

# Selecta Biosciences Presents New Interim Data from Phase 2 Trial of SEL-212, in Development for Chronic Severe Gout, at ACR 2018

- Interim analysis indicates serum uric acid (SUA) control has been maintained into months four and five with once monthly combination treatment, SUA control projected to be 66% at end of study period
- Patient imaging has shown reduction in tissue urate deposits as measured by Dual Energy Computed Tomography (DECT) during SEL-212 treatment periods (months 1-5) and maintenance of SUA near 0 mg/dL
- Low flare rates observed to date in new patient cohorts over treatment period
- No new safety signals have been observed in the five combination treatment cohorts
- Phase 3 program planned to begin in 2018 with proposed dose regimens
- Company to host conference call and live webcast today at 8:00 a.m. ET

Watertown, Mass., October 23, 2018 – Selecta Biosciences, Inc. (Nasdaq: SELB), a clinical-stage biopharmaceutical company focused on unlocking the full potential of biologic therapies by mitigating unwanted immune responses, today presented new interim Phase 2 data from patients receiving SEL-212, a product candidate in development for the treatment of chronic severe gout designed to lower SUA, at the 2018 American College of Rheumatology (ACR)/Association for Rheumatology Health Professionals (ARHP) Annual Meeting in Chicago, IL.

SEL-212 is a combination product candidate designed to sustain control of SUA levels in patients with chronic severe 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 (formerly known as pegsiticase), a pegylated uricase, co-administered with SVP-Rapamycin, 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 therapeutic modalities and disease states including chronic severe gout.

The interim data reported today at ACR consist of new cohorts of patients that received five monthly doses of SEL-212, at doses of 0.1 or 0.15 mg/kg of SVP-Rapamycin in combination with 0.2mg/kg of pegadricase. In the new cohorts, projections based on the rate of SUA control for patients who have completed the treatment period suggest that approximately 66% of the evaluable patients may maintain SUA level control below 6 mg/dL throughout five months of therapy with concurrent mitigation of ADAs against the pegadricase enzyme. Final data are still pending for five of these patients. Our projection for these five patients is based on the observation that all other patients in these cohorts that had serum uric acid levels <6 mg/dL at week 12 successfully maintained control of SUA through the entire five-month period. However, caution should be exercised in drawing any conclusions from projections of clinical data. Furthermore, the observed sustained maintenance of SUA near 0 mg/dL has led to rapid reduction in tissue urate deposits as measured by DECT imaging. DECT scans were performed as an exploratory measure to evaluate reduction of tissue urate burden in a subset of patients of the Phase 2 trial.

"Today's reported interim data have met our goal of showing sustained SUA control over the five-month combination period. In addition, SEL-212 provides the added convenience of monthly dosing with a low incidence of flares observed in the Phase 2 clinical trial to date. And importantly, during months four and five of treatment, there have been no new emerging safety findings in the trial," said Werner Cautreels, Ph.D., President and CEO of Selecta. "The reduction in tissue urate deposits in joints and tissue as shown by our DECT data presented today at ACR represents a potentially important benefit for patients whose disease is not responding to other treatments. With these data now in hand, we believe we are well positioned to execute on our Phase 3 program, which is expected to start later this year."

Approximately 29% of the patient population treated with SEL-212 in the ongoing Phase 2 trial has experienced gout flares during the first month after treatment with continued reduction of gout flare rates out to month five. 96% of flares have been mild or moderate, and no flares have been reported as a serious adverse event (SAE) nor resulted in discontinuations of the study drug.

SEL-212 has been generally well tolerated at clinically active doses following repeated administrations in the trial. There have been 21 SAEs reported, 11 of which were reported to be not related or unlikely to be related to study drug, nine of which were infusion reactions that were previously reported by the company in June 2018, one of which was an infusion reaction that occurred in the most recent cohorts and one of which was reported to be related to study drug. No infusion reactions have been reported after treatment period two. As far as the Company is aware, all SAEs have been successfully treated without further issues.

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 severe 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.

#### **Conference Call Reminder**

The company will host a conference call via live webcast today at 8:00 a.m. ET. The live webcast of the presentation can be accessed via the Investors & Media section of the company's website, http://selectabio.com. Individuals may also participate in the live call via telephone by dialing 1-844-845-4170 (domestic) or 1-412-717-9621 (international) and may access a teleconference replay for one week by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using confirmation code 10124095.

# About Selecta Biosciences, Inc.

Selecta Biosciences, Inc. is a clinical-stage biopharmaceutical company that is focused on unlocking the full potential of biologic therapies by mitigating unwanted immune responses. Selecta plans to combine its tolerogenic Synthetic Vaccine Particles (SVP™) to a range of biologics for rare and serious diseases that require new treatment options. The company's current proprietary pipeline includes SVP-enabled enzyme, oncology and gene therapeutic candidates. SEL-212, the company's lead candidate in Phase 2, is being developed to treat severe gout patients and resolve their debilitating symptoms, including flares and gouty arthritis. A Phase 1 trial was initiated for a combination therapeutic candidate consisting of

SVP-Rapamycin and LMB-100 (Selecta's SEL-403 product candidate) for the treatment of patients with malignant pleural or peritoneal mesothelioma. Selecta's proprietary gene therapy product candidates are being developed for rare inborn errors of metabolism and have the potential to enable repeat administration. We believe the use of SVP also holds potential in the development of vaccines and treatments for allergies and autoimmune diseases. Selecta is based in Watertown, Massachusetts. For more information, please visit http://selectabio.com and follow @SelectaBio on Twitter.

## **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 progress of the Phase 2 clinical trial of SEL-212, whether SEL-212 mitigates immunogenicity and enables sustained control of serum uric acid levels, low rate of gout flares and monthly dosing, the anticipated timing for advancing into Phase 3 (if at all), whether current evaluable SEL-212 patients will be predictive of future evaluable SEL-212 patients, whether projections regarding serum uric acid control for patients who have yet to complete the 20-week study period will be consistent with actual data, whether 5-monthly combination doses of SEL-212 have the potential to extend serum uric acid control and maintain safety over the entire treatment period, whether monthly dosing of SEL-212 leads to significant reduction in uric acid deposits, projections based on the rate of SUA control for patients who have completed the treatment period, the potential of SEL-212 to significantly reduce tophi/heavy urate burden and/or rapidly eliminate tissue urate burden, whether patients receiving SEL-212 will be able to complete full therapy cycles over 6 months, whether SEL-212 has the ability to reduce gout flares frequency initially and over time during SEL-212 therapy, the severity of gout flares experienced by patients receiving SEL-212, whether SEL-212 will continue to be generally well-tolerated, the company's commercial plans, the ability of the company's SVP platform, including SVP-Rapamycin, to mitigate unwanted immunogenicity, unlock the full potential of biologic therapies, enable new therapies and improve the efficacy and safety of existing biologics, the potential of SEL-212 to treat severe gout patients and resolve their debilitating symptoms, the potential of SEL-403 to treat mesothelioma, the potential treatment applications for products utilizing the SVP platform in areas such as enzyme therapy, gene therapy, oncology therapy, vaccines and treatments for allergies and autoimmune diseases, the company's plan to apply its SVP platform to a range of biologics for rare and serious diseases, the potential of the company's two gene therapy product candidates to enable repeat administration, the potential of the SVP-Rapamycin platform generally, 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 their 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 or whether results of early clinical trials will be indicative of the results of later clinical trials, the unproven approach of the company's SVP 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, substantial fluctuation in the price of its common stock, and other important factors discussed in the "Risk Factors" section of the company's Quarterly Report on Form 10Q filed with the Securities and Exchange Commission, or SEC, on August 8, 2018, and in other filings that the company makes with the SEC. 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 obligation to update any forward-looking statements included in this press release.

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