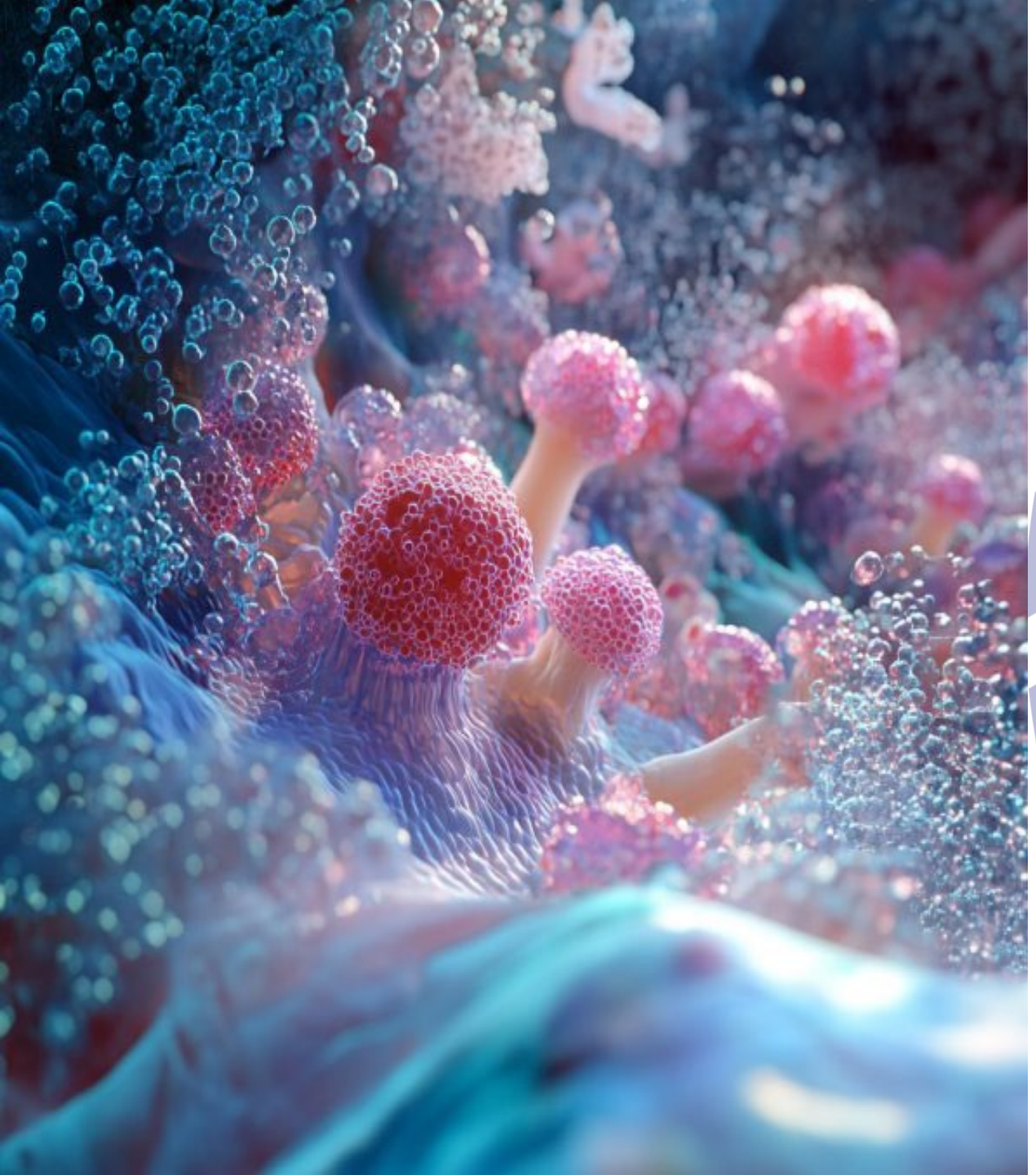
SAB Biotherapeutics

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.

The SAB logo and other trademarks of SAB appearing in this presentation are the property of SAB. All other trademarks, services marks, and trade names in this presentation are the property of their respective owners.

SAB-142 Value: Fully Human Multi-target Immunotherapy

SAB-142 is the first

and only fully human multi-target,

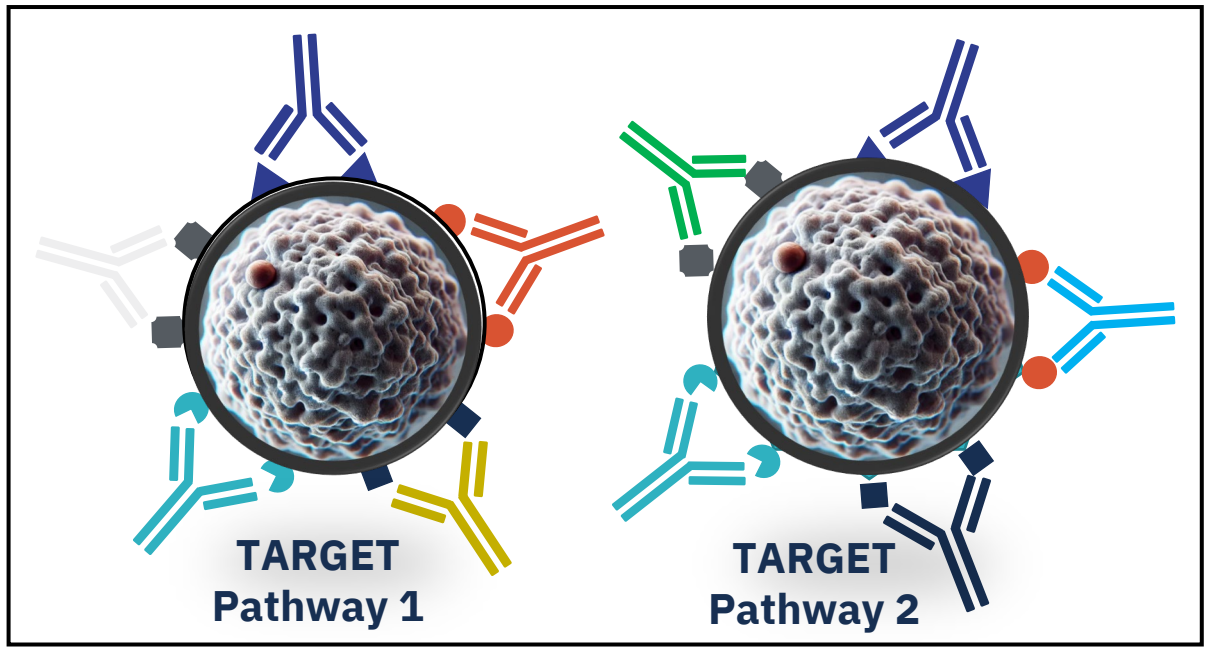
multi-epitope biologic

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



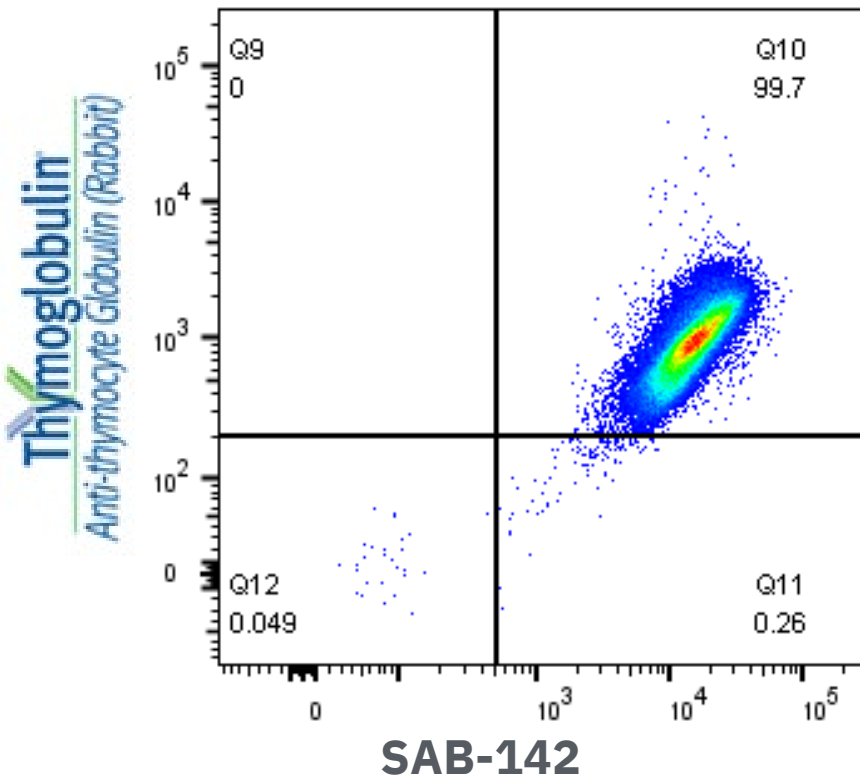
Key product differentiators vs monoclonal antibodies, animal biologics, or small molecule modalities

- 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

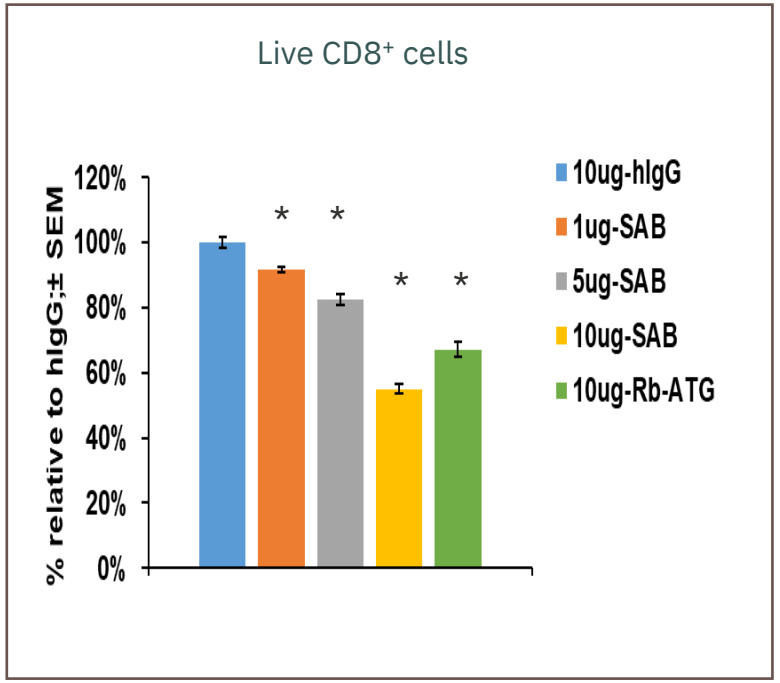
Identical in vitro Binding vs Thymoglobulin

SAB-142 vs. Rabbit THYMO-AF488



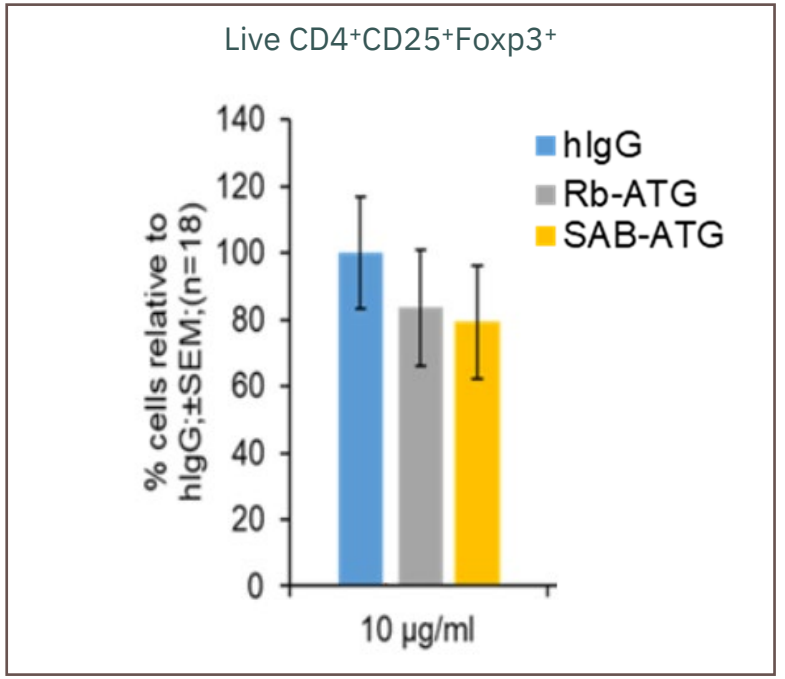
SAB-142 Preserves Treg Cells

CD8 T Cells - Reduction



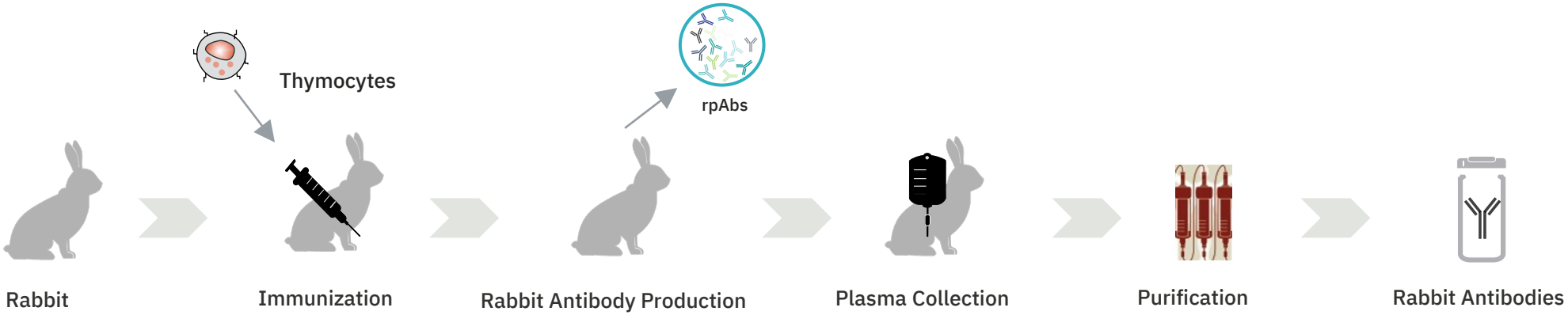
* Indicates p<0.05 compared to negative control hIgG

Treg Cells – No Change

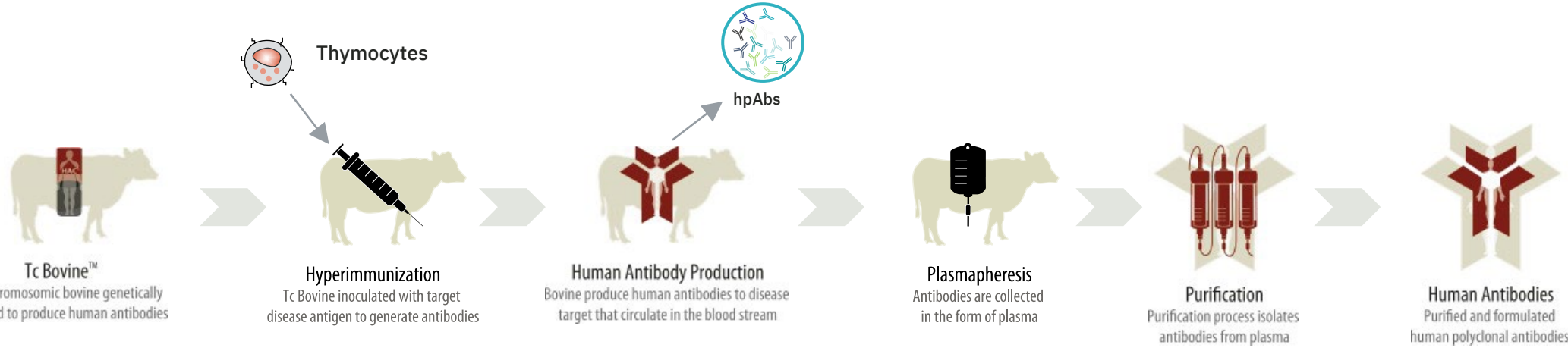


SAB-142 Production is Similar to Thymoglobulin®

Thymoglobulin®
Anti-thymocyte Globulin (Rabbit)



SAB-142
Anti-Thymocyte
Globulin (Human)



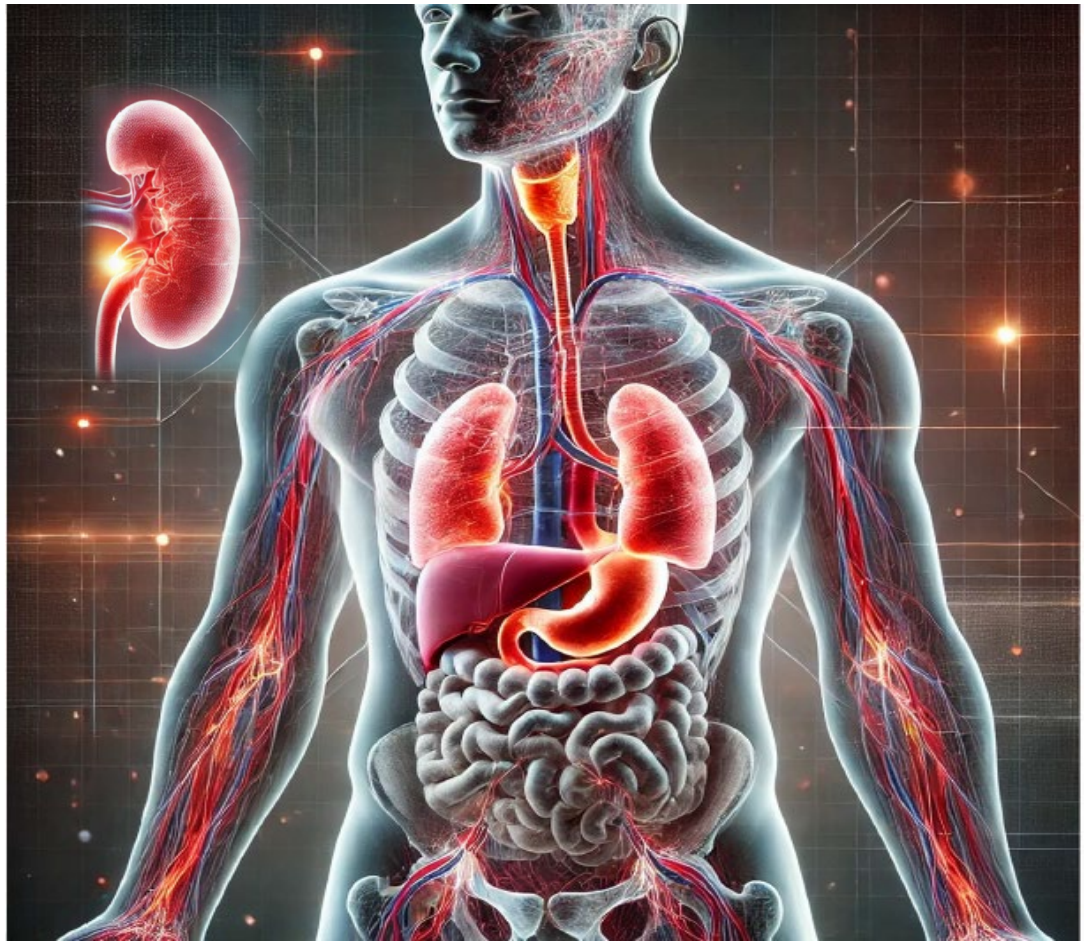
Serum Sickness Associated with Heterologous Biologics

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®

	Thymoglobulin® Anti-thymocyte Globulin (Rabbit)	SAB-142
Safety	Majority of patients develop **grade 3-4 serum sickness**	**No serum sickness** due to fully human product
Efficacy	Lower half-life and **inability to re-dose** due to anti-drug antibodies	**No immunogenicity** allows safe and reliable **re-dosing**

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

ZERO Subjects with Serum Sickness

ZERO Subjects with neutralizing ADA

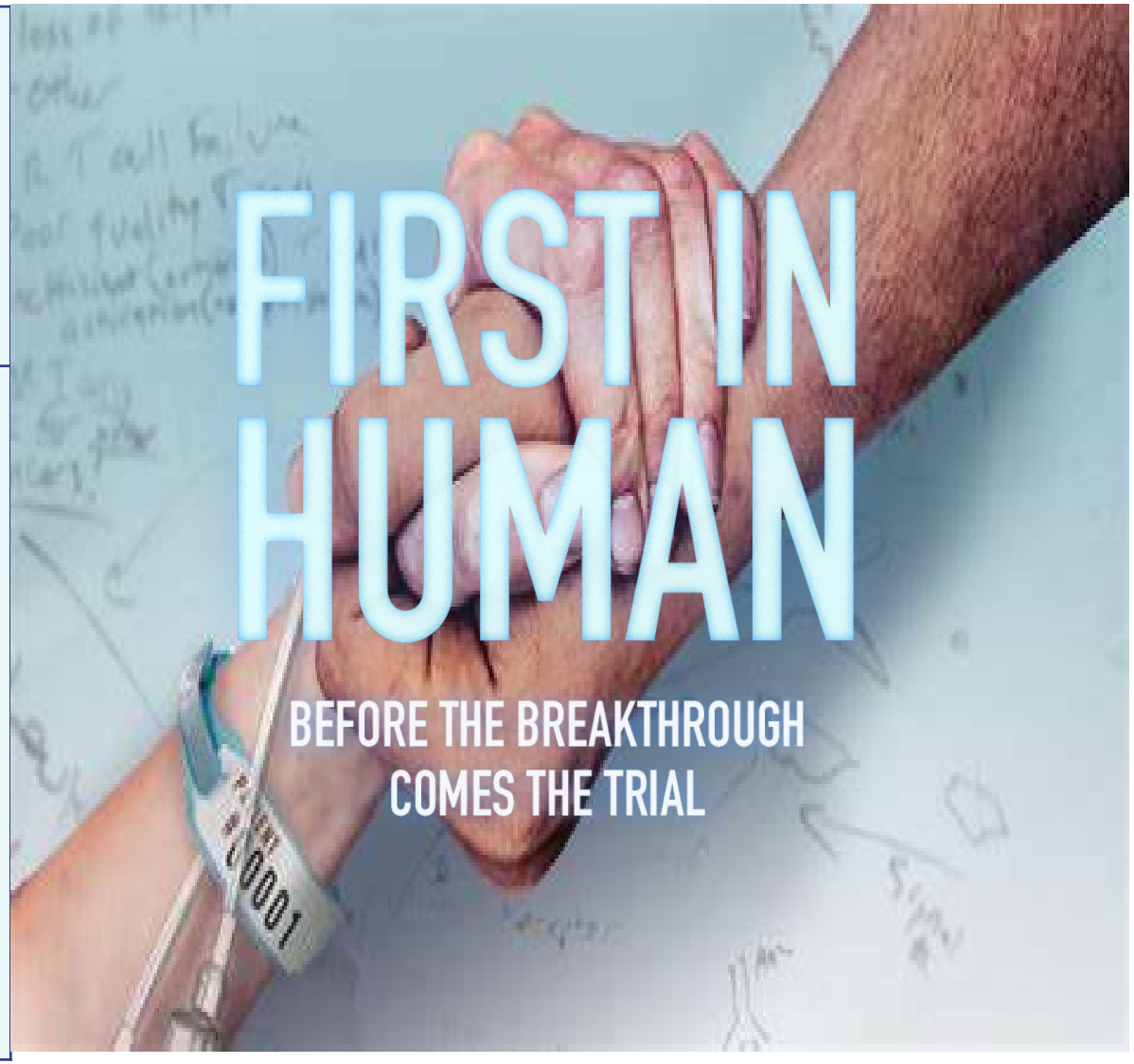
Safe and reliable Re-dosing with SAB-142

* 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 Efficacy of human anti-thymocyte immunoGlobUlin
SAB-142 ARresting progression of type 1 Diabetes


United States (FDA)


Europe (EMA)


United Kingdom (MHRA)


Australia (TGA)

4 INDs , 1 CTA, & 1 CTN

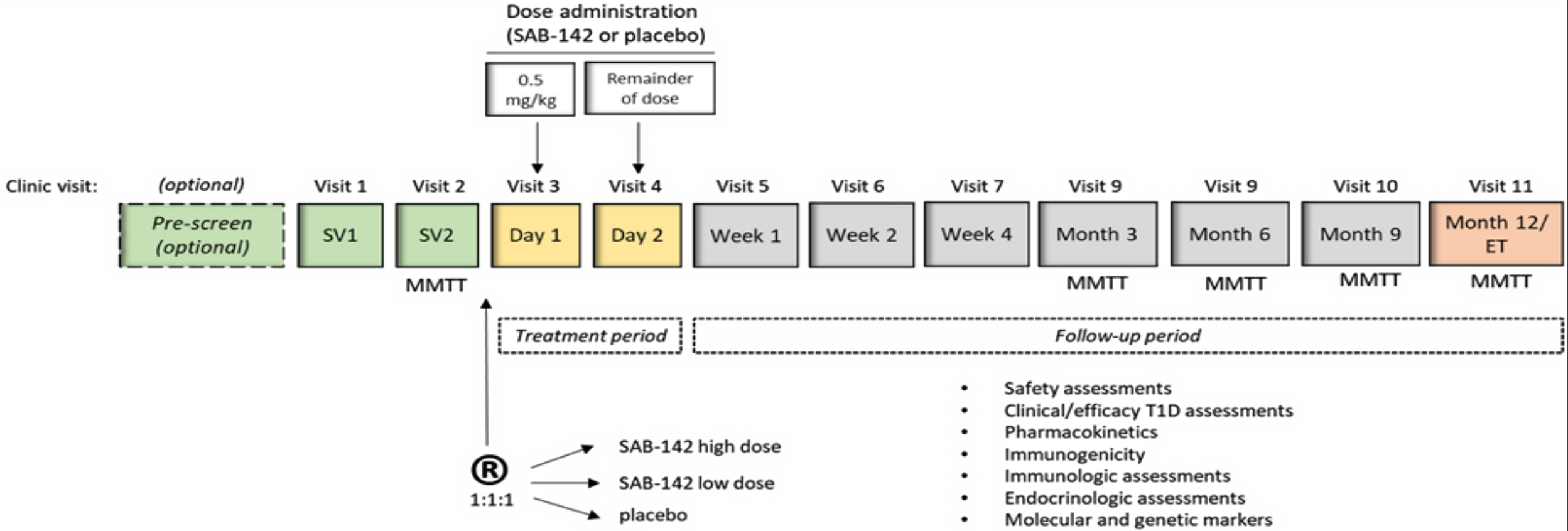
Filed in US and ex-US

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