



# **HUMAN ANTI-THYMOCYTE BIOLOGIC DEVELOPED TO DELAY ONSET OR PROGRESSION OF TYPE 1 DIABETES**

**SAB BIOTHERAPEUTICS INTRODUCTION**

**Q2 2024**

**NASDAQ: SABS**

# Forward-Looking Statements



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# Executive Summary



- SAB Biotherapeutics is a next generation polyclonal antibody platform company with human data in 700 patients, currently focused on prevention of Type 1 Diabetes (T1D).
- Well-capitalized by a syndicate of investors including top tier funds and experts in diabetes.
- Lead candidate is SAB-142, which offers the potential for durable disease modification in T1D based on clinical evidence and has the support of key opinion leaders.
- Strategic validation for new drugs for prevention of T1D was demonstrated by Sanofi's acquisition of Provention Bio for \$2.9B in 2023.
- Phase 1 data for SAB-142 is expected by YE 2024 with a goal of demonstrating a best-in-class therapeutic profile for the prevention and disease modification of T1D.

## Committed T1D Clinical Development and Investor Partners

- **T1D Committed Investor Partners:** Financing of up to \$110 million in gross proceeds dedicated to clinically advance SAB-142 to 2026 and Topline Phase 2 results:
  - ❖ Sessa Capital
  - ❖ BVF Partners
  - ❖ RTW Investments
  - ❖ Marshall Wace
  - ❖ ATW
  - ❖ JDRF T1D Fund
- **T1D Clinical Development Partner:** SAB-142 clinical development plan designed in partnership with the Juvenile Development Research Foundation (JDRF)

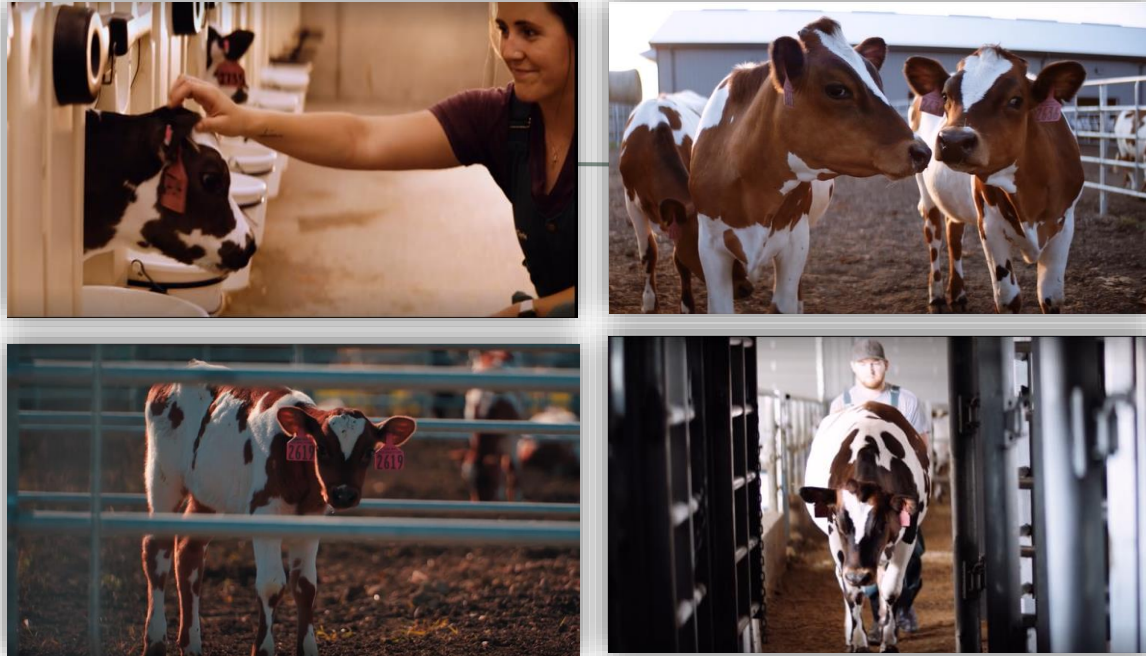




# **SAB Platform:** Transchromosomic Bovine, **Tc Bovine™**

# Human Immunoglobulin G Produced in Transchromosomal Bovine

Tc Bovine™ contain all the human immunoglobulin genes



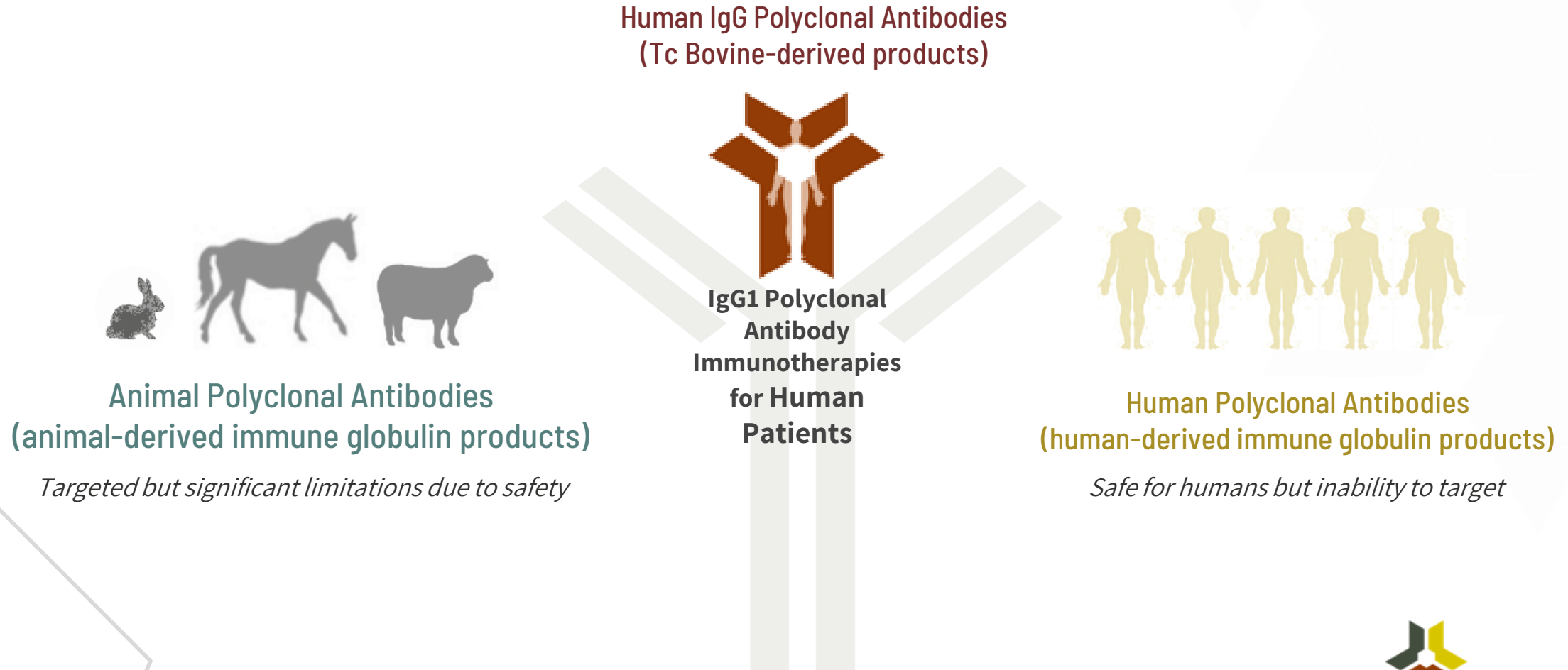
## Tc Bovine™

- Only transgenic animal that carries the entire human immunoglobulin (Ig) heavy and light ( $\kappa$ ) chain loci.
- HAC is subject to mitosis along with the other 60 Tc Bovine™ chromosomes.
- HAC present in the Tc Bovine™ allows for the highest production of human immunoglobulin repertoire most similar to humans.
- Human Artificial Chromosome (HAC) ~17Mb contains the entire unarranged VDJ human immunoglobulin loci (IgH + Ig $\kappa$ )

**Tc Bovine™ allows SAB to be the only company in the world that can produce truly polyclonal human antibodies without the need for human donors.**

# Clinical Regulatory Path for IgG Polyclonal Antibody Products

40+ FDA Approved through the Center for Biologics Evaluation and Research (CBER)



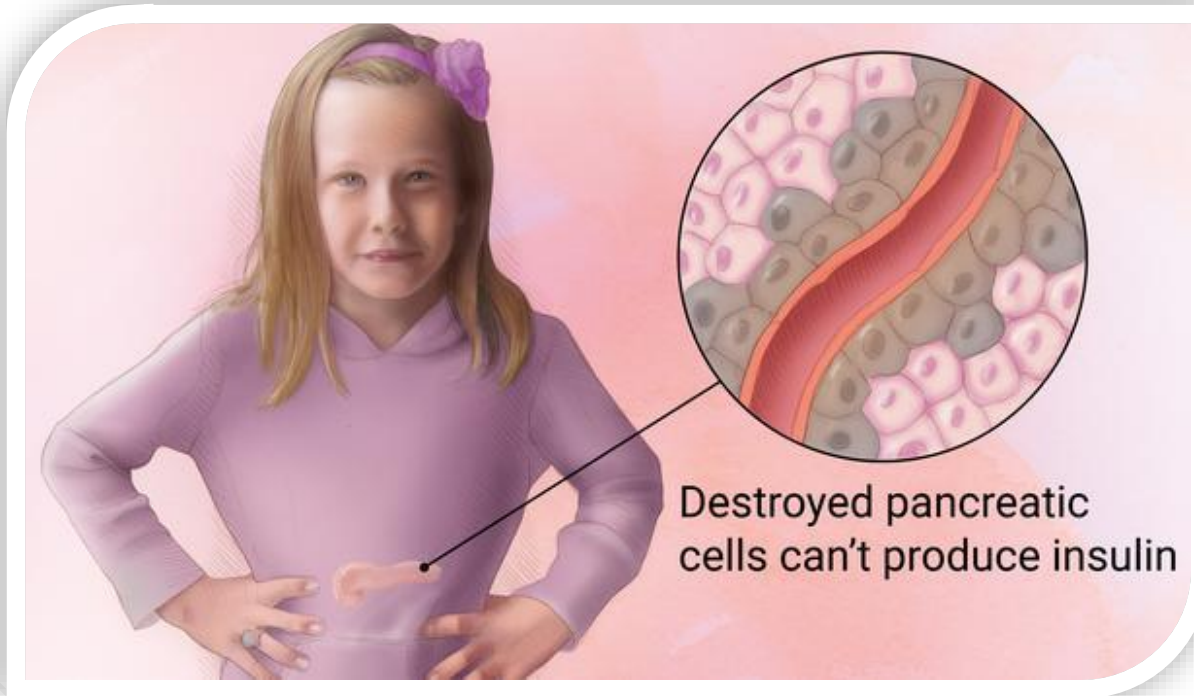


## **SAB-142:**

Human Anti-Thymocyte Globulin for the  
Prevention of Type 1 Diabetes (T1D)

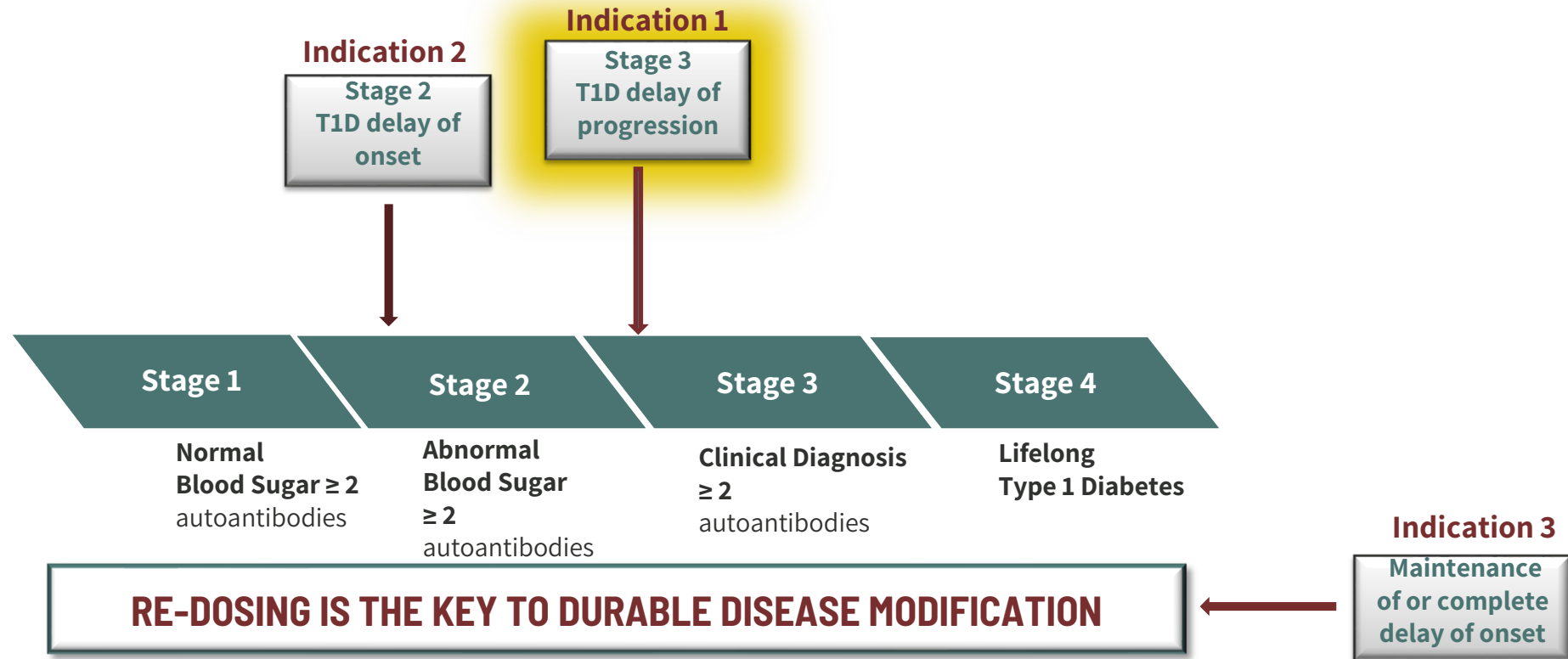


# What is Type 1 Diabetes?



- ❖ **Type 1 Diabetes is an autoimmune disorder** caused by destruction of insulin producing beta-cells in the pancreas from the patient's own immune system.
- ❖ Anyone can get it, but it is most often diagnosed in young children with an **average age at diagnosis of 13 years old** with increased risk if a parent has been diagnosed with the disease.
- ❖ It is a **lifelong disease** with no current cures and many **life-altering** implications.

# SAB-142 has Strong Potential to Control or Prevent T1D Over the Entire Life Span



**Ages: from birth to early adulthood  
average age of onset: 13 years old**

**Ages: Average life expectancy  
~72 years of age**

# Disease Modification is Just Beginning

SAB-142: Fully-human profile has the potential to advance Standard of Care



## Stage 2 Prevention Market



Projected to reach >\$1B in WW sales<sup>1</sup> by 2028

## Stage 3 Recent Onset Market

64k

64k patients are diagnosed with T1D in the US every year<sup>2</sup>

*In the US, only family relatives are screened for T1D (<10% of patients), but screening programs are expanding*

*With insulin as the only treatment option, patients lose residual beta-cell function over time*



\$2.9B Sanofi acquisition of Provention Bio illustrates **value of prevention market**



SAB-142 – **currently in clinical development** – is positioned to address unmet need in recent onset patients

1. Source: Analyst consensus forecast (Evaluate Pharma)  
2. Rogers MAM, Kim C, Banerjee T, Lee JM. Fluctuations in the incidence of type 1 diabetes in the United States from 2001 to 2015: a longitudinal study. BMC Med. 2017 Nov 8;15(1):199. doi: 10.1186/s12916-017-0958-6. PMID: 29115947; PMCID: PMC5688827.



# **SAB-142:** Mechanism of Action

# Proven Mechanism of Action

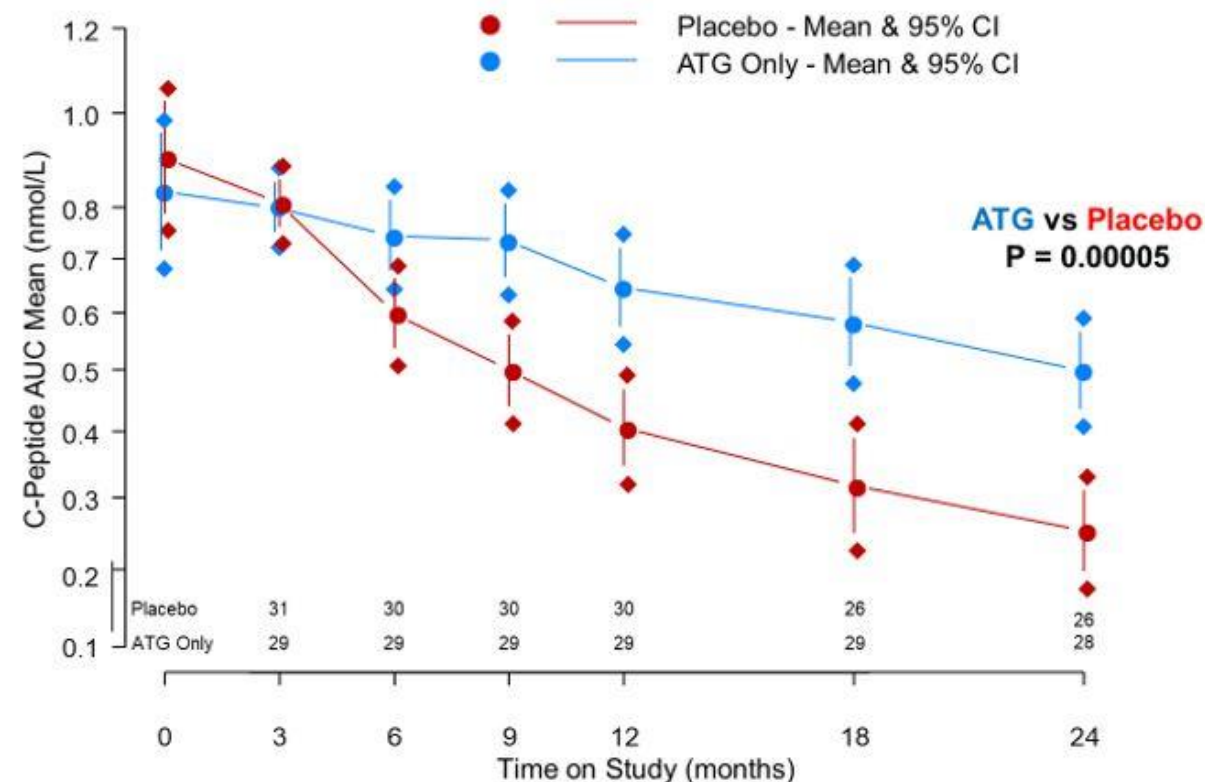
2 Years: Low-Dose ATG\* Preserved C-Peptide in New Onset T1D



**Thymoglobulin**  
Anti-thymocyte Globulin (Rabbit)

C-peptide is a measure of person's ability to produce endogenous insulin and is an accepted marker for pancreatic beta cell function.

Decline in C-Peptide AUC Mean Over Time by Treatment Group

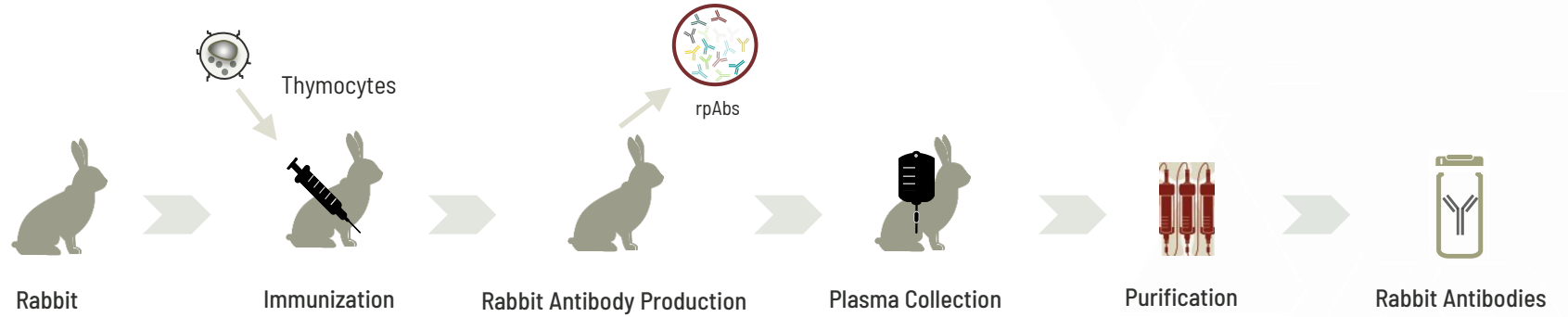


Haller et al. Diabetes. 2019. Jun;68(6):1267-1276

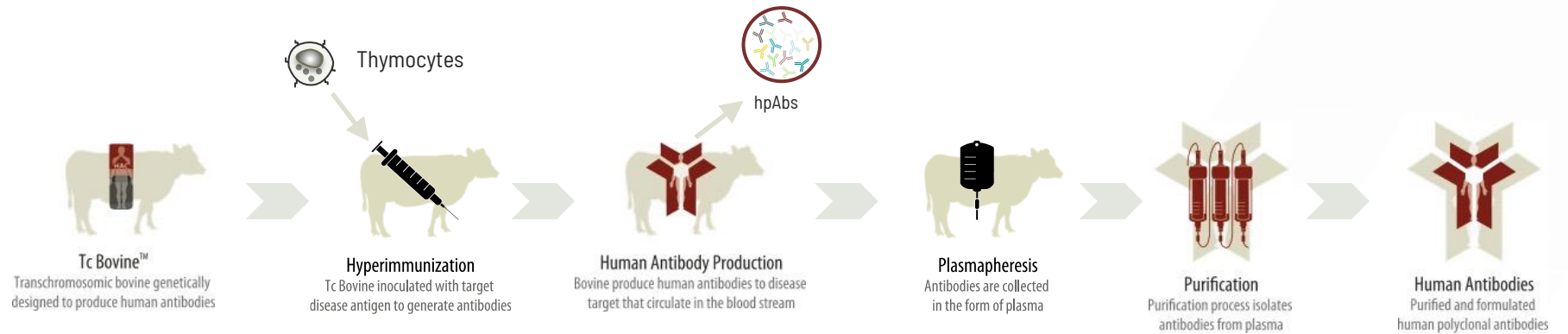
Haller MJ, Long SA, Blanchfield JL, Schatz DA, Skyler JS, Krischer JP, Bundy BN, Geyer SM, Warnock MV, Miller JL, Atkinson MA, Becker DJ, Baidal DA, DiMeglio LA, Gitelman SE, Goland R, Gottlieb PA, Herold KC, Marks JB, Moran A, Rodriguez H, Russell WE, Wilson DM, Greenbaum CJ; Type 1 Diabetes TrialNet ATG-GCSF Study Group. Low-Dose Anti-Thymocyte Globulin Preserves C-Peptide, Reduces HbA<sub>1c</sub>, and Increases Regulatory to Conventional T-Cell Ratios in New-Onset Type 1 Diabetes: Two-Year Clinical Trial Data. Diabetes. 2019 Jun;68(6):1267-1276.

# SAB-142 Production Analogous to FDA-Approved rabbit ATG

**Thymoglobulin<sup>®</sup>**  
*Anti-thymocyte Globulin (Rabbit)*

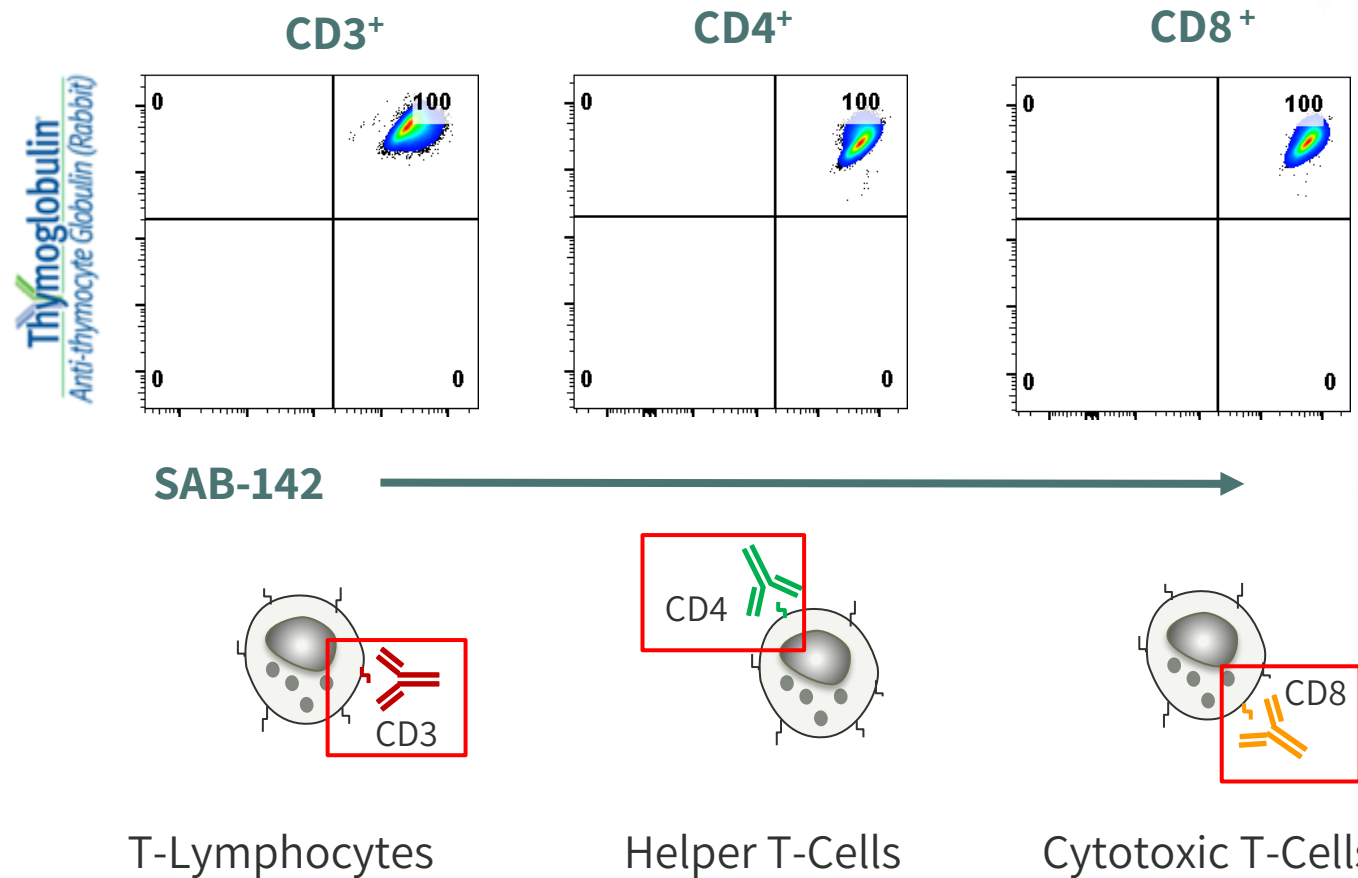


**SAB-142**  
*Anti-Thymocyte Globulin (Human)*



# SAB-142 Demonstrates Similar T-Cell Subset Binding Profile as rATG

Targets T-cells (CD3<sup>+</sup>), T-Helper Cells (CD4<sup>+</sup>), and T-Killer Cells (CD8<sup>+</sup>) similar to rATG suggesting similar multi-target binding



# SAB-142 Offers Several Distinct Advantages to rabbit ATG



**Thymoglobulin**  
*Anti-thymocyte Globulin (Rabbit)*

**SAb**  
BIOThERAPeUTICS



Safety

Majority of patients develop **grade 3 serum sickness**



**No serum sickness expected** due to fully human product



Efficacy

Lower half-life and **inability to re-dose** due to anti-drug antibodies



Improved PK and **opportunity to re-dose**

**SAB-142 Human Safety & Immunogenicity Database in >700 Subjects**

**ZERO Subjects with Serum Sickness**

**ZERO Subjects with neutralizing ADA**



# Comparing Teplizumab & Thymoglobulin in Stage 3

	<b>Teplizumab (TzielD) Phase 3 study</b>	<b>Thymoglobulin Phase 2 data</b>	<b>Take-away/Added Value</b>
<b>Age</b>	8-17yo	12-45yo	<b>Rabbit ATG shown to work in the broader range of patients, i.e. adults &amp; pediatric/adolescent</b>
<b>Dosing</b>	Two courses of IV daily therapy for 12 days, at Month 1 and Month 6	A single dose of IV administered over 2 days	<b>ATG has more convenient dosing regimen</b>
<b>Primary time point</b>	Week 78 (1.5 years)	Week 52 (1 year)	<b>Requires 2 courses and longer time to primary end point</b>
<b>Sample size</b>	200 on TZIELD, 100 on PBO	29 on ATG, 31 on PBO	<b>ATG has stronger efficacy that required smaller sample size to show significant results</b>
<b>C-peptide</b>	Primary end point of C-peptide levels met at Week 78	Primary end point of C-peptide AUC met at Week 52	<b>ATG showed larger AUC C-peptide efficacy vs PBO</b>
<b>HbA1C</b>	No stat significant data	Statistically significant data at Week 52	<b>ATG showed stat significant clinical results on HbA1C</b>



# **SAB-142:** Clinical Development Plan



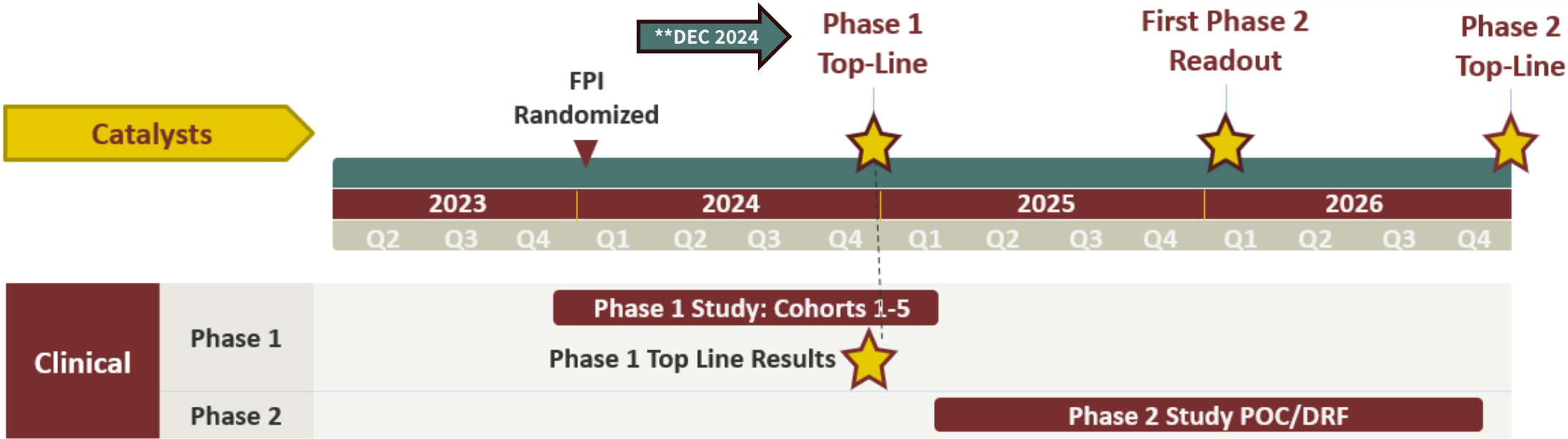
## Phase 1: Randomized, Single Ascending Dose trial SAB-142 dose range: 0.03mg/kg up to 2.5mg/kg

### 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 CD3, CD8, CD4, CD8/CD4 ratio, Tregs compared to rabbit ATG (cross study)

**Topline Data Expected in Q4 2024**

# SAB-142 Key Milestones



### Phase 1 / Phase 2 Major Outcomes:

- 0% serum sickness
- 0% Anti-Drug Antibodies
- Superior efficacy vs TZIELD on C-peptide
- Superior efficacy vs TZIELD on HbA1C

**COMPANY PHASE I UPDATE: Third cohort has been fully enrolled and dosed  
No Serum Sickness Observed**



# Durable Disease Modification Can Change the Lives of T1D Patients



- An 8-year-old girl, whose father also has also type 1 diabetes, tested positive for auto-islet auto antibodies.
- Diagnosis of stage 2 T1D was later confirmed, and her physician administered a single 2.5mg/kg dose of rabbit ATG.
- After 4 years of follow-up, the patient had not progressed to stage 3 T1D. In fact, this patient is no longer experiencing dysglycemia. Her most recent oral glucose tolerance test was entirely normal.
- **She does not require insulin four years after treatment.**

With permission from Michael J. Haller, MD, MS-CI  
University of Florida College of Medicine  
Professor and Chief Silverstein Family Eminent Scholar Pediatric Endocrinology

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