

Selecta Biosciences Announces Preclinical Data Showing SVP-Rapamycin's Potential Benefit in Treatment of Pompe Disease

February 15, 2017 8:00 AM ET

WATERTOWN, Mass., Feb. 15, 2017 (GLOBE NEWSWIRE) -- [Selecta Biosciences, Inc.](#) (Nasdaq:SELB), a clinical-stage biopharmaceutical company focused on developing biologic therapies for rare and serious diseases that avoid unwanted immunogenicity, today announced that results from preclinical studies involving the use of SVP-Rapamycin in combination with alglucosidase alfa (marketed as Myozyme[®] and Lumizyme[®]) to treat Pompe disease are being presented at the [13th Annual WORLDSymposium](#) by a research team led by Priya Kishnani, MD. Dr. Kishnani is Chief of Medical Genetics at Duke University Medical Center and is one of the world's leading experts in the treatment of Pompe disease.

"The preclinical data suggest that co-administration of an antigen-specific immune tolerance therapy could induce immune tolerance to the enzyme replacement therapy alglucosidase alfa," said Dr. Kishnani. "We look forward to additional studies to determine whether this novel approach has the potential to improve clinical outcomes for patients."

Pompe disease is an inherited and often fatal disorder caused by a deficiency of alpha-glucosidase, an enzyme that is required to break down a form of sugar called glycogen that is used by the cells of the body for energy. Impacting one in approximately 12,000 to 40,000 people in the United States, this disease typically manifests within months of birth or early in childhood, causing an accumulation of glycogen in the heart, skeletal muscle and other tissues and resulting in impaired motor skills, muscle weakness, breathing challenges and reduced growth rates. If untreated, Pompe disease can lead to death from respiratory or heart failure.

While the availability of enzyme replacement therapies (ERT) such as alglucosidase alfa have already dramatically improved the overall survival and quality of life for patients with Pompe disease, these therapies are known to cause the development of anti-drug antibodies (ADAs) that can severely compromise their efficacy and safety for many patients. Data included in the prescribing information for alglucosidase alfa indicate that ADAs were detected in 89% of its clinical trial patients and adverse infusion reactions were reported in 51% of clinical trial patients.

Entitled "Immunomodulation to ERT with Tolerogenic Nanoparticles Containing Rapamycin for Pompe Disease," the presentation by Dr. Kishnani's group described a recent Duke University Medical Center preclinical study demonstrating that SVP-Rapamycin induces antigen-specific immunological tolerance and mitigates ADAs to alglucosidase alfa in a mouse model of Pompe disease. Animals treated with alglucosidase alfa and SVP-Rapamycin had significantly increased glycogen clearance in skeletal muscles and improved motor function as compared to treatment with alglucosidase alfa alone or with the global immunosuppressant methotrexate.

"The preclinical data presented by Dr. Kishnani's team further illustrates the potential use of Selecta's SVP-Rapamycin to generate novel biologics that avoid unwanted immunogenicity," said Takashi Kei Kishimoto, Ph.D., Chief Scientific Officer of Selecta. "We believe this would enhance the efficacy and safety of treatments, increase the number of treatable patients and enable entirely new novel biologic therapeutics. With our lead product candidate, SEL-212, in a Phase 2 trial for refractory gout and proprietary and licensed gene therapy programs underway, we are making progress in developing our pipeline in the field of antigen-specific immune tolerance."

About Selecta Biosciences, Inc.

Selecta Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on developing biologic therapies for rare and serious diseases that avoid the immune responses that compromise efficacy and lead to life-threatening complications. Selecta is applying its proprietary Synthetic Vaccine Particles (SVP[™]) to a range of therapeutic areas in which immunogenicity is a key challenge. SEL-212, the company's lead candidate in Phase 2, is being developed to treat chronic refractory gout patients and reduce their debilitating symptoms, including flares and inflammatory arthritis. Further,

Selecta's two proprietary gene therapy product candidates have the unique potential to enable repeat administration, allowing for dose adjustment in patients and maintenance of therapeutic activity over time. The company is seeking to expand the use of its SVP platform in other areas, such as immuno-oncology, allergies, autoimmune diseases and vaccines. Selecta is based in Watertown, Massachusetts. 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 development of its pipeline, statements regarding the potential use of SVP-Rapamycin in combination with Myozyme[®] (alglucosidase alfa) to treat Pompe disease, the progress of the Phase 1/2 clinical program of SEL-212 including 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 in areas such as gene therapy, immuno-oncology, allergies, autoimmune diseases and vaccines, whether the company's proprietary gene therapy product candidates will enable repeat administration, allow for dose adjustment in patients or maintain therapeutic activity over time, any future development of the company's initiatives in peanut allergy and celiac disease, 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, 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 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 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 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.

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



Selecta Biosciences