Selecta Biosciences Commences Dosing in Phase 1 Clinical Trial of Nicotine Vaccine for Smoking Cessation and Relapse Prevention

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- Selecta Applies SVPTM Technology for Immune Stimulation to Address Significant Public Health Issue
- Program Being Funded Primarily by U.S. National Institutes of Health (NIH)

WATERTOWN, Mass., May 11, 2017 (GLOBE NEWSWIRE) -- <u>Selecta Biosciences, Inc.</u> (NASDAQ:SELB) today announced that patient dosing has commenced in a Phase 1 clinical trial to assess the safety, tolerability and pharmacodynamic profile of SELA-070, a nicotine vaccine candidate in development for smoking cessation and relapse prevention. The project is being funded primarily by an \$8 million grant (#U01DA037592) from the National Institute on Drug Abuse (NIDA), part of NIH.

Selecta's Synthetic Vaccine Particles (SVPTM) technology is designed to be a versatile platform and is being utilized in a series of programs aimed at inducing either antigen-specific immune tolerance or immune stimulation. SELA-070, an immune stimulation product candidate, delivers nicotine conjugated to the surface of nanoparticles that encapsulate immune stimulating agents. This second-generation product candidate is intended to induce a strong and durable immune response by triggering the production of a high level of anti-nicotine antibodies that bind to the nicotine inhaled by smokers, thus preventing nicotine from crossing the blood-brain barrier and triggering an addictive response.

"Smoking continues to profoundly impact our society and remains as one of our greatest public health challenges," said Werner Cautreels, Ph.D., CEO and Chairman of Selecta. "We are very proud and motivated to be teaming with NIDA on this trial to determine if SELA-070 might benefit the millions of smokers in the U.S. and worldwide who are seeking ways to overcome their addiction and improve their health."

Approved by the Federal Agency for Medicines and Health Products in Belgium, the Phase 1 trial is a double-blind, placebo-controlled, dose escalation study that is expected to enroll 48 smokers in Belgium. Patients will receive three injections of SELA-070 or a placebo over a period of 12 weeks followed by 8 weeks of monitoring. In addition to safety, the study will evaluate the vaccine's potency through the measurement of concentrations of nicotine-specific antibodies.

The Need for Smoking Cessation and Relapse Prevention Treatments

According to Centers for Disease Control and Prevention (CDC), smoking causes 6 million deaths per year worldwide, and this figure is expected to increase to 8 million per year by 2030. For 2015, CDC estimated that:

- Approximately 35.6 million U.S. adults (16.7% of males and 13.6% of females) were smoking cigarettes;
- Each day, more than 3,200 people in the U.S. younger than 18 years of age smoke their first cigarette;
- More than 16 million Americans were estimated to be living with a disease caused by smoking; and
- Cigarette smoking was the leading cause of preventable disease and death in the U.S., accounting for more than 480,000 annual deaths.

The CDC also reported in 2015 that 68% of U.S. smokers expressed interest in quitting, 55% had attempted to quit within the past year but only 7.4% were successful, demonstrating the need for additional and more effective treatment options.

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 (SVPTM) 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 progress of the Phase I trial for SELA-070, statements regarding the ability of SELA-070 to achieve smoking cessation and relapse prevention, whether SELA-070 will induce a strong and durable immune response in smokers, whether SELA-070 triggers the production of a high level of anti-nicotine antibodies and ultimately prevents nicotine from crossing the blood-brain barrier, 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 28, 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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Primary Logo

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