Selecta Presents Phase 1 Clinical Data for Lead Product Candidate, SEL-212, in Patients with Hyperuricemia at 11th Annual IMVAC Summit

December 7, 2016 8:01 AM ET

- *SEL-212 Designed to be First Non-Immunogenic Uricase Therapeutic for Severe Gout*
- *Data Show Substantial and Sustained Reduction of Serum Uric Acid Levels for 30 Days or Longer After Single Dose*
- *Company to Host Conference Call Tomorrow Morning*

WATERTOWN, Mass., Dec. 07, 2016 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ:SELB), a clinical-stage biopharmaceutical company developing a novel class of targeted antigen-specific immune therapies, today announced that it has completed all patient visits for its Phase 1a/b trials of SEL-212, which is being developed for the treatment of chronic refractory and tophaceous gout. Data from these trials will be presented today at the 11th Annual Immunization and Vaccine Summit (IMVACS) in Boston, MA by Takashi Kei Kishimoto, Ph.D., Chief Scientific Officer of Selecta.

Therapeutics utilizing uricase, an enzyme that metabolizes uric acid, have previously demonstrated the ability to significantly reduce uric acid levels and dissolve the uric acid deposits in refractory and tophaceous gout patients. Their efficacy and safety, however, have been adversely impacted by the formation of anti-drug antibodies (ADAs). Leveraging Selecta's proprietary immune tolerance Synthetic Vaccine Particles (SVP™) platform, SEL-212 (SVP-Rapamycin in combination with pegsiticase) is designed to be the first non-immunogenic version of uricase.

"We are pleased to have completed all patient visits in our Phase 1 clinical trials with data that met our key objectives," said Dr. Kishimoto. "The results indicate that, by combining SVP-Rapamycin and pegsiticase, ADAs can be prevented, enabling the pegsiticase enzyme to substantially and sustainably reduce serum uric acid levels for 30 days or longer after a single dose. SEL-212 was generally well tolerated at clinically active doses. Leveraging these learnings, we recently initiated our Phase 2 trial to evaluate multiple monthly doses of SEL-212 in patients with symptomatic gout and hyperuricemia."

The Phase 1a trial enrolled 22 U.S. patients with hyperuricemia (uric acid level of >6mg/dL), evaluating the effect of a single intravenous infusion in a range of 0.1 to 1.2 mg/kg of pegsiticase administered alone. Pegsiticase was generally well tolerated at all tested dose levels. Serum uric acid levels for all patients initially dropped to less than 0.1 mg/dL within approximately 10 hours. However, these levels began rebounding by 14 to 21 days after dosing in a majority of patients. The loss of uric acid level control (defined as uric acid of >6 mg/dL) correlated with the formation of ADAs. The 0.4 mg/kg dose of pegsiticase was selected as the dose level to carry forward into the Phase 1b trial.

The multicenter Phase 1b trial enrolled 63 U.S. patients. One group received a single intravenous infusion of 0.4 mg/kg of pegsiticase alone. Four groups received either placebo or a single intravenous infusion of SVP-Rapamycin alone in a range of 0.03 to 0.5 mg/kg. As expected, SVP-Rapamycin alone did not significantly affect uric acid levels in these patients. Two serious adverse events (stomatitis), already previously reported by Selecta, were observed at the highest dose level tested (0.5 mg/kg), leading Selecta to set 0.3 mg/kg as the maximum tolerated dose of SVP-Rapamycin for the Phase 1b trial. The serious adverse events (SAEs) resolved completely during the study period.

Four additional groups received a single fixed dose of 0.4 mg/kg dose of pegsiticase by intravenous infusion in combination with 0.03, 0.1, 0.15 or 0.3 mg/kg of SVP-Rapamycin:

- At the 0.03 mg/kg dose, serum uric acid levels were controlled for at least 21 days in four of the five patients.
- At the 0.1 mg/kg dose, serum uric acid levels were controlled through Day 30 in seven of 10 patients.
- At the 0.15 mg/kg dose, serum uric acid levels were controlled through Day 30 in all five patients.
- At the 0.3 mg/kg dose, serum uric acid levels were controlled through Day 30 in all five patients.

The substantial and sustained reduction in uric acid levels through at least Day 30 was correlated with the prevention of

ADAs. These data supported a monthly dosing regimen in the ongoing multi-dose Phase 2 clinical trial.

SEL-212 was generally well tolerated at the clinically active dose levels. One SAE was already previously reported at the 0.1 mg/kg dose level for a grade 2 rash that was classified as an SAE due to an emergency room visit. This SAE resolved without further issues. No SAEs were observed at the 0.03, 0.15 or 0.3 mg/kg dose levels.

“Patients with the most severe forms of gouty arthritis have markedly impaired health-related quality of life. In gout, crystals of the sodium salt of uric acid form and accumulate in and around joints, triggering excruciatingly painful flare ups of acute arthritis, which can become very frequent in patients,” said Robert A. Terkeltaub, M.D., Professor at UC San Diego School of Medicine. “While uricase enzymes have long held the potential to quickly and substantially improve clinical outcomes in gout, the swift development of treatment-emergent antibodies to uricase therapeutic agents has presented a major roadblock to therapeutic success. The early clinical data regarding SEL-212 suggest that it holds the potential to overcome these challenges and address the unmet need for patients with the most severe forms of gout.”

Conference Call Reminder

Selecta will host a conference call tomorrow at 8:30 a.m. ET to discuss the Phase 1 data. Investors and the public can access a live and archived webcast of this call via the Investors & Media section of the company’s website, www.selectabio.com. Individuals may also participate in the live call via telephone by dialing (844) 309-6574 (domestic) or (484) 747-6923 (international) and may access a teleconference replay for one week by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and using confirmation code 14490302.

About Chronic Refractory and Tophaceous Gout

More than 8 million patients in the United States suffer from gout[i], which is caused by elevated levels of uric acid that result in harmful crystalline uric acid deposits in joints and surrounding tissues that cause painful inflammation and can lead to joint damage. Severe gout is often poorly controlled with conventional oral medications, resulting in painful and debilitating disease, flares and nodular masses of uric acid crystals termed tophi. Approximately 50,000 patients in the United States have been diagnosed with chronic refractory gout[ii], an orphan indication defined as uric acid levels that cannot be controlled by high doses of available oral therapies. It is also estimated that more than 200,000 patients in the United States suffer from chronic gout with tophi[iii], or tophaceous gout, which typically affects joints and surrounding soft tissues at the fingers, toes or elbows. Tophi are a difficult to treat source of chronic pain, inflammation, and can cause joint damage. Tophi typically take many years to resolve, or may fail to resolve, with conventional oral uric acid lowering therapy for gout[iv]. Treatment options to improve chronic refractory and tophaceous gout are very limited. Currently available uricase therapy fails to resolve gout and tophi in a majority of patients, largely because of unwanted immune reactions leading to the formation of antibodies that compromise efficacy and can cause serious adverse events[v].

About Selecta Biosciences, Inc.

Selecta Biosciences, Inc. is a clinical-stage biopharmaceutical company developing targeted therapies that use immunomodulators encapsulated in nanoparticles to induce antigen-specific immune responses to prevent and treat disease. Selecta’s proprietary Synthetic Vaccine Particle (SVP) technology is a highly flexible nanoparticle platform, capable of incorporating a wide range of antigens and immunomodulators, allowing the SVP-based products to either induce antigen-specific tolerance or activate the immune system.

Selecta's focus and strategy is to leverage its SVP immune modulating platform to develop and commercialize highly differentiated life-sustaining biologic drugs that are uniquely capable of mitigating the formation of anti-drug antibodies (ADAs). Proprietary programs that use SVP-Rapamycin to enhance efficacy and safety of therapy include SEL-212, Selecta’s lead Phase 2 clinical program in chronic refractory gout, and two gene therapies programs for genetic metabolic diseases. Tolerance-inducing SVP biological products also have potential applications in the treatment of allergies and autoimmune diseases.

Selecta is also developing SVP product candidates that activate the immune system to prevent and treat cancer, infections and other diseases.

Selecta is based in Watertown, Massachusetts, USA. For more information, please visit http://selectabio.com.

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 1/2 clinical program of SEL-212 including the number of centers in the Phase 2 clinical trial of SEL-212 and the announcement of data, conference presentations, the ability of the company's SVP platform, including SVP-Rapamycin, to mitigate immune response and create better therapeutic outcomes, the potential treatment applications for products utilizing the SVP platform, the sufficiency of the company's cash, cash equivalents, investments, and restricted cash 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 or licenses, 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 are eligible to be sold into the market in the near future, 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 November 10, 2016, 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 this release 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.

Contact Information:
Jason Fredette
Selecta Biosciences, Inc.
617-231-8078
jfredette@selectabio.com

Footnotes:

[i] Khanna et al., "2012 American College of Rheumatology Guidelines for Management of Gout", American College of Rheumatology 2012, Vol. 64, No. 10, October 2012, pp 1431–1446, DOI 10.1002/acr.21772

[ii] FDA 2009 Briefing Document for Arthritis Advisory Committee Division of Anesthesia, Analgesia, and Rheumatology Products FDA Arthritis Advisory Committee Meeting 16 June 2009

[iii] Eswar Krishnan, "Gout and crystal atrophies", first edition, ISBN 978-1-4377-2864-4, Chapter 6

[iv] Chhana A(1), Dalbeth N., "The gouty tophus: a review."Curr Rheumatol Rep. 2015 Mar;17(3):19. doi: 10.1007/s11926-014-0492-x.

[v] Baraf HS(1), Yood RA, Ottery FD, Sundy JS, Becker MA, "Infusion-related reactions with pegloticase, a recombinant uricase for the treatment of chronic gout refractory to conventional therapy." J Clin Rheumatol. 2014 Dec;20(8):427-32. doi: 10.1097/RHU.0000000000000200.

Selecta Biosciences Inc