SAB BIO Highlights Data in Multiple Presentations at EASD

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-As SAB initiates its Phase 2b SAFEGUARD study for SAB-142 in new-onset Stage 3 autoimmune T1D patients, EASD provided an opportunity to connect with many T1D thought leaders that will participate in the study-

-Data in multiple SAB presentations and INNODIA's MELD-ATG study provide further validation for SAB-142 as a novel, potentially best-in-class, disease-modifying immunotherapeutic approach poised to redefine treatment of T1D-

MIAMI, Sept. 19, 2025 (GLOBE NEWSWIRE) -- SAB Biotherapeutics, Inc. (Nasdaq: SABS), ("SAB BIO" or the "Company"), a clinical-stage biopharmaceutical company that is developing human anti-thymocyte immunoglobulin (ATG) for delaying the onset or progression of type 1 diabetes (T1D), today highlighted multiple presentations made at the 61st Annual Meeting of the European Association for the Study of Diabetes (EASD) held from September 15-19, 2025.

The Company had four oral presentations, as well as one invited presentation at an INNODIA-hosted symposium at EASD.

Samuel J. Reich, Chairman and CEO of SAB BIO, stated, "SAB was honored to present both preclinical and Phase 1 data for our multi-specific, fully human anti-thymocyte IgG, SAB-142, which is being evaluated for new-onset Stage 3 autoimmune T1D patients in our Phase 2b SAFEGUARD clinical study. At the conference, we also connected with global patient advocacy groups, principal investigators, and key opinion leaders, to continue building strong partnerships to support the success of this important trial."

Select Presentation Highlights

- On September 15, 2025, Executive Vice President and Chief Medical Officer of SAB BIO, Alexandra Kropotova, M.D., presented at the EASD INNODIA-hosted symposium, "Working to Change the Lives of People Impacted by Type 1 Diabetes Through Unique Disease-Modifying Therapy", on September 16, 2025, Dr. Kropotova presented "Immunomodulation without Sustained Lymphodepletion: SAB-142, a Fully Human Anti-Thymocyte Globulin", and on September 18, 2025, presented "Mechanism of Action of a Fully Human Anti-Thymocyte Globulin, SAB-142, for the Treatment of Type 1 Diabetes".

  In all three presentations, Dr. Kropotova discussed how SAB-142 demonstrated a clinically validated, multi-specific mechanism of action with sustained immunomodulation in a Phase 1 clinical study. Further, SAB-142 does not cause a sustained lymphodepletion unlike rabbit ATG, which causes a decrease in $CD4^+$ T-cells for up to two years. The Phase 1 study was a randomized, double-blind, placebo-controlled, single- and multiple-ascending dose, adaptive design clinical study in 68 healthy volunteers and patients with established T1D. Based on results from the study, SAB-142 has the potential to be a best-in-class T1D immunotherapy.

- On September 18, 2025, Eric Sandhurst, Ph.D., Director, Program Management, at SAB BIO presented, "Novel Pharmacokinetic Assay for Measuring SAB-142, a Fully Human Anti-Thymocyte Globulin", showing SAB-142 demonstrates a dose-proportional and reproductible pharmacokinetic (PK) profile, as measured by a novel PK assay that was validated for accuracy, precision, selectivity and range. Specifically, the study found that SAB-142 offers the optimal combination of a short PK profile and a sustained immunomodulatory effect out to Day 120 and that there were no major differences in the SAB-142 PK profile between healthy volunteers and T1D patients.

Dr. Alexandra Kropotova of SAB BIO commented, “SAB has been working closely with ATIC on advancing SAB-142 from its early days of clinical development and enrollment of Phase 1 patient cohort to the recently initiated Phase 2b SAFEGUARD study. ATIC is leading the charge to bring revolutionary disease modifying therapies to patients in the T1D field. We were very fortunate to be able to leverage their collaborative clinical trial network of leading researchers throughout Australia and New Zealand to have a timely completion of our Phase 1 trial of SAB-142.”

Additionally, at EASD, results from the INNODIA-sponsored MELD-ATG study confirmed the disease-modifying potential of rabbit ATG in new-onset Stage 3 autoimmune T1D patients. The trial met its primary endpoint of C-peptide preservation at 12 months with the 2.5 mg/kg dose, while also identifying 0.5 mg/kg as the minimum effective low dose. In addition, a favorable trend in metabolic outcomes was observed with statistically significant results for HbA1C improvement vs. placebo with the minimum effective low dose.

Mr. Reich commented on the results, “The MELD-ATG study findings presented today further demonstrate the great therapeutic potential of a multi-specific anti-thymocyte therapy for patients with newly diagnosed T1D. The study showed that patients who received rabbit ATG had statistically significant preservation of C-peptide and statistically significant improvement in glycemic control. These results strengthen our confidence and excitement in SAB’s fully human, multi-specific ATG because it has the same validated mechanism of action as rabbit ATG with the potential for an improved safety profile and the ability to re-dose patients which is critical in this patient population.”

INNODIA, which conducted the MELD-ATG study, serves as SAB’s key partner in Europe. Notably, SAB is collaborating with INNODIA and the same leading European T1D centers that recently completed the MELD-ATG study. The INNODIA organization and these centers will now bring their expertise to advance SAB-142 into a Phase 2b clinical study.

About MELD-ATG

Minimum Effective Low Dose (MELD)-anti-thymocyte globulin (ATG) was a Phase 2, double-blind, randomized, placebo-controlled, multi-arm, adaptive dose-ranging, parallel-cohort trial done in 14 accredited trial centers in eight European countries. The study evaluated rabbit ATG in participants aged 5–25 years, diagnosed with clinical, stage 3 type 1 diabetes 3–9 weeks before treatment.

About INNODIA

INNODIA is the largest European Network dedicated to preventing and curing type 1 diabetes and represents the point of contact between those who want to develop new therapies and those who have the tools and experience to do so. INNODIA accelerates the development of therapies to prevent and cure type 1 diabetes.

For more information, visit https://www.innodia.org/.

About EASD Annual Meeting

The EASD Annual Meeting is one of the largest diabetes conferences in the world, attracting thousands of delegates. The program showcases the latest results from basic and clinical research.

For more information, visit https://www.easd.org/annual-meeting/easd-2025/.

About SAB BIO

SAB BIO is a clinical-stage biopharmaceutical company focused on developing human, multi-specific, 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 autoimmune T1D with a disease-modifying therapeutic approach that aims to change the T1D 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 BIO’s 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.

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 Company’s expectations regarding the completion, timing and size of the private placement, the potential exercise of warrants in the private placement, the Company’s expected cash runway, the intended use of the net proceeds, and 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.

CONTACTS

Investor Relations:
Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com

Media Inquiries:
SAB BIO
Sheila Carlson

scarlson@sab.bio