SAB BIO Announces Additional Phase 1 Data for SAB-142 in Adult Patients with Established Autoimmune Type 1 Diabetes

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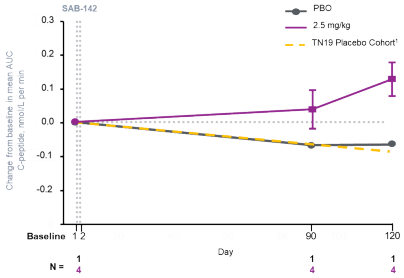
Results demonstrated early signals of C-peptide preservation

T1D key opinion leader, Michael J. Haller, MD, provided a recorded webinar reviewing the SAB-142 Phase 1 data

MIAMI, March 10, 2026 (GLOBE NEWSWIRE) -- SAB Biotherapeutics, Inc. (Nasdaq: SABS), a clinical-stage biopharmaceutical company developing a fully human anti-thymocyte immunoglobulin (hATG) for type 1 diabetes (T1D) and other autoimmune diseases, today announced additional data from the Phase 1 **HU**man anti-thymocyte biologic in first-in-**MAN** (HUMAN) clinical trial of SAB-142. The established T1D adult patient cohort demonstrated early signals of C-peptide preservation which aligned with the anticipated mechanism of action of SAB-142. In the T1D cohort (n=6), SAB-142 treated study participants (n=4) showed no decrease in C-peptide levels at Day 120 compared to baseline. The placebo study participant showed a decrease in C-peptide at Day 120 compared to the baseline.

Figure 1



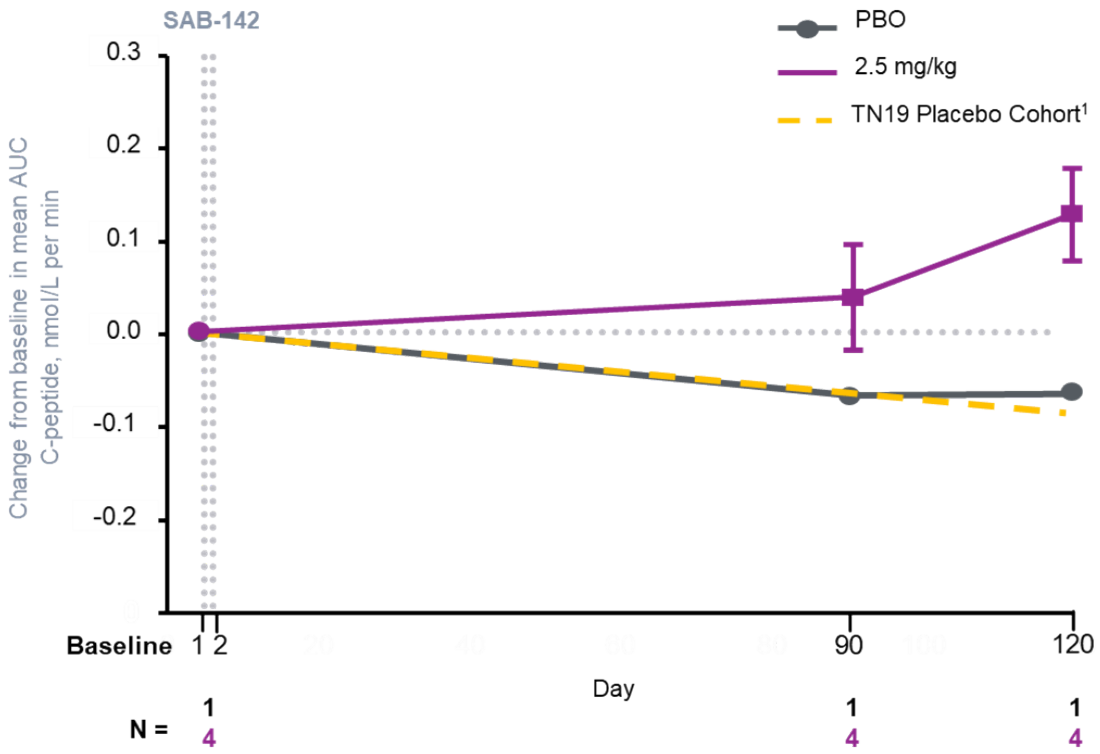
T1D Cohort – MMTT C-Peptide Mean AUC (nmol/L) / Min ± SEM

"People living with T1D need novel treatment options to alter the course of their disease, and we know that the preservation of C-peptide as the marker of endogenous insulin production has a positive clinical effect for patients. While exploratory and early, the initial C-peptide data are encouraging and exactly the type of signal I hope to see at this stage. Additionally, these clinical observations were supported by biomarker evidence of T cell exhaustion consistent with prior studies, strengthening confidence that the therapy is engaging its intended biological mechanism," said Michael J. Haller, M.D., Professor and Chief of Pediatric Endocrinology, University of Florida. "I am excited about SAB-142's potential as a disease modifying therapy for T1D."

The Phase 1 T1D cohort included six adult participants (n=6), with four receiving SAB-142 at 2.5 mg/kg (n=4) and two receiving placebo (n=2). Participants ranged in age from 19 to 40 years. All established T1D patients (Stage 3 T1D diagnosis within 28-40 months at the time of randomization) had residual beta cell function (C-peptide >0.2 nmol/L) and at least one T1D autoantibody at baseline. Phase 1 study exploratory efficacy endpoints were measured at the End of Study Day 120 post SAB-142 administration. One placebo participant (n=1) completed through Day 120 as the other placebo participant discontinued early due to personal reasons.

Participants treated with SAB-142 (2.5 mg/kg) demonstrated preservation in C-peptide levels compared to baseline with mean values increasing above baseline by Day 120. In contrast, the placebo-treated participant showed a decline in C-peptide consistent with the predicted rate of disease progression. For reference, the TN19 Placebo Cohort[1] is modeled using a historical C-peptide trajectory based on historical placebo arm from the TN19 study[1]. By Day 120, participants receiving SAB-142 show divergence from both the study's placebo-treated participant and the TN19 modeled placebo cohort, supporting a PD effect consistent with the preservation of beta cell function in adult patients with established T1D.

Figure 1: T1D Cohort – MMTT C-Peptide Mean AUC (nmol/L) / Min ± SEM



Note: [1] Predicted decline was estimated using placebo MMTT C-peptide AUC data from TN19 (n=31 at screening). Linear modeling of decline was based on Weeks 48, 72, and 96 (n=30, 26, and 26, respectively; post–2-hour values masked). A linear slope (–0.6108) was applied to estimate the rate of decline: AUC_BL – (–0.6108 × [Study Day/7]). Source: Haller et al. Diabetes. 2019 Jun;68(6):1267–1276.

MMTT = Mixed Meal Tolerance Test; AUC = Area Under the Curve; SEM = Standard Error the Mean.

"We believe these Phase 1 data provide an opportunity to bring our early findings to investigators, clinicians, and patients, giving them greater visibility into the science behind SAB-142. By sharing this exploratory C-peptide trend openly, we aim to support informed engagement from the T1D community. While no statistical conclusions can be made, these findings align with our expectations and provide additional confidence as we clinically execute on SAFEGUARD, which is designed and powered to evaluate the safety and efficacy of SAB-142 for patients with new onset T1D," said Samuel J. Reich, CEO, SAB BIO.

Previously, the Company announced the Phase 1 study met its primary objectives of establishing a safety profile and characterizing the PD activity for SAB-142. These results enabled SAB BIO to advance SAB-142 into the registrational Phase 2b **SAF**ety and **E**fficacy of human anti-thymocyte immuno**G**lob**U**lin SAB-142 **AR**resting progression of type 1 **D**iabetes (SAFEGUARD) trial, which is evaluating SAB-142 in adult, adolescents, and pediatric patients with new-onset, Stage 3 T1D. The SAFEGUARD trial is enrolling and dosing participants at multiple sites around the world with topline data expected 2H 2027.

The Phase 1 data is available on the Company's website in the SAB BIO Corporate Presentation, available in the Investors & Media section.

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[1] Haller MJ, Long SA, Blanchfield JL, et al; Type 1 Diabetes TrialNet ATG-GCSF Study Group. Low-Dose Anti-Thymocyte Globulin Preserves C-Peptide, Reduces HbA1c, and Increases Regulatory to Conventional T-Cell Ratios in New-Onset Type 1 Diabetes: Two-Year Clinical Trial Data. Diabetes. 2019;68(6):1267-1276. doi:10.2337/db19-0057

Webinar Details
T1D key opinion leader, Michael J. Haller, M.D., Professor and Chief of Pediatric Endocrinology, University of Florida, provided a recorded webinar reviewing the SAB-142 Phase 1 data, available at: SAB-142 Phase 1 Data in Adult Patients with Autoimmune T1D: Expert Perspective Webinar. The webinar is also available on the Events page of the Company's website.

About the Phase 1 HUMAN Trial of SAB-142
The Phase 1 **HU**man anti-thymocyte biologic in first-in-**MAN** (HUMAN) clinical trial of SAB-142 is a randomized, double-blind, placebo-controlled, single-ascending dose and redose, adaptive design clinical study among healthy volunteers and one cohort of adult participants with established T1D. The study objectives include establishing safety, tolerability, pharmacokinetic (PK), immunogenicity, and pharmacodynamic (PD) profile for SAB-142 with a single 0.03-4.5mg/kg dose plus one cohort with an additional 1.5mg/kg dose.

About the SAFEGUARD Trial
SAFety and **E**fficacy of human anti-thymocyte immuno**G**lob**U**lin SAB-142 **AR**resting progression of type 1 **D**iabetes (SAFEGUARD) trial is a double-arm, multi-center Phase 2b study designed to assess the safety, efficacy, and tolerability of SAB-142 in patients with Stage 3 new onset T1D. SAB-142 is in development as a novel, potentially best-in-class, disease-modifying immunotherapeutic approach to treat T1D by delaying the progression of disease. SAFEGUARD Part A is a dose-ranging study in adult patients. SAFEGUARD Part B is a randomized double-blind, placebo-controlled, dose-ranging study. Enrolled patients will receive two SAB-142 or placebo infusions six months apart. All patients, including the placebo-control group, are eligible for the 12-month long-term extension study upon study completion. Additional details are available on www.clinicaltrials.gov (NCT07187531) and at https://safeguardstudy.com/.

About SAB-142

SAB-142 is a potentially disease-modifying, redosable immunotherapy in clinical development for the treatment of autoimmune type 1 diabetes (T1D). SAB-142 is a multi-specific, fully human anti-thymocyte globulin (hATG) with a mechanism of action analogous to that of rabbit ATG (rATG). rATG has demonstrated in multiple clinical trials the ability to slow disease progression in patients with new- or recent-onset of Stage 3 T1D. SAB-142, like rATG, directly targets multiple immune cells involved in destroying pancreatic beta cells, including modulation of “bad acting” T-lymphocytes. By stopping immune cells from attacking beta cells, this treatment has the potential to preserve insulin-producing beta cells.

About SAB BIO
SAB BIO is a clinical-stage biopharmaceutical company focused on developing multi-specific, high-potency, human immunoglobulin G (hIgG) to treat and prevent immune and autoimmune disorders. Using advanced genetic engineering and antibody science, SAB BIO developed a proprietary technology which holds the potential to generate additional novel therapeutic candidates utilizing the human immune response, without the need for human donors or convalescent plasma. SAB BIO has optimized genetic engineering in the development of transchromosomic cattle, or Tc-Bovine™, to produce hIgG. SAB BIO’s drug development production system is able to generate a diverse repertoire of specifically targeted, high-potency hIgGs that can address a wide range of serious unmet needs in human diseases. The Company’s lead candidate, SAB-142, targets autoimmune T1D with a disease-modifying therapeutic approach that aims to change the T1D treatment paradigm by delaying onset and potentially preventing disease progression of Stage 3 T1D patients. SAB-142 is currently being evaluated in newly diagnosed Stage 3 autoimmune T1D patients in a registrational Phase 2b clinical trial called SAFEGUARD. For more information, visit www.sab.bio.

Forward-Looking Statements
Certain statements made in this press release 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 statements about the development, timing, and clinical trial results of the Company’s 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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A figure accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/ae23719c-8cb3-4ace-8649-929e852b9731