE I, as compared with placebo**: Serum urate levels were reduced by an average of 5.3 mg/dL (computed by subtracting baseline SU from mean SU during the treatment period 6) for patients treated with both doses of SEL-212 (p<0.001) compared to 0.3 mg/dL increase in patients receiving placebo

- **SEL-212 was observed to have a favorable safety profile and was well-tolerated across both doses of ImmTOR:** The adverse events (AEs) identified in the trials were expected, including mild to moderate stomatitis which was seen in 3.4% of the low dose group and 9.2% of the high dose group versus 0% in placebo and a greater number of infusion reactions at 24 hours and 1 hour after drug administration in both treatment groups versus placebo. Treatment-related serious AEs were observed in six patients, including two cases of anaphylaxis and one gout flare in both the high and low dose treatment groups. Only 4.5% of patients receiving the low dose of SEL-212 and 3.4% at the high dose of SEL-212 had infusion reactions, evaluated 1 h post dose. All infusion reactions occurred within the first three infusions, and each occurred during infusions and completely resolved with infusion halt and symptomatic treatment. There was one death in the six-month extension phase of the trial, which was caused by a motor vehicle accident unrelated to the study drug. There was no difference in gout flares when both treatment groups were compared to placebo.

The six-month extension period in the DISSOLVE I trial, showed that the majority (75%) of patients who completed 6 months of SEL-212 treatment as a responder, continued to be successfully treated through 12 months with no infusion reactions or safety signals.

Peter Traber, M.D., Chief Medical Officer of Selecta, said, “We are very pleased by the robust response rate in the high dose group of SEL-212, especially across older patients (≥50 years) and the observed durability of response with no infusion reactions or new safety signals through the extension period. We believe the results of SEL-212 observed in these two Phase 3 trials suggest the potential to provide a new treatment solution with convenient once monthly dosing.”

Carsten Brunn, Ph.D., President and Chief Executive Officer of Selecta, commented, "The positive readout of the DISSOLVE program is a pivotal milestone for SEL-212, a novel once-monthly treatment option, and for the many patients suffering from chronic refractory gout. We believe the strong efficacy and favorable safety data observed across both doses of ImmTOR in this program positions ImmTOR as the only immune tolerance platform with positive Phase 3 data. We have dosed over 400 patients to date, and plan to continue to leverage our growing safety database to drive forward our clinical pipeline powered by our ImmTOR technology."

Guido Oelkers, Ph.D., President and Chief Executive Officer of Sobi, added, "We are thrilled with the positive results of the DISSOLVE program and the potential to bring this new treatment option to improve the lives of patients with chronic refractory gout. We are poised to move SEL-212 forward towards commercialization and intend to file marketing authorization applications in the U.S. in the first half of 2024."

Anders Ullman, M.D., Ph.D., Head of Research & Development and Medical Affairs, Chief Medical Officer of Sobi, commented, "Altogether, the DISSOLVE program data instils confidence in SEL-212, and we look forward to further exploring its therapeutic potential as we drive forward development on a potential commercial path forward. We remain committed to bringing our therapies to the global patient community as quickly as possible."

Detailed results from the DISSOLVE I and DISSOLVE II trials are expected to be presented at an upcoming medical meeting. Regulatory submission in the U.S. is anticipated in the first half of 2024.

Sobi licensed SEL-212 from Selecta in June 2020 and is responsible for development, regulatory and commercial activities in all markets outside of China. Selecta is responsible for ImmTOR manufacturing. The Phase 3 program for SEL-212 was run by Selecta and funded by Sobi. Under the terms of the agreement with Sobi, Selecta is eligible to receive additional development and regulatory milestone payments totaling $65 million and up to an additional $550 million in commercial milestones. Selecta is also eligible to receive tiered double-digit royalties on sales.

**DISSOLVE clinical program**

The Phase 3 DISSOLVE clinical program consisted 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 was 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. In DISSOLVE I, safety and efficacy were evaluated at six months and with a six-month blinded extension to evaluate safety. DISSOLVE II assessed safety and efficacy at only the six-month time point, with no extension. The primary endpoint in both studies was serum urate (SU) 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).

**SEL-212**

SEL-212 is a novel investigational combination medicine designed to reduce serum urate (SU) levels in people 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, reducing their efficacy and tolerability, which remains an issue across multiple therapeutic modalities and disease states including chronic refractory gout.

**Chronic refractory gout**

Gout is the most common form of inflammatory arthritis with more than 8.3 million people 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 people in the United States suffer from chronic gout refractory to conventional medicines, a painful and debilitating condition in people with SU levels above 6 mg/dL and therefore have several flares per year and can develop nodular masses of uric acid crystals known as tophi. Elevated SU 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 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 programs 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.

**Sobi®**

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare and debilitating diseases. Providing reliable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East, Asia and Australia. In 2022, revenue amounted to SEK 18.8 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com, LinkedIn and YouTube.

**Selecta Forward-Looking Statements**

Any statements in this press release about the future expectations, plans and prospects of Selecta Biosciences, Inc. (the "Company"), including without limitation, statements regarding the Company's cash runway, the unique proprietary technology platform of the Company, and the unique proprietary platform of its partners, the potential of ImmTOR to enable re-dosing of AAV gene therapy and to mitigate immunogenicity, the potential of ImmTOR and the Company's product pipeline to treat chronic refractory gout, MMA, IgAN, other autoimmune diseases, lysosomal storage disorders, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's and its partners' ability to conduct its and their clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, gout and autoimmune disease, the ability of the Company and its partners where applicable to develop gene therapy products using ImmTOR, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human study subjects will translate to studies performed with human beings, the potential of any therapies developed by the Company to fulfill unmet medical needs, the Company's plan to apply its ImmTOR technology platform to a range of biologics for rare and orphan genetic diseases, the potential of the Company's technology to enable repeat administration in gene therapy product candidates and products, the ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, the potential to safely re-dose AAV, the ability to restore transgene expression, the potential of the ImmTOR technology platform generally and the Company's ability to grow its strategic partnerships and enrollment in the Company's clinical trials and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including proof of concept trials, including the uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's ImmTOR technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, its reliance on third parties to manufacture its product candidates and to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital

expenditure requirements, the Company's recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any intention to update any forward-looking statements included in this press release, except as required by law.

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For details on how to contact the Sobi Investor Relations Team, please click here. For Sobi Media contacts, click here.

This information is information that Sobi is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, on 21 March 2023 at 08:30 CET.

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