Selecta Biosciences Announces Top Line Data from the Phase I SEL-399 AAV Empty Capsid Study, Highlighting Potential Benefits of ImmTOR™ in Gene Therapy

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- At day 30, of subjects in the 0.3mg/kg ImmTOR cohort, 100% showed NAb titers of ≤ 1:25, and 67% showed NAb titers of ≤ 1:5 -

- With co-administration of AAV8 empty capsids and ImmTOR, Selecta observed dose-dependent response to ImmTOR with a safety profile in line with prior human studies -

- Based on these data Selecta intends to rapidly advance its wholly owned gene therapy pipeline, and continue to selectively evaluate gene therapy partnership opportunities utilizing ImmTOR -

- Selecta to host conference call and webcast today at 8:30 a.m. ET -

WATERTOWN, Mass., Nov. 08, 2021 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company leveraging its ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses, today announced top-line results from a joint Selecta and AskBio Phase I randomized, placebo controlled, double blind, dose-escalation study to evaluate the potential of its ImmTOR™ platform in mitigating the formation of neutralizing antibodies against an adeno-associated viral serotype 8 (AAV8) serotype capsid used in gene therapies. At day 30, in those subjects administered a single 0.3 mg/kg dose of ImmTOR, Selecta observed a median anti-AAV8 neutralizing antibody titer of 1:5, a 250-fold lower level than that observed in subjects dosed with AAV8 capsid alone.

“We believe these data demonstrate ImmTOR’s potential to address one of the biggest current limitations in gene therapy, the inability to re-dose life-saving gene therapies due to the formation of neutralizing antibodies against AAV capsids,” said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. “We observed that a single 0.3 mg/kg dose of ImmTOR mitigated the formation of neutralizing antibodies through 30 days. We believe these results, combined with our compelling preclinical data where we observed that two additional monthly doses of ImmTOR inhibited the formation of neutralizing antibodies in non-human primates through at least 84 days and in mice through at least 168 days, suggests that ImmTOR has the potential to enable the redosing of life-altering gene therapies. With our extensive experience with monthly dosing of ImmTOR in humans through the SEL-212 asset in Phase 3 we look forward to leveraging these exciting and novel findings in the clinic across our wholly owned gene therapy pipeline and alongside our world class gene therapy partners to achieve our goal of improving the lives of those living with monogenic diseases.”

In the Phase I study, researchers evaluated the administration of a single intravenous (IV) dose of a AAV8 empty capsid containing no DNA with and without a single dose of ImmTOR. Healthy subjects (n=23) were enrolled in a randomized 3:1 ratio of AAV8 dose of 2e12 vector genomes (vg)/kilogram (kg) alone (n=8) or in combination with either 0.15 mg/kg (n=9) or 0.3 mg/kg (n=6) of ImmTOR. The primary endpoints evaluated were safety and neutralizing anti-AAV8 antibody titers.

Key findings include:

- No Serious Adverse Events were reported. All treatment-related adverse events were expected for ImmTOR, readily monitorable, and transient.
- AAV8 empty capsids elicited a strong immune response with peak median anti-AAV8 neutralizing antibody (NAb) titers of 1:6875
- Median day 30 titers of neutralizing anti-AAV8 antibodies were 1:25 and 1:5 in the 0.15 mg/kg and 0.3 mg/kg ImmTOR cohorts, respectively
- Median day 30 titers of neutralizing anti-AAV8 antibodies were 50-fold and 250-fold lower in the 0.15 mg/kg and 0.3 mg/kg ImmTOR cohorts, respectively, compared to the median titer of control subjects dosed with AAV8 empty capsid alone
- At 30 days, of subjects who received 0.3 mg/kg of ImmTOR, 6 of 6, or 100%, exhibited an anti-AAV8 neutralizing antibody titer of 1:25 or less, and 4 of 6 or 67% had a titer of 1:5 or less
- At 30 days, of subjects that received 0.15 mg/kg of ImmTOR, 6 of 9, or 67%, exhibited an anti-AAV8 neutralizing antibody titer of 1:25 or less, and 2 of 9, or 22% had a titer of 1:5 or less
- By comparison, of subjects that received AAV8 empty capsid alone, only 1 of 8, or 12.5%, had a neutralizing antibody titer of 1:25 or less at 30 days, and no subjects (0/8) had a titer of 1:5 or less
- At 90 days 2 of 6 subjects in the 0.3 mg/kg cohort were observed to have sustained control of neutralizing antibodies with titers of 1:25 or less
- Consistent with preclinical data, we observed that the single dose ImmTOR cohorts saw delayed formation of neutralizing antibodies eventually reaching similar median levels of neutralizing antibodies to the control group by day 90

While most subjects treated with a single dose of ImmTOR showed increases in antibody titers by Day 90, preclinical studies in mice and nonhuman primates indicate that if antibodies can be controlled at Day 30, we can maintain control with additional two monthly doses of ImmTOR.

Jude Samulski, Ph.D., president and chief scientific officer of AskBio added, “Today’s promising results from the Phase 1 clinical trial suggest that ImmTOR in combination with the widely used AAV8 capsid has the potential to overcome the significant challenge of the formation of neutralizing anti-AAV8 antibodies. Reduction of capsid immunity could be transformative for the field of gene therapy, by making gene therapies safer and possibly enabling repeat dosing. We also look forward to presenting details characterizing the immune response of healthy subjects to empty capsids in a peer-reviewed scientific manuscript and at a major gene therapy conference.”

Dr. Brunn added, “SEL-302, Selecta’s gene therapy candidate to treat Methylmalonic acidemia (MMA) will be the first human gene therapy clinical trial to co-administer ImmTOR and test its ability to inhibit the formation of neutralizing antibodies; thus, enabling redosing. MMA is a disease where redosing of gene therapy would be absolutely critical to ensuring continued therapeutic benefit for patients. We look forward to bringing hope to those patients suffering from this rare and debilitating genetic disorder.”

As of the issuing of this press release, the FDA’s 30-day review period for our IND to conduct a Phase 1/2 clinical trial of our SEL-302 product candidate in pediatric patients with methylmalonic acidemia has expired. However, we have been informed orally by FDA that they are still considering certain aspects of our filing related to chemistry, manufacturing and control, or CMC. We intend to wait for formal clearance from FDA before initiating the proposed Phase 1/2 clinical trial.

Conference Call and Webcast Today:
Selecta management will host a conference call and webcast at 8:30 a.m. ET today to discuss top line data from the Phase I SEL-399 AAV Empty Capsid Study. The live webcast can be accessed in the Investors & Media section of the company’s website, www.selectabio.com or by clicking here. Investors may also listen to the live call via telephone by dialing (844) 845-4170 (domestic) or (412) 717-9621 (international) and may access a teleconference replay for one week by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and using confirmation code 10161951. A replay will be available after completion of the call and can be accessed in the in the Investors & Media section of the company’s website.

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.

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 proprietary technology platform of the Company, and the proprietary platform of its partners, the programs and disease indication targets anticipated under this collaboration, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the Company’s ability to conduct those clinical trials and studies, the timing or making of any regulatory filings, the ability of the Company and its partners where applicable to develop gene therapy products using ImmTOR, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human primate and mouse 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 ability to re-dose patients and the potential of ImmTOR to allow for re-dosing, the potential to safely re-dose AAV, the ability to restore transgene expression, 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 or topline 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 non-human primates and mice, the unproven approach of the Company’s ImmTOR technology, the Company’s partners’ ability to re-engineer or develop any protein therapeutics, 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, 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 to be filed for the quarter ended September 30, 2021, 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.

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