FDA Provides Clearance to IND Application for Type 1 Diabetes Therapy SAB-142 by SAB Biotherapeutics

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This regulatory clearance enables clinical development of SAB-142 in patients with type 1 diabetes in the US

MIAMI, May 21, 2024 (GLOBE NEWSWIRE) -- SAB Biotherapeutics (Nasdaq: SABS) (the “Company” or “SAB”), today announced that the U.S. Food and Drug Administration (FDA) has provided clearance for the Company’s investigational new drug (IND) application to proceed for its phase 1 clinical trial for type 1 diabetes (T1D) therapy SAB-142. SAB is a clinical-stage biopharmaceutical company with a novel immunotherapy platform developing a human anti-thymocyte immunoglobulin (hIgG) for delaying the onset or progression of T1D.

The IND allows for enrollment of patients with type 1 diabetes in the United States into the ongoing HUMAN trial designed to generate data enabling an upcoming Phase 2B trial. The **HUMAN** trial – fully **HU**man anti-thymocyte biologic in first-in-**MAN** clinical study – is a phase 1 randomized, double-blind, placebo-controlled, single-ascending dose, adaptive design clinical study designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of intravenous SAB-142 in healthy volunteers and participants with T1D.

“We are thrilled by FDA’s clearance of our IND for SAB-142, which marks a significant step forward in our mission to slow disease progression in patients with new or recent onset stage 3 type 1 diabetes,” states Samuel J. Reich, Chairman and CEO of SAB. “We look forward to expanding our clinical program with SAB-142 as we work to change the lives of people impacted by type 1 diabetes through our unique disease-modifying therapy.”

Trial Design

Phase 1 of SAB-142 is a first-in-man study to establish safety, tolerability, pharmacokinetic (PK), immunogenicity, and pharmacodynamic (PD) profile of a human anti-thymocyte biologic SAB-142. The study is designed as a randomized, double-blind, single-ascending dose trial, with a dose range of .03mg/kg up to 2.5mg/kg which is a similar dose range studied in the MELD-ATG study, a dose-ranging rabbit ATG study in patients with new onset T1D that will announce its topline result in 2025. Anticipated outcomes include validation of differentiated safety, immunogenicity, and tolerability profile of SAB-142 based on anticipated 0% serum sickness and nAbs. The study further aims to validate mechanism of action of SAB-142 in humans and establish proof of biological activity. SAB provided a Phase 1 update on April 16, 2024 which noted the third cohort has been fully enrolled and dosed with no observed serum sickness.

About SAB-142

SAB-142 is a human alternative to rabbit anti-thymocyte globulin (ATG). SAB-142’s mechanism of action is analogous to that of rabbit ATG, which has been clinically validated in multiple clinical trials T1D, 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 biologic treatment, 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 an animal ATG.

About SAB Biotherapeutics, Inc.

SAB Biotherapeutics (SAB) is a clinical-stage biopharmaceutical company focused on developing 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 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, 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/ and follow SAB on Twitter and LinkedIn.

Forward-Looking Statements

Certain statements made in this current report 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.

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, 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.

CONTACTS

Media Relations:

khollon@sab.bio

Investor Relations:

Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com

Chris Calabrese
LifeSci Advisors
ccalabrese@lifesciadvisors.com