Selecta Biosciences and AskBio Initiate First-in-Human Dose-Escalation Study to Evaluate ImmTOR™ in Gene Therapy

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– Clinical trial commences in healthy adult volunteers to determine appropriate dose of ImmTOR to mitigate formation of antibodies to AAV capsids used in gene therapy –

WATERTOWN, Mass. and RESEARCH TRIANGLE PARK, N.C., Feb. 17, 2021 (GLOBE NEWSWIRE) -- Selecta Biosciences, Inc. (NASDAQ: SELB) and Asklepios BioPharmaceutical, Inc. (AskBio), a wholly owned and independently operated subsidiary of Bayer AG, today announced the initiation of a Phase 1 dose-escalation trial of SEL-399, an adeno-associated viral serotype 8 (AAV8) empty vector capsid (EMC-101) containing no DNA combined with ImmTOR™. The trial aims to determine the optimal dose of ImmTOR to mitigate the formation of antibodies to AAV8 capsids used in gene therapies.

"We are pleased to further evaluate ImmTOR's ability to reduce the formation of antibodies to AAV capsids and potentially enable gene therapy redosing by having initiated this dose-escalation study of SEL-399," said Carsten Brunn, Ph.D., president and chief executive officer of Selecta. "This trial builds upon our strong preclinical data in non-human primates and marks the first time that ImmTOR in conjunction with an AAV capsid has been dosed in humans, which is a significant milestone. Data from this study will inform the design of future clinical trials in patients as we seek to unlock the full potential of gene therapy."

The dose-escalation trial of SEL-399 is designed to evaluate the safety and preliminary efficacy of ImmTOR in gene therapy. The study, being conducted in healthy volunteers at the SGS Life Sciences Clinical Pharmacology Unit in Antwerp, Belgium, plans to enroll up to 45 subjects to investigate increasing doses of ImmTOR and EMC-101. Subjects will be randomized in a 3:1 ratio of ImmTOR plus empty AAV8 capsid to empty capsid alone. Preliminary efficacy will be measured by assessing levels of AAV8-specific neutralizing antibodies.

Jude Samulski, Ph.D., chief scientific officer and co-founder of AskBio said, "By determining the dose at which ImmTOR is able to inhibit the formation of AAV-specific antibodies, this study could be a significant first step toward overcoming some of the unwanted immune responses associated with gene therapies. We look forward to using these findings to inform future studies as we work to develop strategies for repetitive dosing of AAV, thus extending durability of expression."

Selecta and AskBio expect to report initial results from this clinical trial in the fourth quarter of 2021.

About Selecta Biosciences, Inc.
Selecta Biosciences Inc. (NASDAQ: SELB) is leveraging its clinically validated 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. The company's first program aimed at addressing immunogenicity to AAV gene therapies is expected to enter clinical trials in early 2021 in partnership with AskBio for the treatment of methylmalonic acidemia (MMA), a rare metabolic disorder. A wholly-owned program focused on addressing IgA nephropathy driven by ImmTOR and a therapeutic enzyme is also in development among additional product candidates. Selecta recently licensed its Phase 3 clinical product candidate, SEL-212, in chronic refractory gout to Sobi. For more information, please visit www.selectabio.com.

About AskBio
Asklepios BioPharmaceutical, Inc. (AskBio), a wholly owned and independently operated subsidiary of Bayer AG acquired in 2020, is a fully integrated AAV gene therapy company dedicated to developing life-saving medicines that cure genetic diseases. The company maintains a portfolio of clinical programs across a range of neuromuscular, central nervous system, cardiovascular and metabolic disease indications with a clinical-stage pipeline that includes therapeutics for Pompe disease, Parkinson's disease and congestive heart failure, as well as out-licensed clinical indications for hemophilia and Duchenne muscular dystrophy. AskBio's gene therapy platform includes Pro10™, an industry-leading proprietary cell line manufacturing process, and an extensive AAV capsid and promoter library. With global headquarters in Research Triangle Park, North Carolina, and European headquarters in Edinburgh, UK, the company has generated hundreds of proprietary third-generation AAV capsids and promoters, several of which have entered clinical testing. Founded in 2001 and an early innovator in the gene therapy field, the company holds more than 500 patents in areas such as AAV production and chimeric and self-complementary capsids. Learn more at www.askbio.com or follow us on LinkedIn.

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, visit www.bayer.com.

AskBio Forward-Looking Statements
This press release contains "forward-looking statements." Any statements contained in this press release that are not statements of historical fact may

be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include without limitation statements regarding AskBio's pipeline of development candidates; AskBio's collaboration with Selecta; AskBio's clinical trials, including its ability to enroll subjects, the timing of any such trials and any potential side effects; whether ImmTOR will be able to reduce the formation of antibodies to AAV capsids and potentially enable gene therapy redosing; the timing of and results from the SEL-399/101 trial; whether the SEL-399/101 study could be a significant first step in overcoming the immunogenicity concerns associated with gene therapies; AskBio's strategies for repetitive dosing of AAV, extending durability of expression; AskBio's goal of developing life-saving medicines aimed at curing genetic diseases; and the potential benefits of AskBio's development candidates to patients. These forward-looking statements involve risks and uncertainties, many of which are beyond AskBio's control. Known risks include, among others: AskBio may not be able to execute on its business plans and goals, including meeting its expected or planned regulatory milestones and timelines, clinical development plans and bringing its product candidates to market, due to a variety of reasons, including the ongoing COVID-19 pandemic, possible limitations of company financial and other resources, manufacturing limitations that may not be anticipated or resolved in a timely manner, potential disagreements or other issues with our third-party collaborators and partners, and regulatory, court or agency feedback or decisions, such as feedback and decisions from the United States Food and Drug Administration or the United States Patent and Trademark Office. Any of the foregoing risks could materially and adversely affect AskBio's business and results of operations. You should not place undue reliance on the forward-looking statements contained in this press release. AskBio does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

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 enable re-dosing of AAV gene therapy, the potential treatment applications of product candidates utilizing the ImmTOR platform in areas such as gene therapy, the ability of the Company and AskBio to develop gene therapy products using ImmTOR and AskBio's technology, the novelty of treatment paradigms that the Company is able to develop, whether the observations made in non-human primate study subjects will translate to studies performed with human beings, the potential of any therapies developed by the company and AskBio 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 company's intellectual property to enable repeat administration in gene therapy product candidates and products, 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 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, 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.

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