SAB BIO Announces Positive Topline Phase 1 Clinical Results with Potentially Disease-Modifying T1D Therapy SAB-142

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- *SAB-142 was generally well-tolerated among healthy volunteers; data from Phase 1 trial confirms SAB-142 does not cause serum sickness or anti-drug antibodies at target dose*
- *Study results support that SAB-142 is well-positioned for re-dosing in outpatient setting for type 1 diabetes*
- *Results will be presented in an R&D webinar event today at 8:00 am ET; registration details below*

MIAMI, Jan. 28, 2025 (GLOBE NEWSWIRE) -- SAB BIO (Nasdaq: SABS), ("SAB BIO" or the "Company"), a clinical-stage biopharmaceutical company with a novel immunotherapy platform that is developing human anti-thymocyte immunoglobulin (hIgG) for delaying the onset or progression of type 1 diabetes (T1D), today announced positive topline data from a Phase 1 trial of SAB-142 in a single-ascending dose among healthy volunteers. The study met its primary objectives related to safety and pharmacodynamic activity enabling SAB-142 to advance to Phase 2b clinical development.

"I am particularly excited with the analysis of the results of our Phase 1 trial, as it marks the successful achievement of another critical milestone for SAB-142," stated Samuel J. Reich, Chairman and CEO of SAB BIO. "These data show clear and positive pharmacologic activity and strong safety profile for SAB-142, and underscore SAB-142's potential to change the lives of people impacted by type 1 diabetes. With our initial study objectives met, we believe SAB-142 is now well-positioned to be a transformative therapy in autoimmunity by delaying the progression or onset of type 1 diabetes, and we look forward to advancing this product candidate into Phase 2b clinical development in 2025."

Phase 1 Trial Summary Data

The SAB-142 Phase 1 trial was designed as a randomized, double-blind, placebo-controlled, single-ascending dose, adaptive design clinical study among healthy volunteers and one cohort of participants with T1D. The objectives include establishing the safety, tolerability, pharmacokinetic (PK), immunogenicity and pharmacodynamic (PD) profile for SAB-142. The topline results reported today showed the following outcomes among healthy volunteer cohorts:

- **Favorable Safety Profile:** SAB-142 was generally well-tolerated and demonstrated a favorable safety profile that supports the chronic dosing of SAB-142 in an ambulatory setting.
  - The SAB-142 Phase 1 dose range was between 0.03mg/kg up to 2.5mg/kg, which demonstrated favorable safety profile based on the 0% reported serum sickness and anti-drug antibodies.
- **Sustained Immunomodulation:** SAB-142 demonstrated a clinically validated multi-target MOA with sustained immunomodulation.
- **MoA Analogous to Rabbit ATG:** The mechanism of action (MoA) of SAB-142 was shown to be analogous to rabbit ATG
  - The SAB-142 MoA was shown to be analogous to rabbit ATG across multiple parameters correlative to C-peptide preservation.

"Our topline data, which we plan to discuss in further detail at our webinar this morning, successfully demonstrates SAB-142's impactful autoimmune response," said Dr. Alexandra Kropotova, M.D., MBA, Executive Vice President and Chief Medical Officer at SAB BIO. "This is consistent with what we've seen preclinically, and we believe this validates SAB-142's unique role as potentially the first and only fully human biologic with a validated and broad mechanism of action to enable outpatient dosing to delay the onset or progression of type 1 diabetes."

Based on the data, SAB BIO plans to advance SAB-142 into a Phase 2b trial in 2025 to evaluate the therapeutic candidate in adult and pediatric patients with new-onset T1D.

Webinar Details and Registration Information

Today's webinar will feature presentations from SAB BIO's management team and T1D Key Opinion Leader (KOL), Michael Haller, MD, the division chief of the Pediatric Endocrinology Division at the University of Florida and Silverstein Family Eminent Scholar Chair in Pediatric Endocrinology.

Date: Tuesday, January 28, 2025

Time: 8:00 a.m. ET

Register for the event here or join the conference call through the Events section of the SAB BIO Company website.

A live question and answer session will follow the formal presentations. A replay of the call will be available in the Presentation section of the SAB BIO Company website upon conclusion of the event.

About SAB BIO

SAB BIO (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 data, development, clinical results, and efficacy of our T1D program and other discovery programs.

These statements are based on the current expectations of SAB BIO 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 BIO 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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