Selecta Biosciences Reports Data from Ongoing Phase 2 Trial of Lead Candidate, SEL-212, in Development for Chronic Severe Gout

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WATERTOWN, Mass., June 15, 2017 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ:SELB), a clinical-stage biopharmaceutical company focused on unlocking the full potential of biologic therapies by avoiding unwanted immune responses, today announced data from its ongoing Phase 2 trial of SEL-212 (SVP-Rapamycin in combination with the uricase enzyme pegsiticase), which is being developed for patients with chronic severe gout.

Key observations and findings based upon the clinical data generated through June 12, 2017 from the 60 patients currently enrolled in this open-label, dose ranging Phase 2 trial include:

- **Mitigated anti-drug antibodies (ADAs) after repeat monthly administrations of SEL-212** – The prevention of ADAs in a dose-dependent manner resulted in durable control of serum uric acid (sUA) levels (defined as sUA <6 mg/dl). The clinical data demonstrate a correlation between the prevention of ADAs and the maintenance of pegsiticase activity and serum uric acid control.
- **Demonstrated induction of immune tolerance** – A majority of patients in the minimum effective dose group maintained sUA control following three monthly injections of SEL-212 and two monthly "challenge" injections of pegsiticase alone. Maintenance of sUA in the challenge portion of the trial provides evidence at this stage that the use of SVP-Rapamycin is enabling immune tolerance, meaning a prevention of ADAs to pegsiticase, which is typically immunogenic when administered alone.
- **Reduced rate of gout flares with SEL-212** – In the control cohorts receiving pegsiticase alone, within the first month of treatment, 50% of patients reported experiencing a gout flare, which is a sudden and severe attack of pain, inflammation and tenderness of the joints. By comparison, only 15% of patients receiving SEL-212 reported a gout flare in the first month of treatment, with reports declining further in subsequent months. These data also appear to be in contrast with the increased incidence of flares reported in clinical trials involving other urate lowering therapies.
- **Identified minimum effective dose of SEL-212** – A key objective of the Phase 2 trial was to determine a minimum effective monthly dose of the two components of SEL-212 (i.e. pegsiticase and SVP-Rapamycin) through an ascending dose matrix design. A majority of the initial patients dosed with 0.4 mg/kg of pegsiticase in combination with 0.08 mg/kg of SVP-Rapamycin maintained sUA control beyond five treatments. As a result, the company has determined this to be a minimum monthly effective dose of SEL-212. Additional patients are now being added to this cohort, and higher dose levels of SVP-Rapamycin are being tested to further determine the dose regimens that may be taken forward into Phase 3.
- **SEL-212 generally well tolerated** – Consistent with the expected reduction in immunogenicity of pegsiticase when SVP-Rapamycin doses increase, SEL-212 has been generally well tolerated at clinically active doses. There have been a total of eight serious adverse events (SAEs) reported in the trial through June 12, 2017. Seven were infusion reactions, four of which occurred in the cohorts receiving pegsiticase alone or the lowest dose of SVP-Rapamycin and two of which were due to dosing errors. One additional SAE, cholecystitis, was determined to not be related to the study drug. All of the SAEs were successfully treated and resolved without further issues.

"The implications of these trial data are profound for both SEL-212 and for the development of Selecta's immune tolerance platform," said Werner Cautreels, Ph.D., CEO and Chairman of Selecta. "First and foremost, the clinical data demonstrate SEL-212's potential to address substantial unmet needs for patients with chronic severe gout, a debilitating disease that has been associated with both increased morbidity and mortality. We believe that a reduction of serum uric acid levels to near zero during treatment, a reduction in the incidence of flares and the convenience of safe monthly dosing with SEL-212 would prove to be a compelling treatment option. Leveraging these data, we are beginning to prepare for a Phase 3 program that we plan to initiate in 2018 following further dialogue with the U.S. Food and Drug Administration. Importantly, we also believe that our technology has shown for the first time in a clinical setting the potential to induce

tolerance to a highly immunogenic biologic, which helps to inform the continued development of our other proprietary novel biologic programs."

These and other data are being reported today at the Annual European Congress of Rheumatology (EULAR 2017) in Madrid, Spain and at the Federation of Clinical Immunology Societies' Annual Meeting (FOCIS 2017) in Chicago, IL. The company also has posted a presentation to its website entitled "Selecta June 2017 Phase 2 Trial Presentation" that can be accessed by clicking here.

Conference Call Reminder

At 8:30 a.m. ET today, Selecta will host a conference call to discuss the data. Those interested can access a live and archived webcast of this call 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 (877) 270-2148 (domestic) or (412) 902-6510 (international) and may access a teleconference replay for one week by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and using confirmation code 10108095.

About Chronic Severe Gout, SEL-212 and Selecta's Ongoing Phase 2 Trial

According to market research, more than 500,000 gout patients in the U.S. are treated by rheumatologists and approximately 160,000 of these patients have chronic severe gout. These patients typically have an inflammatory build-up of uric acid deposits called tophi in their joints and tissue that causes pain, inflammation of joints and debilitating flares. If untreated, these deposits also can potentially exacerbate kidney and cardiovascular disease and increase morbidity. In fact, a study published in 2016 involving more than 600 patients diagnosed with tophaceous gout showed a 60% increased risk of mortality when compared to more than 2,800 patients without tophi.[1]

Published data show that uricase enzymes have the unique ability to rapidly eliminate uric acid crystal deposits and tophi in patients with chronic severe gout.[2] However, since these are biologic enzymes that are recognized as "foreign" by the immune system, anti-drug antibodies (ADAs) are induced in most patients early in their treatment, compromising efficacy and safety as well as preventing further administrations.

SEL-212 (SVP-Rapamycin in combination with the uricase enzyme pegsiticase) is designed to be the first monthly uricase treatment and the first uricase treatment that avoids immunogenicity. It is intended to remove the patient's uric acid burden through a short induction treatment cycle, thereby improving acute symptoms such as pain, inflammation of joints and debilitating flares. Selecta also envisions that additional SEL-212 treatment cycles could be re-administered if severe gout symptoms were to recur.

In the fourth quarter of 2016, Selecta began enrolling patients with symptomatic gout and elevated serum uric acid levels in an open-label, multiple ascending dose Phase 2 clinical trial of SEL-212. The primary and secondary endpoints for this trial include safety, tolerability, pharmacokinetics, reduction of serum uric acid levels and reduction of ADA levels. Data also are being collected regarding flares and other patient-related observations. Patients are being enrolled in multiple ascending dose cohorts to enable the identification of the optimal dose ratio of SVP-Rapamycin and pegsiticase, the minimal effective dose level of SEL-212 for repeat monthly administration, and the dose regimen to take forward into Phase 3. More information about the trial (NCT02959918) is available at www.clinicaltrials.gov.

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 avoiding 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 therapies. 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. Selecta's clinical oncology candidate, LMB-100, is in a Phase 1 program targeting pancreatic cancer and mesothelioma. Its two proprietary gene therapy product candidates are being developed for rare inborn errors of metabolism and have the potential to enable repeat administration. The use of SVP is also being explored 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, the ability of SEL-212 to avoid unwanted immune responses, the ability of SVP-Rapamycin to induce immune tolerance against pegsiticase, the ability of SEL-212 to improve acute symptoms during a short induction cycle, the ability of SEL-212 to be re-administered if severe gout symptoms recur, whether the company will determine an appropriate dose of SEL-212 for a Phase 3, whether the company will advance to a Phase 3 for SEL-212 at all, whether the Phase 2 clinical data of SEL-212 demonstrate the potential of SEL-212 to address a substantial unmet need for gout patients, the company's ability to unlock the full potential of biologic therapies, the company's plan to apply its SVP platform to a range of biologics for rare and serious diseases, 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 potential of SEL-212 to treat severe gout patients and resolve their debilitating symptoms, the potential of the company's two gene therapy product candidates to enable repeat administration, 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 unproven approach of the company's SVP technology, 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, a significant portion of the company's total outstanding shares have recently become eligible to be sold into the market, and other important factors discussed in the "Risk Factors" section of the company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 11, 2017, 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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[1] Vincent Z et al, Predictors of Mortality in People with Recent Onset of Gout: A Prospective Observational Study, ACR, Sept. 2016

[2] Araujo E, Bayat S, Petsch C, Matthias E, Faustini F, Kleyer A, Hueber A, Cavallaro A, Lell M, Dalbeth N, et al. June 2015. Tophus resolution with pegloticase: a prospective dual-energy CT study. Rheumatic & Musculoskeletal Diseases.

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