SAB Biotherapeutics Presents Positive IND-Enabling GLP Toxicology Study for SAB-142, a Novel Immunotherapeutic for Type 1 Diabetes at FOCIS 2023

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SAB highlights results from GLP toxicology study confirming SAB-142's mechanism of action at the 23rd Federation of Clinical Immunology Societies (FOCIS)

Study shows SAB's fully-human multi-target immune modulating therapeutic for treatment of Type 1 Diabetes is well tolerated

SIOUX FALLS, S.D., June 21, 2023 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (Nasdaq: SABS), (SAB), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that produces specifically targeted, high-potency, fully-human multi-target immunoglobulin (hIgG) antibodies (fully-human polyclonal antibodies) without the need for human donors, today announced the presentation of positive safety and pharmacologic data from a GLP toxicology study for SAB-142, a first in class fully human immunotherapeutic being developed for delaying onset and progression of Type 1 Diabetes (T1D), at the Federation of Clinical Immunology Societies (FOCIS) in Boston. Results from the IND-enabling GLP tox study confirmed that SAB-142 affects the same subsets of immune cells associated with T1D as commercially available rabbit-derived anti-thymocyte globulin (rATG) *in vivo*.

SAB-142 is a first-in-class fully-human, multi-target anti-thymocyte immunoglobulin treatment aimed to provide a superior profile for delaying onset or progression of T1D. SAB-142's unique multi-target strategy can be directed at the multiple immunological cell subsets associated with T1D and other autoimmune diseases. Another anti-thymocyte product produced in rabbits and FDA-approved for kidney transplantation, rATG, was investigated in patients with Type 1 Diabetes and showed significant efficacy in delaying progression of the disease by preserving C-peptide levels, a surrogate measure for endogenous insulin production by pancreatic beta cells. Commercially available products for T-cell mediated autoimmune diseases, such as fully-animal antibodies often induce immune-mediated reactions such as serum sickness. By contrast, SAB-142, which is a fully-human polyclonal antibody therapeutic, may be administered multiple times without causing these immune-related adverse reactions, which is particularly desirable for patients with lifelong diseases such as T1D.

Taking place June 20-23, 2023, in Boston, the FOCIS 2023 Annual Meeting is a leading translational immunology conference that explores research developments across immune-mediated diseases with a focus on molecular pathways and their implications in human disease. SAB will present a poster titled, *"Safety and Pharmacodynamic Effects of Novel Fully Human Anti-Thymocyte Polyclonal IgG Antibodies in an IND Enabling GLP Toxicology Study. First in Class, Human ATG (SAB-142) Therapeutic Developed to Delay Onset and Progression of Type 1 Diabetes,"* on June 22 at 6:30pm ET.

"We are excited to present results from our recently completed GLP tox study, which confirms our lead candidate's mechanism of action *in vivo* and paves the way for an IND submission," said Alexandra Kropotova, MD, Chief Medical Officer of SAB. "With over 8.4 million people affected by Type 1 Diabetes worldwide and only a single disease-modifying treatment available for patients, there is a pressing need for new and effective disease-modifying treatments. We are proud to share this milestone study and remain committed to evaluating SAB-142's promising potential as a disease-modifying therapy as we are planning to enter Phase 1 stage of clinical development in the next few months. "

In the in vivo study conducted under GLP conditions, SAB-142 was administered at three dose levels of 1, 5, and 10 mg/kg. Its active control, FDA-approved anti-thymocyte rabbit globulin (ATG) was administered at 5 mg/kg. The study results showed that both SAB-142 and the rabbit ATG modulate key T-cell subsets relevant for T1D in a similar fashion thus confirming that SAB-142's mechanism of action is similar to rabbit ATG. Based on the absence of SAB-142-related findings in any safety parameter evaluated in the study, the No Observed-Adverse-Effect-Level (NOAEL) was determined to be 10 mg/kg SAB-142, the highest dose level evaluated, thus meeting its main objective to generate preclinical safety data in support of upcoming IND and CTA filings.

SAB plans to submit an Investigational New Drug (IND) application for SAB-142 to the U.S. Food and Drug Administration and initiate a Phase 1 trial in the next few months.

For more details on the FOCIS program, please visit the conference website here.

More information on SAB's T1D candidate, SAB-142, can be found on the pipeline page of SAB's website: SAB-142: Type 1 Diabetes.

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics, Inc. (SAB) is a clinical-stage biopharmaceutical company focused on the development of powerful and proprietary immunotherapeutic polyclonal human antibodies to treat and prevent infectious diseases and immune and autoimmune disorders. Our development programs include infectious diseases resulting from outbreaks and pandemics, as well as immunological, gastroenterological, and respiratory diseases that have significant mortality and health impacts on immune compromised patients. SAB has applied advanced genetic engineering and antibody science to develop Transchromosomic (Tc) Bovine™. Our versatile DiversitAb™ platform is applicable to a wide range of serious unmet needs in human diseases. I produces natural, specifically targeted, high-potency, fully-human polyclonal immunotherapies without the need for human donors. SAB currently has multiple drug development programs underway and collaborations with the US government and global pharmaceutical companies. For more information on SAB, visit: https://www.SAb.bio/ and follow SAB on Twitter and LinkedIn.

Forward-Looking Statements

Certain statements made herein that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook" and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding future events, the development and efficacy of our influenza program, C. diff. program, type 1 diabetes program, and other discovery programs, the results, including timing, of the development of SAB-176, SAB-185, SAB-142 and SAB-195, including SAB-176 Fast Track designation and Breakthrough Therapy designation, and the outcome of potential future government and other third-party collaborations or funded programs.

These statements are based on the current expectations of SAB and are not predictions of actual performance, and are not intended to serve as, and must not be relied on, by any investor as a guarantee, prediction, definitive statement, or an assurance, of fact or probability. These statements are only current predictions or expectations, and are subject to known and unknown risks, uncertainties and other factors which may be beyond our control. Actual events and circumstances are difficult or impossible to predict, and these risks and uncertainties may cause our or our industry's results, performance, or achievements to be materially different from those anticipated by these forward-looking statements. A further description of risks and uncertainties can be found in the sections captioned "Risk Factors" in our most recent annual report on Form 10-K, subsequent quarterly reports on Form 10-Q, and other filings with or submissions to, the U.S. Securities and Exchange Commission, which are available at https://www.sec.gov/. Except as otherwise required by law, SAB disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events, or circumstances or otherwise.

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