



## **Co-administration of AAV Vectors with SVP-Rapamycin Enables Vector Re-administration in Pre-clinical Gene Therapy Study Published in Nature Communications by Généthon and Selecta Biosciences**

- Represents a potentially powerful strategy to modulate vector immunogenicity and may open new therapeutic avenues for AAV vector-mediated gene transfer

**EVRY, France and WATERTOWN, Mass., OCTOBER 5, 2018** -- Généthon, a non-profit R&D organization founded by the AFM-Téléthon, and Selecta Biosciences, Inc. (Nasdaq:SELB), a clinical-stage biopharmaceutical company, today announced that Nature Communications has published their jointly authored paper entitled "Antigen-selective modulation of AAV immunogenicity with tolerogenic rapamycin nanoparticles enables successful vector re-administration".

The pre-clinical study led by Genethon demonstrated that co-administration of synthetic vaccine particles encapsulating rapamycin ("SVP-R") with adeno-associated virus ("AAV") gene therapy vectors induced safe and effective mitigation of immune responses against the capsid in an antigen-selective manner. This resulted in safe and efficient vector re-administration in both small and large animal models of hepatic gene transfer.

Immunogenicity of AAV viral vectors has been a major roadblock to vector re-administration which may be required to ensure the durability of gene therapy, particularly for systemic and pediatric applications. For many inherited metabolic and degenerative diseases, early morbidity and mortality requires treatment early in life prior to the onset of irreversible tissue damage. However, expression of the therapeutic transgene is expected to wane over time as pediatric patients grow. Maintaining the ability to re-administer viral vectors such as AAV may therefore be essential to achieve sustained therapeutic efficacy over time.

"Despite exciting therapeutic results achieved to date with AAV-mediated gene therapy, development of antibodies against the vector, hampering efficient re-administration, represents potential obstacles for long-term efficacy of the treatments." said Frédéric Revah, Ph.D., CEO of Généthon. "Safe and effective strategies that reduce AAV vector immunogenicity and allow for stable transgene expression and re-dosing are urgently needed to allow continued advancement of the field. Co-administration of AAV vectors and SVP-R represents a potentially powerful strategy to address this long-standing challenge by modulating vector immunogenicity and enabling vector re-administration in mice and non-human primates, as was shown in the published study."

"The potential to re-administer AAV for retreatment and sustained therapeutic efficacy over time is especially important in pediatric patients," said Werner Cautreels, Ph.D., CEO of Selecta Biosciences. "In addition, the ability to re-dose may increase the proportion of patients able to achieve therapeutic levels of the transgene expression, while avoiding potential toxicities associated with large vector doses. This approach may create new opportunities for AAV vector-mediated gene transfer for diseases requiring systemic transduction or treatment in childhood."

## **About Généthon**

Created by the AFM-Telethon, The French Muscular Dystrophy Association, Genethon, located in Evry, France, is a non-profit R&D organization dedicated to the development of gene therapy for orphan genetic diseases, from research to clinical validation. Genethon has multiple ongoing programs at clinical, preclinical and research stage, led alone or in partnership with external academic or biotech partners for neuromuscular, blood, immune system, liver and eye diseases. [www.genethon.fr](http://www.genethon.fr)

## **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 mitigating unwanted immune responses. Selecta plans to combine its tolerogenic Synthetic Vaccine Particles (SVP™) 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. A Phase 1 trial is ongoing for a combination therapy consisting of SVP-Rapamycin and LMB-100 (Selecta's SEL-403 product candidate) for the treatment of patients with malignant pleural or peritoneal mesothelioma. Selecta's 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 also holds potential 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, statements regarding the company's plans to present at the Janney Healthcare Conference, the potential of SEL-212 to treat chronic severe gout patients and resolve their debilitating symptoms, the progress of the Phase 1 trial for SEL-403, the company's ability to unlock the full potential of biologic therapies by mitigating unwanted immune responses, 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 the company's gene therapy product candidates to treat rare inborn errors of metabolism and enable repeat administration, the potential of the SVP-Rapamycin platform generally, 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, 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, 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 8, 2018, 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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