First Patient Dosed in SAB BIO's SAFEGUARD Clinical Trial of SAB-142 for the Treatment of Stage 3 T1D

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- *Enrollment in the SAFEGUARD trial is ongoing at multiple centers globally*
- *Company on-track to share Phase 2b data in 2H 2027*

MIAMI, Dec. 18, 2025 (GLOBE NEWSWIRE) -- SAB Biotherapeutics, Inc. (Nasdaq: SABS), a clinical-stage biopharmaceutical company developing human anti-thymocyte immunoglobulin (hATG) for type 1 diabetes (T1D) and other autoimmune diseases, today announced the dosing of the first patient with SAB-142 in the Phase 2b registrational **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) clinical trial. SAB-142 is in development as a novel, potentially best-in-class, disease-modifying immunotherapeutic approach to treat stage 3 T1D by delaying the progression of disease.

"The first patient treated in the SAFEGUARD study marks a significant milestone for SAB BIO as we are one step closer to advancing our 'Beyond Insulin' vision to bring a potentially safe and effective disease modifying therapy, SAB-142, to approval. SAB-142 is a fully human biologic that targets multiple immune cells implicated in T1D without necessarily killing them. SAB-142 is emerging as a potentially best-in-class treatment for people living with T1D," said Alexandra Kropotova, M.D., MBA, Chief Medical Officer, SAB BIO. "We are focused on the rapid enrollment of our trial with multiple sites activated around the world. The successful initiation of our global Phase 2b trial, combined with robust Phase 1 safety, immunogenicity, and pharmacodynamic data presented earlier this year at major diabetes conferences, provides strong clinical momentum heading into the new year."

Dr. Kropotova added, "I would like to thank the clinical trial participants, their families, the clinicians, and our colleagues at collaborating institutions, including the Australasian Type 1 Diabetes Immunotherapy Collaborative (ATIC), AK Clinical Research, and SAB BIO's global CRO partner, for their invaluable contributions to our clinical trials. We look forward to sharing more updates from our Phase 2b SAFEGUARD trial in 2026."

The SAFEGUARD trial is currently enrolling additional study participants at multiple centers around the globe, including the U.S., Australia, and New Zealand, with European sites joining soon. The first patient in SAFEGUARD was dosed at The Royal Melbourne Hospital (RMH) in Australia by Professor John Wentworth and team.

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 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).

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 like cytotoxic T-cells. 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. 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. 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. For more information, visit www.sab.bio.

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 statements about the development 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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