SAB Biotherapeutics Announces Commencement of the HUMAN Phase 1 Clinical Trial with SAB-142, a Potential Disease-Modifying Treatment for Type 1 Diabetes

November 29, 2023

First subject has been dosed in the first-in-man Phase 1 clinical study of SAB-142, the first fully-human anti-thymocyte immunoglobulin (ATG)

SAB-142 directly and specifically targets multiple immune cells involved in the destruction of insulin-producing pancreatic beta cells to potentially preserve beta cell function

SAB Biotherapeutics is pursuing IND and CTA filings with U.S. FDA and EMA in 2024 to clinically advance development of SAB-142 into Phase 2b study

SIOUX FALLS, S.D., Nov. 29, 2023 (GLOBE NEWSWIRE) -- SAB Biotherapeutics, Inc. (Nasdaq: SABS), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that is developing fully-human anti-thymocyte immunoglobulin (hIgG) for disease-modification of Type 1 Diabetes (T1D) through delaying the onset and/or progression of the disease, today announced that the first participants of a **HUMAN** trial (Fully **HU**man anti-thymocyte biologic in first-in-**MAN** clinical study) have been dosed in Australia. This Phase 1 randomized, double-blind, placebo-controlled, single-ascending dose, adaptive design clinical study was designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of intravenous SAB-142 in healthy volunteers and participants with T1D. SAB-142 is a first-in-class fully-human anti-thymocyte immunoglobulin being developed as a disease-modifying treatment to delay the onset and progression of T1D.

In October 2023, SAB received approval by the Australian Human Research Ethics Committee (HREC) to commence the Phase 1 clinical trial investigating safety, tolerability, pharmacokinetic, pharmacodynamic, and immunogenicity of SAB-142. The primary objective of the trial is two-fold: 1) to generate data on differentiated safety and immunogenicity of this fully-human immunoglobulin, and 2) to establish a Proof of Biological Activity (POBA) for SAB-142. Establishing POBA will focus on validating the immunological effects associated with an anti-thymoglobulin mechanism of action in modulating autoimmune response associated with progression of T1D. Those immunological effects have been previously elucidated in efficacy trials in T1D patients with rabbit-derived anti-thymocyte globulin (ATG). More information about the Phase 1 clinical trial with SAB-142 (ACTRN:12623001089628) can be found here.

“This marks an important milestone in our development of SAB-142 as our lead asset enters the clinic,” said Alexandra Kropotova, MD, MBA, Executive Vice President and Chief Medical Officer of SAB. “We believe SAB-142 has the potential to be a best-in-class treatment for disease-modification through safe and precise immunomodulation in T1D, based on its validated mechanism of action and safety advantages over rabbit-derived ATG, which has shown significant promise in T1D disease modification. I would also like to extend gratitude on behalf of the entire SAB team to the trial participants and to our Phase 1 partners Avance and Nucleus Network, without whom this trial wouldn’t be possible.”

The program is expected to rapidly expand globally, subject to regulatory approvals in the United States, United Kingdom and European Union countries. SAB is on track to file an Investigational New Drug (IND) application for SAB-142 with the U.S. Food and Drug Administration (FDA) in 2024, along with filings in UK and EU countries to enable efficient progress towards the Phase 2b development.

“For people living with T1D, the burden of disease is significant and there’s increasing focus – and need – within the research community to focus on disease-modification, a departure from the focus on symptom management that has long been the norm,” said Dr. Kristi McLendon, principal investigator at the Nucleus Network, who is leading the Phase 1 trial. “We are grateful to partner with SAB on this Phase 1 investigation that will explore the therapeutic potential of a new, potentially best-in-class immunotherapeutic option for patients.”

About SAB-142
SAB-142 is a fully-human alternative to rabbit anti-thymocyte globulin (ATG). SAB-142’s mechanism of action is similar to that of rabbit ATG, which has been clinically validated in multiple clinical trials for type 1 diabetes, demonstrating the ability to slow down disease progression in patients with new or recent onset of Stage 3 type 1 diabetes.

Two clinical trials have shown that a single, low dose of rabbit ATG has demonstrated the ability to modulate the body’s immune response to help slow beta cell destruction and preserve the ability of these cells to generate insulin, which the body needs to

regulate blood sugar and carry out all human activities.

SAB-142, like rabbit ATG, directly targets multiple immune cells involved in destroying pancreatic beta cells. By stopping immune cells from attacking beta cells, this treatment has potential to preserve insulin-producing beta cells. However, most humans treated with rabbit ATG develop serum sickness and anti-drug antibodies from exposure to the rabbit-derived antibody. SAB-142 is a human antibody, intended to allow safe, consistent re-dosing for type 1 diabetes, a lifelong chronic disease, without the potential risk of inducing the major adverse immune reactions that can occur with administration of a fully animal ATG.

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics (SAB) is a clinical-stage biopharmaceutical company focused on developing fully human, multi-targeted, high-potency immunoglobulins (IgGs), without the need for human donors or convalescent plasma, to treat and prevent immune and autoimmune disorders. The company's lead asset, SAB-142, targets type 1 diabetes (T1D) with a disease-modifying therapeutic approach that aims to change the treatment paradigm by delaying onset and potentially preventing disease progression. Using advanced genetic engineering and antibody science to develop Transchromosomic (Tc) Bovine™, the only transgenic animal with a human artificial chromosome, SAB's DiversitAb™ drug development production system is able to generate a diverse repertoire of specifically targeted, high-potency, fully-human IgGs that can address a wide range of serious unmet needs in human diseases without the need for convalescent plasma or human donors. For more information on SAB, visit: https://www.SAb.bio/.

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," "to be," "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 T1D program, and other discovery programs, the closing of each tranche of the Company's private placement offering, the timely funding to the Company by each investor in the private placement offering, 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.

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, as amended, subsequent quarterly reports on Form 10-Q, as may be amended or supplemented from time to time, 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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