SAB Biotherapeutics Initiates IND-Enabling GLP Toxicology Study for SAB-142, Novel Immunotherapeutic for Type 1 Diabetes

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Study of SAB's fully-human polyclonal therapeutic to delay onset or progression of type 1 diabetes is the last step before investigational new drug (IND) filing

SIOUX FALLS, S.D., Nov. 21, 2022 (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 polyclonal antibodies without the need for human donors, today announced SAB-142 is being progressed as a therapeutic agent to prevent and/or delay onset and progression of Type 1 diabetes (T1D) and potentially other T-cell mediated autoimmune diseases. In an IND-enabling GLP study, SAB-142 will be compared to an FDA-approved T-cell depleting therapeutic, to assess toxicity and pharmacodynamic effects.

Because SAB-142 is a fully-human polyclonal antibody, it is expected to be much less immunogenic, safer, and more effective in preventing and/or delaying onset and progression of T1D as compared to other commercially available products such as fully-animal antibodies and other monoclonal lymphodepletion therapeutics. SAB-142 is fully-human therapeutic that may be administered multiple times without inducing immune-mediated reactions including immediate anaphylaxis or delayed serum sickness.

"Type 1 diabetes is an autoimmune disease that represents a staggering unmet patient need," said Alexandra Kropotova, MD, Chief Medical Officer of SAB Biotherapeutics. "Patients in the Americas are disproportionally affected by Type 1 diabetes. From 1990 to 2019, the death rate increased in the Americas by 13.5%, in contrast to a decreasing global rate of –9.3%. The initiation of this study supports the progression of our SAB-142 immunotherapeutic towards IND filing. As such, we are aiming toward a successful IND submission for this novel immunotherapy that can positively impact the health of millions of patients with Type 1 diabetes across the globe."

In the GLP toxicology study, conducted in an appropriate model, SAB-142 will be dosed at 1, 5, and 10 mg/kg and commercially available anti-thymocyte globulin will be dosed at 5 mg/kg. The study is expected to be completed in the first quarter of 2023.

About SAB Biotherapeutics

SAB Biotherapeutics, Inc. (SAB) We are 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 unme needs in human diseases. It 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, including the development and efficacy of our influenza program, C. diff. program, Type 1 Diabetes program, and other discovery programs, the likelihood that a patent will issue from any patent application, the results, including timing, of the development of SAB-176, SAB-185 and SAB-195 (including any IND filing or proposed clinical trials), financial projections and future financial and operating results (including estimated cost savings and cash runway), the outcome of and potential future government and other third-party collaborations or funded programs (including negotiations with the DoD).

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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