

Selecta Biosciences Presented Preclinical Data Applying SVP-Rapamycin in Gene Therapy at Annual Congress of the European Society of Gene and Cell Therapy

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- *Data underscore potential of SVP-Rapamycin to enhance therapeutic benefit of gene therapies by mitigating unwanted humoral (antibody) and cellular immune responses*

WATERTOWN, Mass., Oct. 20, 2016 (GLOBE NEWSWIRE) -- [Selecta Biosciences, Inc.](#) (NASDAQ:SELB), a clinical stage biotechnology company developing a novel class of targeted antigen-specific immune therapies, announced that encouraging results from preclinical studies conducted in collaboration with Federico Mingozzi, Ph.D., Head of Immunology and Liver Gene Therapy at Genethon in Evry, France were presented at the Annual Congress of the European Society of Gene and Cell Therapy in Florence, Italy in a poster titled, “Antigen-specific modulation of capsid immunogenicity with tolerogenic nanoparticles results in successful AAV vector re-administration”. The new preclinical data elucidate the mechanism by which SVP-Rapamycin mitigates undesired immune responses. Further, the data demonstrate therapeutic benefits of co-administration of SVP-Rapamycin with an AAV8 gene therapy vector expressing Factor IX, a coagulation protein deficient in patients with Hemophilia B.

“These newly presented results underscore the unique advantages of SVP-Rapamycin in gene therapy,” said Dr. Takashi Kei Kishimoto, Ph.D., Chief Scientific Officer of Selecta. “Based on both these preclinical data with AAV and our clinical data showing that a single dose of SVP-Rapamycin mitigates antibody responses to a highly immunogenic enzyme for more than 30 days, I believe that our approach will help to enhance the development of the field. The key advantages of using SVP-Rapamycin would be the ability to re-administer gene therapies, when protein expression levels are not sufficient, and to prevent the type of immune attacks that can reduce expression or damage transduced organs.”

SVP-Rapamycin demonstrated successful mitigation of both humoral (antibody) and cellular immune responses that are associated with gene therapy using adeno-associated viral (AAV) vectors. Antibodies against AAV develop with the first dose of gene therapy and can prevent re-administration of therapy, which may be important in pediatric applications and diseases where sufficient protein expression cannot be achieved with a single dose. Cellular immune responses observed in clinical trials of gene therapies have been associated with an increase in liver enzymes and a loss of transgene expression in patients. Further, the data presented demonstrate that SVP-Rapamycin mitigates immunogenicity to gene therapy via the induction of T regulatory cells and prevention of germinal center formation.

Selecta is advancing gene therapy programs for two rare genetic metabolic disorders, Methylmalonic Acidemia (MMA) and Ornithine Transcarbamylase Deficiency (OTC). For both of these gene therapy applications, SVP-Rapamycin is designed to enable treatment of patients in childhood before the occurrence of disease-associated developmental and neurological issues. The prevention of antibodies and cellular immune responses by SVP-Rapamycin should allow for multiple doses of gene therapies in order to maintain beneficial therapeutic protein expression as the patients age.

Selecta’s lead product candidate, SEL-212, applies SVP-Rapamycin to pegsiticase, a pegylated uricase. SEL-212 is designed to be the first non-immunogenic version of uricase, an immunogenic enzyme which targets uric acid. SEL-212 demonstrated clinical activity in a Phase 1b clinical trial and is being developed for patients with chronic refractory and chronic tophaceous gout.

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 refractory and chronic tophaceous 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.

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 impact of the Company's initial public offering on its financial position and the 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, 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 August 9, 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.

For Selecta media:
Kathryn Morris
The Yates Network
+1-845-635-9828
kathryn@theyatesnetwork.com

For Selecta investors:
Sarah McCabe
Stern Investor Relations, Inc.
+1-212-362-1200
sarah@sternir.com



