SAB Biotherapeutics Receives Australian Approval to Commence Phase 1 Clinical Trial of SAB-142, a Potential Disease-Modifying Treatment for Type 1 Diabetes

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Australian Human Research Ethics Committee (HREC) grants approval for SAB to begin first-in-human Phase 1 clinical study of SAB-142, the first fully human anti-thymocyte immunoglobulin (ATG)

SAB-142 directly targets multiple immune cells involved in destroying insulin-producing pancreatic beta cells to potentially preserve beta cell function

SAB Biotherapeutics is pursuing IND filing with U.S. FDA

SIOUX FALLS, S.D., Oct. 19, 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 delaying the onset or progression of type 1 diabetes (T1D), today announced that it completed the approval process to commence a first-in-human Phase 1 clinical trial investigating SAB-142 in Australia.

The Phase 1 trial will evaluate the company's lead therapeutic candidate, SAB-142, a first in-class fully-human anti-thymocyte immunoglobulin being developed as a disease-modifying treatment to delay the onset and progression of T1D. This first-in-human trial is designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of the SAB-142. Approval by the HREC is confirmation that SAB has successfully completed all pre-clinical safety and efficacy testing required to commence a Phase 1 clinical trial. SAB also intends to submit an Investigational New Drug (IND) application for SAB-142 to the U.S. Food and Drug Administration (FDA) to commence clinical trials in the United States. More information about the Phase 1 clinical trial with SAB-142 (ACTRN:12623001089628) can be found here.

"There is tremendous global need for groundbreaking, disease-modifying treatments that can potentially delay the onset of the clinical disease or delay the progression of type 1 diabetes," said Eddie J. Sullivan, Ph.D., co-founder, President, and Chief Executive Officer of SAB Biotherapeutics. "Today's announcement brings us one step closer to our plans for expanding global regulatory submissions for SAB-142 to other health authorities in the United States, United Kingdom, and European Union. This clinical milestone is an important first step in our role in addressing an unmet need among patients, and we are proud of the approval to initiate Phase 1 clinical study in Australia for what we believe could be a best-in-class option."

"The mechanism of action of anti-thymocyte globulin has been validated with rabbit ATG in several clinical trials in T1D patients for T1D disease modification. We look forward to investigating SAB-142, the first fully-human alternative to rabbit-derived ATG, in this Phase 1 trial, as we believe it could provide important clinical benefits over animal ATG," said Alexandra Kropotova, MD, MBA, Executive Vice President and Chief Medical Officer of SAB. "We'd like to thank our clinical trial partners and express gratitude to everyone involved for their shared dedication to advancing innovative therapeutic options for those living with T1D."

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, Inc. (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/ 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," "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 type 1 diabetes program, and other discovery programs, and the results, including timing, of the development of SAB-142 (including any IND filing or proposed clinical trials).

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.

Media Relations:
SABPR@westwicke.com

Investor Relations:
matt@milestone-advisorsllc.com