Selecta Biosciences Provides Update on Phase 1/2 Clinical Trial of SEL-302 for the Treatment of Methylmalonic Acidemia

November 24, 2021

-U.S. FDA has issued a clinical hold on Phase 1/2 Clinical Trial of SEL-302 due to CMC related questions-

WATERTOWN, Mass., Nov. 24, 2021 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB), a biotechnology company leveraging its clinically validated ImmTOR™ platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses, today announced that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on its Phase 1/2 clinical trial of SEL-302 (which consists of MMA-101 plus ImmTOR) for the treatment of patients with methylmalonic acidemia (MMA).

On November 23, Selecta received a letter from the FDA issuing a clinical hold in order to obtain additional information on the chemistry, manufacturing and controls (CMC) related to the MMA-101 product candidate. There were no outstanding clinical or pre-clinical questions in the FDA letter. This clinical trial had not yet been initiated, and no human patients will be dosed with MMA-101 until all of the FDA's questions are resolved. Selecta intends to work closely with the FDA to address the requests for additional information.

"Patient safety is our primary concern, and we are committed to addressing the FDA's questions regarding CMC as expeditiously as possible," said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. "We look forward to working closely with the FDA to satisfy all outstanding concerns, and to providing additional updates early next year."

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.

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 programs and disease indication targets anticipated under this agreement, the ability of any drug candidate developed under the agreement to offer a therapeutic benefit, the potential of ImmTOR to enable re-dosing of AAV gene therapy, to enhance transgene expression and to mitigate immunogenicity, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, 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, 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 unproven approach of the Company's ImmTOR technology, our partners' ability to develop products under the agreement, undesirable side effects of the Company's technology, its reliance on third parties to manufacture its product candidates and to conduct its development activities, 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, 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 Annual Report on Form 10-K to be filed after this release, 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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Source: Selecta Biosciences, Inc.