UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 09, 2024

SAB BIOTHERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39871**	**85-3899721**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

777 W 41st St **Suite 401** **Miami Beach, Florida**	**33140**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 305 845-2813

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value per share	SABS	The Nasdaq Stock Market LLC
Warrants, each exercisable for one share of Common Stock	SABSW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 9, 2024, SAB Biotherapeutics, Inc., a Delaware corporation (the "Company" or "SAB"), issued a press release (the "Release") announcing that the Company's Chief Medical Officer will provide an update (the "Presentation") at the European Association for the Study of Diabetes (EASD) 60th Annual Meeting, on the Company's Phase 1 clinical trial, investigating safety, tolerability, pharmacokinetic, pharmacodynamic, and immunogenicity of SAB-142. A copy of the Release is filed herewith as Exhibit 99.1, and a copy of the Presentation is filed herewith as Exhibit 99.2.

The information set forth in this Item 7.01, and in Exhibit 99.1 and Exhibit 99.2, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in this Item 7.01, and in Exhibit 99.1 and and Exhibit 99.2, shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company, dated September 9, 2024
99.2	Presentation of the Company, dated September 9, 2024
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SAB Biotherapeutics, Inc.

Date: September 9, 2024

By: */s/ Samuel J. Reich*

Samuel J. Reich
Chief Executive Officer

EXHIBIT 99.1

SAB BIO Provides SAB-142 Clinical Trial Progress Update at the European Association for the Study of Diabetes Annual Meeting

SAB-142 has completed Phase 1 enrollment of all planned cohorts in healthy volunteers and is progressing to enroll patients with type 1 diabetes in the last cohort of the study.

Target dose of SAB-142 2.5mg/kg completed with no observation of serum sickness.

SAB-142 remains on track for a topline Phase 1 data readout by the end of the year.

MIAMI, September 9, 2024 -- SAB BIO (Nasdaq: SABS) (the "Company" or "SAB"), a clinical-stage biopharmaceutical company with a novel immunotherapy platform developing a human anti-thymocyte immunoglobulin (hIgG) for delaying the onset or progression of type 1 diabetes (T1D), today will offer a trial update on SAB-142 during its presentation at the European Association for the Study of Diabetes (EASD) 60th Annual Meeting in Madrid. SAB's Executive Vice President and Chief Medical Officer Alexandra Kropotova, MD, MBA will present "Protecting pancreatic beta cells with multi-target immunotherapy: SAB-142." SAB-142 is a first-in-class human anti-thymocyte immunoglobulin being developed as a disease-modifying treatment to delay the onset and progression of T1D.

"We are pleased with the continued progress of SAB-142 and its emerging safety profile to date," noted Dr. Kropotova on the data. "Our trial results to date definitively demonstrate a lack of serum sickness for our SAB-142 compound, which is a key differentiation compared to rabbit anti-thymocyte globulin. SAB-142 has demonstrated this fully human anti-thymocyte globulin has an improved safety benefit and the potential to preserve endogenous C-peptide and prevent the progression of type 1 diabetes. We continue to gather SAB-142 data that supports our commitment to developing a disease modifying immunotherapy to change the lives of people impacted by type 1 diabetes."

SAB commenced the Phase 1 clinical trial investigating safety, tolerability, pharmacokinetic, pharmacodynamic, and immunogenicity of SAB-142 in November 2023. The primary objective of the trial is two-fold: (1) to generate data on differentiated safety and immunogenicity of this human immunoglobulin, and (2) to establish a proof of biological activity (POBA) for SAB-142.

The Phase 1 study is a randomized, double-blind, placebo-controlled, single-ascending dose, adaptive design clinical study designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of intravenous SAB-142 first in healthy volunteers and thereafter in participants with T1D.

Enrollment of healthy volunteers has been completed for all planned cohorts. SAB has completed the dosing of 2.5mg/kg with SAB-142 – its targeted dose - with no observation of serum sickness. Additionally, SAB has elected to add a T1D patient cohort to establish safety, tolerability, pharmacokinetic and immunogenicity profile of SAB-142 in patients with T1D prior to initiation of an upcoming Phase II SAFEGUARD study in patients with new-onset T1D. SAB is now progressing to enroll patients with T1D to supplement the last cohort of the study.

About SAB-142

SAB-142 is a human alternative to rabbit anti-thymocyte globulin (ATG). SAB-142's mechanism of action is analogous 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 2.5mg/kg 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 the 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 major adverse immune reactions that can occur with the administration of an animal ATG.

About SAB Biotherapeutics, Inc.

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 can 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: www.SAB.bio and follow SAB on 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 development and efficacy of our T1D program and other discovery programs, including the results of our clinical studies related to SAB-142.

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, 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.

CONTACTS

Kaelan Hollon
Media Relations:
khollon@sab.bio

Investor Relations:

Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com

Chris Calabrese
LifeSci Advisors
ccalabrese@lifesciadvisors.com

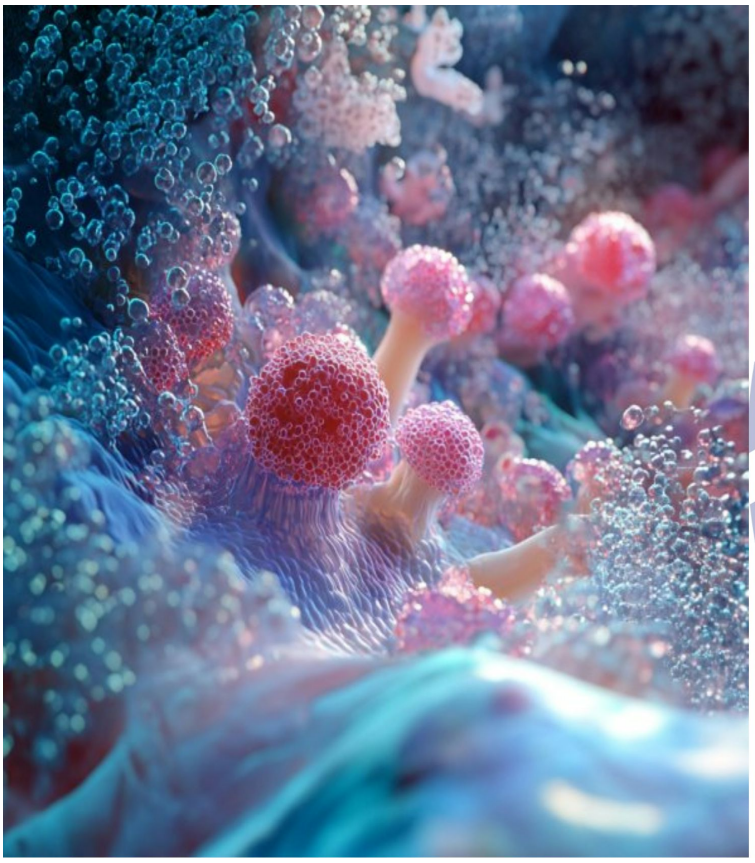
EXHIBIT 99.2

SAB Biotherapeutics

European Association for the Study of Diabetes
60th Annual Meeting

INNODIA SYMPOSIUM

Madrid, Spain
September 9, 2024



Protecting Pancreatic Beta Cells with Multi-target Immunotherapy:

SAB-142

Forward-Looking Statements

The material in this presentation has been prepared by SAB Biotherapeutics, Inc. ("SAB") and is general background information about SAB's activities current as of the date of this presentation. This information is given in summary form and is not intended to be complete. Information in this presentation, including financial forecasts, should not be considered advice or a recommendation to investors or potential investors in relation to holding, purchasing, or selling securities or other financial products or instruments and does not take into account any particular investment objectives, financial situation or needs.

This presentation may contain forward-looking statements including statements regarding our intent, belief, or current expectations with respect to SAB's businesses and operations, market conditions, results of operations and financial condition, capital adequacy, specific provisions, and risk management practices. Readers are cautioned not to place undue reliance on these forward-looking statements. SAB does not undertake any obligation to update any information herein for any reason or to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof to reflect the occurrence of unanticipated events unless required by law. While due care has been used in the preparation of forecast information, actual results may vary in a materially positive or negative manner and the presentation may contain errors or omissions. Forecasts and hypothetical examples are subject to uncertainty and contingencies outside SAB's control. Past performance is not a reliable indication of future performance. The forward-looking statements contained or implied in this presentation are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in SAB's most recent Annual Report on Form 10-K with the Securities and Exchange Commission (the "SEC") and in other filings that SAB makes with the SEC.

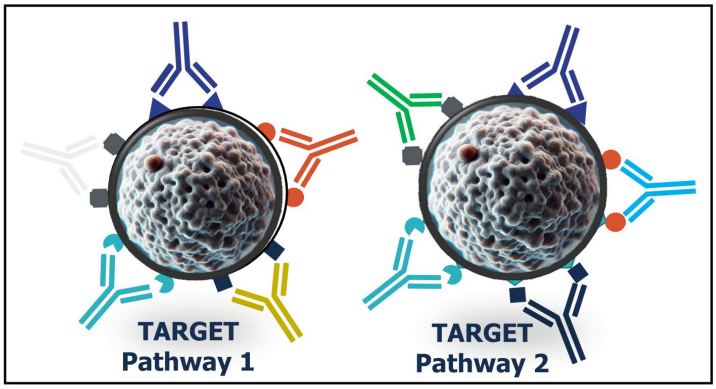
Unless otherwise specified, information is current at the date hereof.

SAB-142 Value: Fully Human Multi-target Immunotherapy

SAB-142 is the first and only fully human multi-target, multi-epitope biologic to enable safe and reliable dosing over a patient's lifetime to delay onset and/or progression of Type 1 Diabetes

SAB-142 Human Anti-Thymocyte Immunoglobulin: Next Generation of Biologics

Natural mixture of many human immunoglobulins that bind to multiple epitopes is regulated as a single product



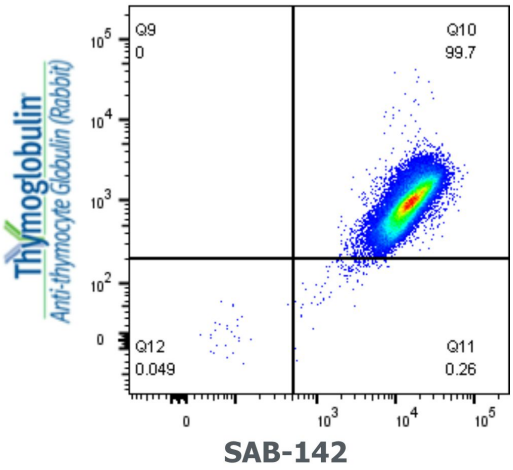
Key product differentiators vs monoclonal antibodies, animal biologics, or small molecule modalities

- Multi-target capability in a single therapeutic
  - Natural multi-epitope targeted hIgG selected and produced *in vivo*
  - Ability to target multiple T1D disease pathways at once
- Specifically driven high-potency titers and avidity
- Potential for better safety & reliable re-dosing due to low risk for immunogenicity and lack of serum sickness

Complex Pathophysiology of T1D Demands Multi-Target Approach

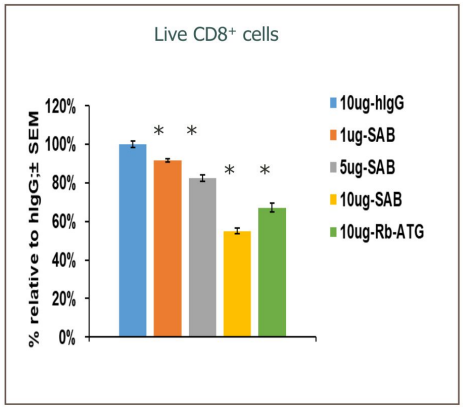
Identical in vitro Binding vs Thymoglobulin

SAB-142 vs. Rabbit THYMO-AF488



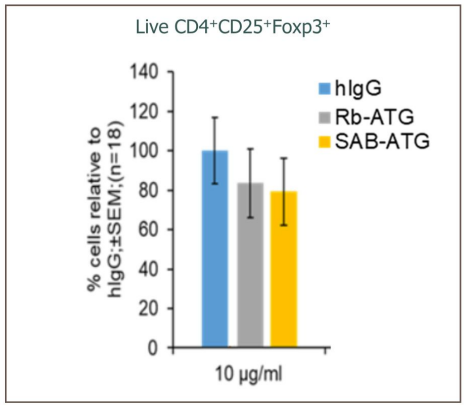
SAB-142 Preserves Treg Cells

CD8 T Cells - Reduction

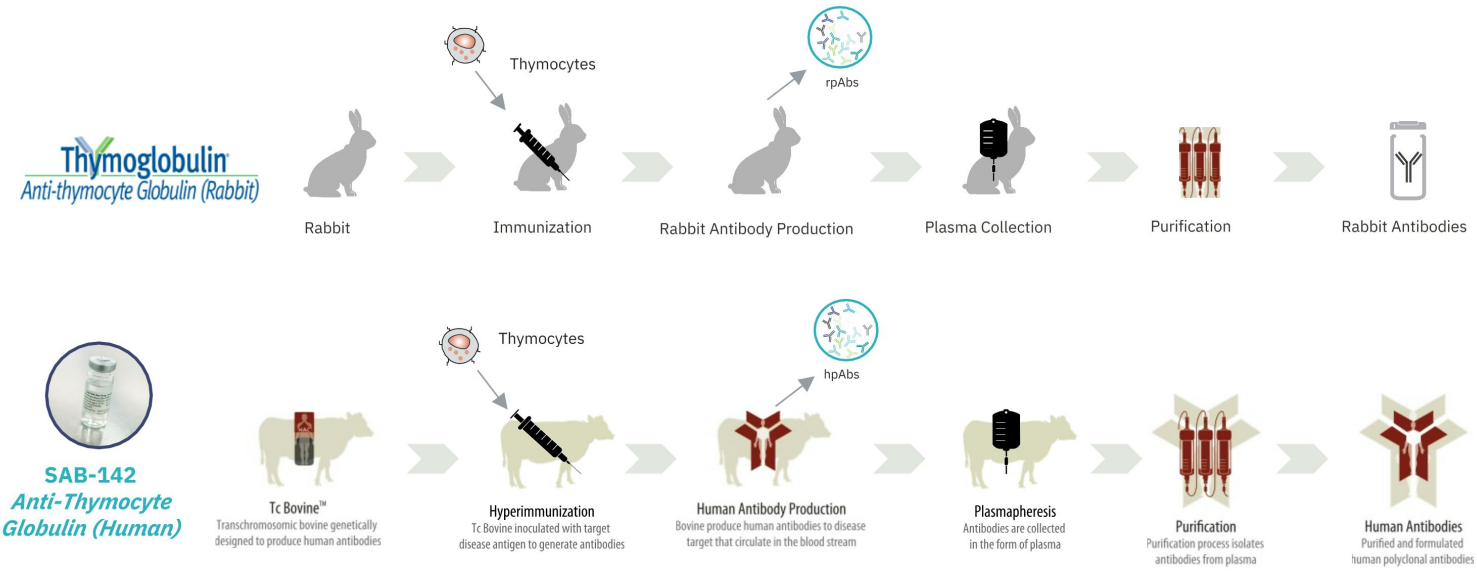


* Indicates p<0.05 compared to negative control hIgG

Treg Cells – No Change



SAB-142 Production is Similar to Thymoglobulin®



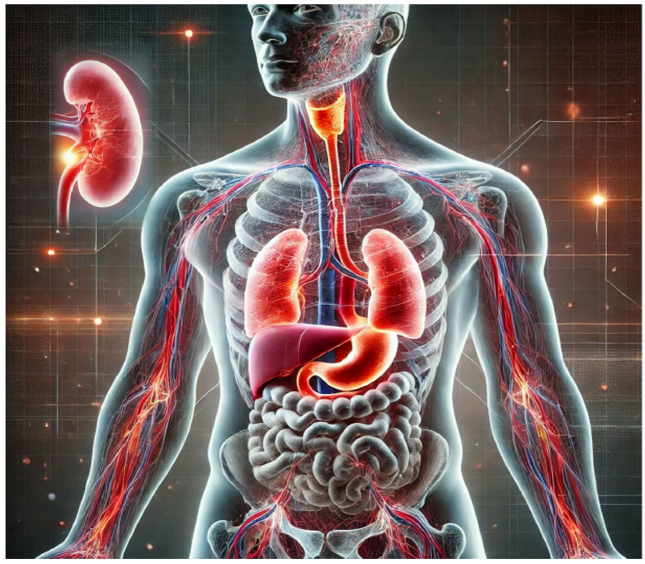
Serum Sickness Associated with Heterologous Biologics

Pathophysiology and treatment

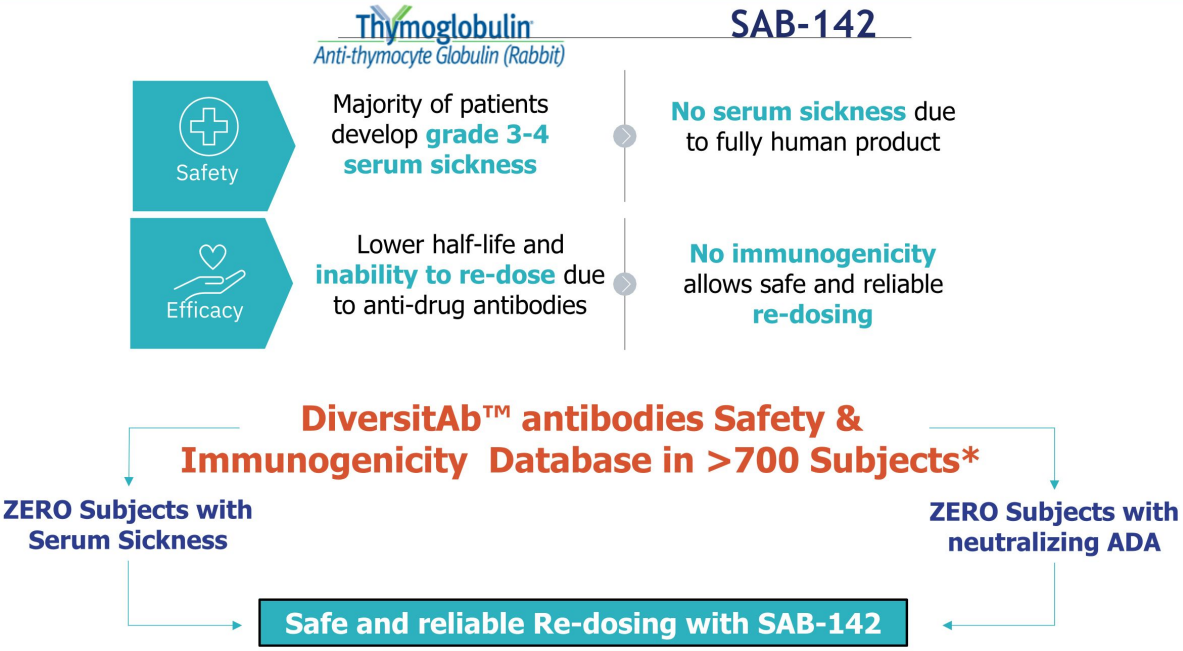
Serum sickness is a type III hypersensitivity reaction that is induced by administration of foreign proteins

- Mediated by immune complex deposition, which leads to complement activation and recruitment of neutrophils by interaction of immune complexes with Fc immunoglobulin G (IgG) receptors
- Circulating immune complexes result in blotchy rash, peripheral edema, join pain, nephrotoxicity, vasculitis classically seen with serum sickness
- Typically managed with systemic steroids administered over several days

Clinical Pathology



SAB-142 Offers Several Distinct Advantages Over Thymoglobulin®



DiversitAb™ antibodies Safety & Immunogenicity Database in >700 Subjects*

ZERO Subjects with Serum Sickness

ZERO Subjects with neutralizing ADA

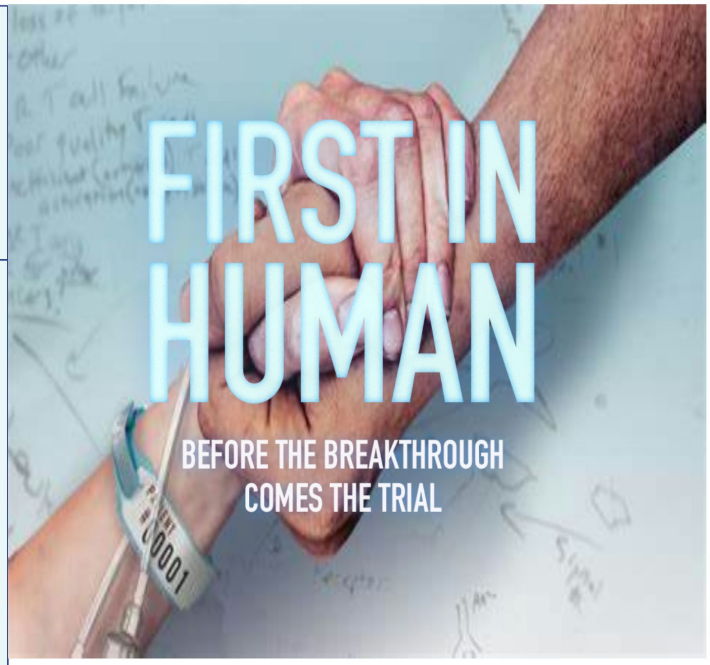
Safe and reliable Re-dosing with SAB-142

* Total patients dosed across multiple DiversitAb™ products

HUMAN Clinical Trial

Fully **HU**man Anti-Thymocyte Biologic in First-in-**MAN**

STUDY DESIGN	**Phase 1: First in Human, Randomized, Double-Blind, Placebo-controlled, Single Ascending Dose trial in healthy volunteers with adaptation to patients with T1D** **SAB-142 doses: 0.03mg/kg, 0.1, 0.5, 1.5 & 2.5mg/kg**
ENDPOINTS	**Primary end point:** Acute (serum sickness, CRS) and long-term (rate of infections) safety **Secondary end points:** pharmacokinetics, pharmacodynamics, immunogenicity/ADA **Major outcomes:** • **Validate safety superiority based on the anticipated 0% of serum sickness and nAbs** • **Validate MoA of SAB-142 in humans** • **Proof of Biological Activity (POBA): change vs baseline in PD markers such as CD3, CD8, CD4, CD4/CD8 ratio, Tregs, and other subsets compared to rATG (cross study)**



Established Differentiated Safety Profile of SAB-142 to Allow Safe and Reliable Dosing: Proven No Serum Sickness

Study Progress

- Completed all planned HV cohorts
- Completed dosing with 2.5mg/kg of SAB-142, preliminary target dose
- Established differentiated safety profile to allow safe and reliable dosing: proven no serum sickness

Completed all planned HV cohorts

SAFEGUARD Trial: Global Collaboration Across Key T1D Centers

SAFEGUARD

SAFety and **E**fficacy of human anti-thymocyte immuno**G**lob**U**lin
SAB-142 **AR**resting progression of type 1 **D**iabetes


United States (FDA)


Europe (EMA)


United Kingdom (MHRA)


Australia (TGA)

4 INDs , 1 CTA, & 1 CTN

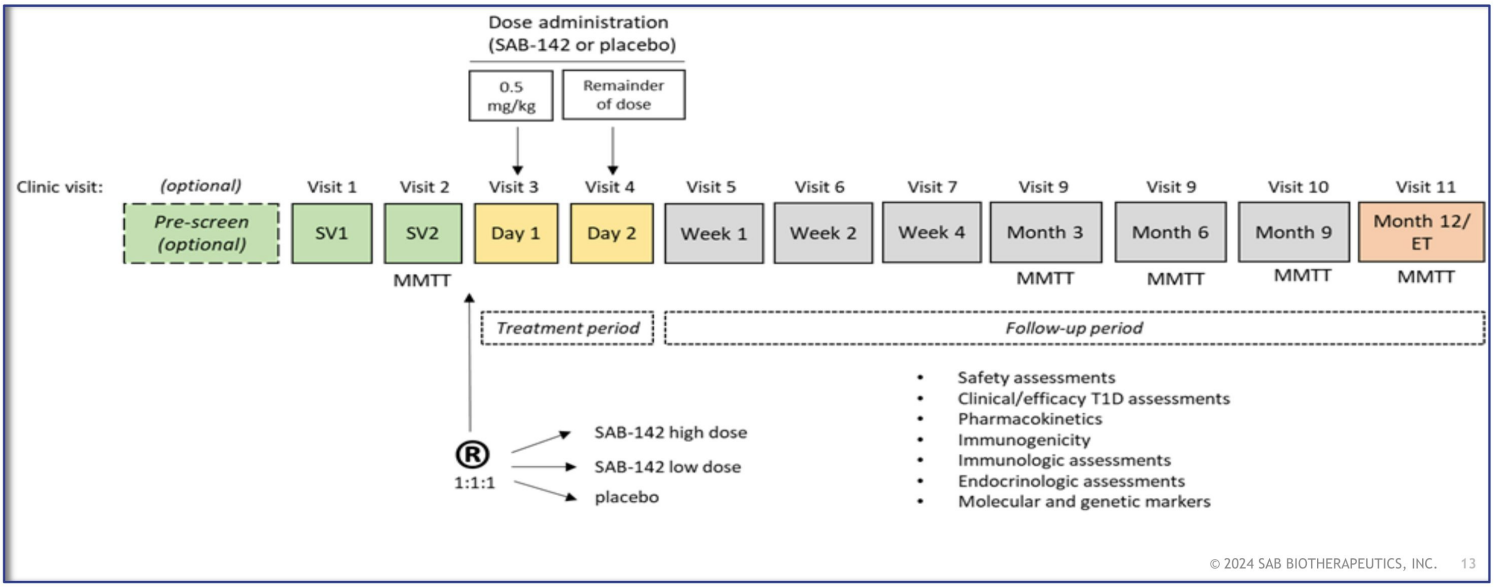
Filed in US and ex-US

8 Clinical Trials

Span from Phase 1 to Phase 3 across 3 indications

SAFEGUARD Study Design

A Phase 2B, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study Evaluating the Efficacy and Safety of SAB-142 for the delay of progression of Type 1 Diabetes in new/recent onset Stage 3 T1D patients



Questions?

- **Contact us @ SAFEGUARD@sab.bio**
- **www.safeguardstudy.com**
- **www.safeguardt1dtrial.net**