Selecta Biosciences Initiates Phase 2 Clinical Trial of SEL-212, First Non-Immunogenic Biologic in Development for Treatment of Gout

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- *First Immunotherapeutic Candidate to Leverage Selecta's Proprietary Synthetic Vaccine Particle (SVP™) Platform*
- *SEL-212 Targeting Unmet Needs of Chronic Refractory and Tophaceous Gout Patients*
- *Initial Phase 2 Trial Results Expected in First Half of 2017*

WATERTOWN, Mass., Oct. 26, 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 dosed the first patient in its Phase 2 clinical trial of SEL-212, the company's lead proprietary immunotherapeutic product candidate for the treatment of chronic gout in patients refractory to conventional therapy. This trial will assess the safety, tolerability and clinical activity of SEL-212, a combination product candidate consisting of pegsiticase (pegylated uricase) and SVP-Rapamycin. SEL-212 is designed to be the first non-immunogenic enzyme therapy for gout. Initial results from this trial are expected in the first half of 2017.

"SEL-212 has the potential to address the large unmet need of severe gout patients, who are currently lacking effective treatment options. By lowering serum uric acid levels and total body uric acid burden with multiple doses of SEL-212 covering up to 6 months of treatment, SEL-212 is designed to eliminate inflammatory deposits that cause debilitating pain and often serious damage to joints and organs," said Earl Sands, M.D., Selecta's Chief Medical Officer. "The initiation of this trial marks an important advancement for our Synthetic Vaccine Particles (SVP) immunotherapeutic platform, which has the potential to enable and enhance a large number of biologic therapies including enzyme therapies, gene therapies and biologic cancer treatments by antigen-specific mitigation of undesired immune responses such as neutralizing antibodies."

This Phase 2 clinical trial of SEL-212 is being conducted at 15 centers in the United States and is expected to enroll more than 36 symptomatic gout patients with elevated uric acid levels. The primary and secondary endpoints of the trial include safety and tolerability of multiple doses of SEL-212, reduction of serum uric acid levels and mitigation of anti-drug antibodies (ADAs). Exploratory endpoints include measurement of uric acid deposits by Dual Energy Computed Tomography (DECT) imaging. Multiple dose treatment with SEL-212 has the potential to significantly lower total uric acid crystal burden in joints and tissues, which cannot be effectively or rapidly achieved by oral gout therapy. The removal of the uric acid crystal deposits is expected to reduce overall inflammation and the frequency of debilitating gout flares.

SEL-212 exemplifies Selecta's strategy to combine its SVP-Rapamycin platform with targeted biologics that require repeat administration to prevent the formation of ADAs. Undesired immune responses such as ADAs are a common complication with biologics including enzyme therapies, gene therapies, and cancer treatments. Application of the SVP platform may yield a pipeline of products with improved therapeutic benefit resulting from the reduction of unwanted immune responses. Selecta aims to advance a series of programs, including novel gene therapy products.

Phase 1 Data to be Presented December 7-8, 2016

In the Phase 1 clinical program of SEL-212, active and generally well-tolerated doses of pegsiticase and SVP-Rapamycin were identified in two single ascending dose trials with more than 75 patients. SVP-Rapamycin prevented the formation of ADAs and enabled pegsiticase to maintain sustained control of serum uric acid levels for at least 30 days after a single dose.

On Wednesday, December 7, 2016 at the 11th Annual Immunization and Vaccine Summit (IMVACS) in Boston, MA, Selecta will present results from this Phase 1 program. These results will also be discussed on a live conference call and webcast on Thursday, December 8, 2016 at 8:30 a.m. ET.

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 SEL-212

SEL-212 is Selecta's proprietary product candidate for the treatment of chronic refractory gout. SEL-212 consists of SVP-Rapamycin co-administered with pegsiticase, a pegylated uricase. Selecta believes that SEL-212 has the potential to offer an effective treatment for patients with chronic refractory and tophaceous gout, while also demonstrating the clinical effectiveness of the company's SVP technology.

About Selecta

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 for 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 products 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 Selecta's future expectations, plans and prospects, including without limitation, statements regarding the impact of the company's initial public offering on its financial position and development of its pipeline, the timing of the Phase 2 clinical trial of SEL-212, including initiation, announcement of data, conference presentations, the number of centers in the Phase 2 clinical trial of SEL-212, 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 SVP products, 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: the uncertainties inherent in the initiation, completion and cost of clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a 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, expectations for regulatory approvals, 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 factors discussed in the "Risk Factors" section of Selecta's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2016, 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 this release and should not be relied upon as representing its views as of any subsequent date. Selecta specifically disclaims any obligation to update any forward-looking statements included in this press release.

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.

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