



## **Selecta Biosciences Announces Appointment of Jude Samulski, Ph.D. as Gene Therapy Special Advisor and the Publication of Data Evaluating ImmTOR™ with AAV vectors for the treatment of Methylmalonic Acidemia**

July 26, 2021

*– Selecta appoints gene therapy pioneer Jude Samulski, Ph.D. as a special advisor to help guide Selecta’s gene therapy programs into the clinic –*

*– Data demonstrate that ImmTOR enhances transgene expression after both initial and repeat dosing –*

*– Publication further validates use of ImmTOR in Selecta’s gene therapy pipeline, including its lead candidate, MMA-101, for the treatment of methylmalonic acidemia (MMA) –*

WATERTOWN, Mass., July 26, 2021 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB, “Selecta”), a biotechnology company leveraging its clinically validated ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses, today announced the appointment of world renowned AAV gene therapy pioneer Jude Samulski, Ph.D., as a special advisor to assist with the development of their gene therapy programs. Additionally, Selecta has published a peer-reviewed online article describing pre-clinical data from its study investigating the efficacy of co-administration of ImmTOR™ nanoparticles with AAV vectors in transgene expression in methylmalonic acidemia (MMA) in the journal *Molecular Therapy Methods & Clinical Development*. The publication, entitled, “ImmTOR nanoparticles enhance AAV-driven transgene expression after initial and repeat dosing in a mouse model of methylmalonic acidemia,” was led by Petr Ilyinskii, Ph.D., a senior director at Selecta.

“Overcoming immunogenicity is a huge challenge for the entire gene therapy field,” said Dr. Samulski. “The preclinical data presented in this study supports Selecta’s ImmTOR technology potential to be a game-changing technology. Ultimately this could directly translate into improved safety and efficacy for patients.”

Dr. Samulski is professor of pharmacology and has been the director of the University of North Carolina Gene Therapy Center for over two decades. He was awarded the first patent for AAV as a viral vector and was the first recipient of the American Society of Gene & Cell Therapy Outstanding Achievement Award for lifetime achievements in gene therapy. Dr. Samulski has advanced gene therapies into human clinical trials for hemophilia, Duchenne muscular dystrophy, giant axonal neuropathy, Pompe disease and heart failure, and is the president, chief scientific officer and co-founder of Asklepios BioPharmaceutical Inc. (AskBio), a biotechnology company focused on AAV-driven gene therapy.

Carsten Brunn, Ph.D., president and chief executive officer of Selecta, added, “A major barrier to current efforts in AAV-driven gene therapy is the inability to re-dose patients due to the generation of neutralizing antibodies formed against the vector after the initial dose. The data outlined in this publication demonstrate that ImmTOR, when co-administered with AAV vectors, can both enhance transgene expression and provide specific suppression of the adaptive immune response to AAV vectors to allow redosing. These data are of particular interest to our MMA program, and we look forward to building on these findings as we advance our lead candidate, MMA-101, into the clinic and expect to file an IND by the end of 2021.”

In the study, performed in collaboration with the National Human Genome Research Institute, researchers evaluated the therapeutic efficacy of co-administration of ImmTOR and an AAV vector in a mouse model of MMA. After the initial dose, immediate increases in transgene expression and reduction of plasma methylmalonic acid, a marker of therapeutic activity, were observed in mice treated with both ImmTOR and AAV. Repeated administration of AAV vectors enabled by ImmTOR resulted in increased vector transduction and further decreases in plasma methylmalonic acid that was dose dependent. The combination was well-tolerated and led to near complete inhibition of neutralizing antibodies to the AAV vector. These data support the use of ImmTOR in combination with AAV-driven gene therapy to mitigate the current detrimental impacts of immunogenicity to AAV, potentially enabling re-dosing and elevated transgene expression at the initial dose.

The full pre-print publication can be accessed at: <https://www.sciencedirect.com/science/article/pii/S2329050121001170>

### **About MMA**

MMA is a rare metabolic disease that affects the body’s ability to metabolize certain amino acids and fats. The condition may lead to metabolic acidosis, hyperammonemia and long-term complications including feeding problems, developmental delays, intellectual disability and chronic kidney disease.

### **About Selecta Biosciences, Inc.**

Selecta Biosciences Inc. (NASDAQ: SELB) is a clinical stage biotechnology company leveraging its ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses. With a proven ability to induce tolerance to highly immunogenic proteins, ImmTOR has the potential to amplify the efficacy of biologic therapies, including redosing of life-saving gene therapies, as well as restore the body’s natural self-tolerance in autoimmune diseases. Selecta has several proprietary and partnered programs in its pipeline focused on enzyme therapies, gene therapies, and autoimmune diseases. Selecta Biosciences is headquartered in the Greater Boston area. For more information, please visit [www.selectabio.com](http://www.selectabio.com).

### **Selecta 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 unique proprietary technology platform of the company, and the unique proprietary platform of its partners, the potential of ImmTOR to treat autoimmune disease indications, the potential of ImmTOR to promote a tolerogenic environment in the liver, the timing of*

any clinical trials in the field of autoimmune disease, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as autoimmune disease, the ability of the company to develop products using the ImmTOR technology, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in pre-clinical study subjects will translate to studies performed with human beings, the potential of any therapies developed by the company to fulfill unmet medical needs, the company's plan to apply its ImmTOR technology platform to a range of biologics for rare and orphan genetic diseases, the potential of the ImmTOR technology platform generally and the company's ability to grow its strategic partnerships, 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 proof of concept trials, including the 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 ability to predict results of studies performed on human beings based on results of studies performed on mice or other animals, the unproven approach of the company's ImmTOR 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, the company's recurring losses from operations and negative cash flows from operations raise substantial doubt regarding its ability to continue as a going concern, substantial fluctuation in the price of its common stock, and other important factors discussed in the "Risk Factors" section of the company's most recent Quarterly Report on Form 10-Q, 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 its publication and should not be relied upon as representing its views as of any subsequent date. The company specifically disclaims any intention to update any forward-looking statements included in this press release.

**For Investors:**

Bruce Mackle  
LifeSci Advisors, LLC  
+1-929-469-3859  
[bmackle@lifesciadvisors.com](mailto:bmackle@lifesciadvisors.com)

**For Media:**

Brittany Leigh, Ph.D.  
LifeSci Communications, LLC  
+1-646-751-4366  
[bleigh@lifescicomms.com](mailto:bleigh@lifescicomms.com)



Source: Selecta Biosciences, Inc.