



# CORPORATE PRESENTATION

SAB BIO Introduction  
Q4 2024



**NASDAQ: SABS**

# Forward-Looking Statements



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- **Founded in 2014**
- **Public on Nasdaq since 2021**
- **Lead candidate is SAB-142 for type 1 diabetes (T1D), a human anti-thymocyte globulin**
- **Top line 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**



**SAB BIO Corporate Headquarters, Miami, FL**



**SAB BIO R&D facilities, Sioux Falls, SD**

# Investment Summary



**First-ever transgenic platform** can generate a diverse repertoire of specifically targeted, high-potency, human IgGs without the need for convalescent plasma or human donors



**Human safety and immunogenicity data in over 700 patients** on the fully human IgGs produced by the proprietary platform



Lead candidate is **SAB-142 for T1D patients, which potentially offers durable disease modification and infrequent annual dosing** based on prior clinical evidence in a validated mechanism of action



Strategic validation for **new disease-modifying therapies in T1D was demonstrated by Sanofi's acquisition of Provention Bio** (TZIELD, post-approval) for \$2.9B in 2023



**Well-capitalized** by a syndicate of investors including both top tier funds and diabetes experts

**Phase 1 data for SAB-142 is expected by YE 2024** with a goal of demonstrating a favorable safety and pharmacodynamic profile



# Committed T1D Investor and Clinical Development Partners



- **T1D Committed Investor Partners:** Financing of up to \$110 million in gross proceeds dedicated to clinically advance SAB-142 into 2026:
  - ❖ Sessa Capital
  - ❖ BVF Partners
  - ❖ RTW Investments
  - ❖ Marshall Wace
  - ❖ ATW
  - ❖ T1D Fund
- **T1D Clinical Development Partner:** SAB-142 clinical development plan designed in partnership with Breakthrough T1D (formerly JDRF)



**SAB Platform:**  
Transchromosomal Bovine  
**Tc Bovine™**



# Our Revolutionary Platform: Human Immunoglobulin G (IgG) Produced in Transchromosomal Bovine



Tc Bovine™ contain all the human immunoglobulin genes



## Tc Bovine™

- Cows are the only transgenic animal that carry the entire human immunoglobulin (Ig) heavy and light ( $\kappa$ ) chain loci
- Human Artificial Chromosome (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
- HAC ~17Mb contains the entire unarranged VDJ human immunoglobulin loci (IgH + Igk)

**SAB is the only company in the world that can produce truly polyclonal human antibodies without the need for human donors through its Tc Bovine™ platform.**

# Established Regulatory Path for IgG Polyclonal Antibody Products



40+ FDA-approved IgG products through the Center for Biologics Evaluation and Research (CBER)

Human IgG Polyclonal Antibodies  
(Tc Bovine-derived products)

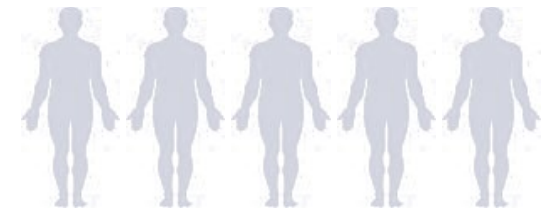


**IgG1 Polyclonal  
Antibody  
Immunotherapies  
for Human  
Patients**



Animal Polyclonal Antibodies  
(animal-derived immune globulin products)

*Targeted but significant limitations due to safety*



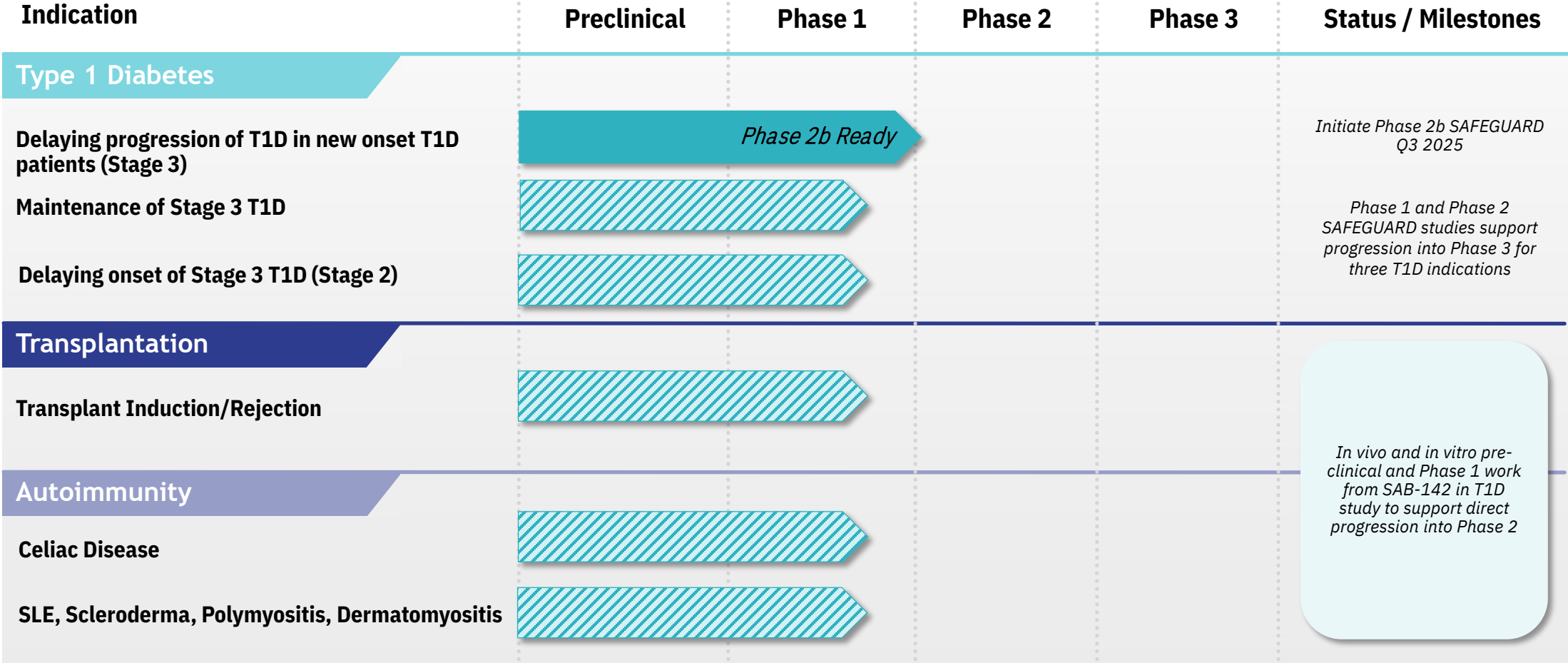
Human Polyclonal Antibodies  
(human-derived immune globulin products)

*Safe for humans but inability to target*

*Aiming for a targeted therapy and improved safety profile*



# SAB-142: Pipeline Overview



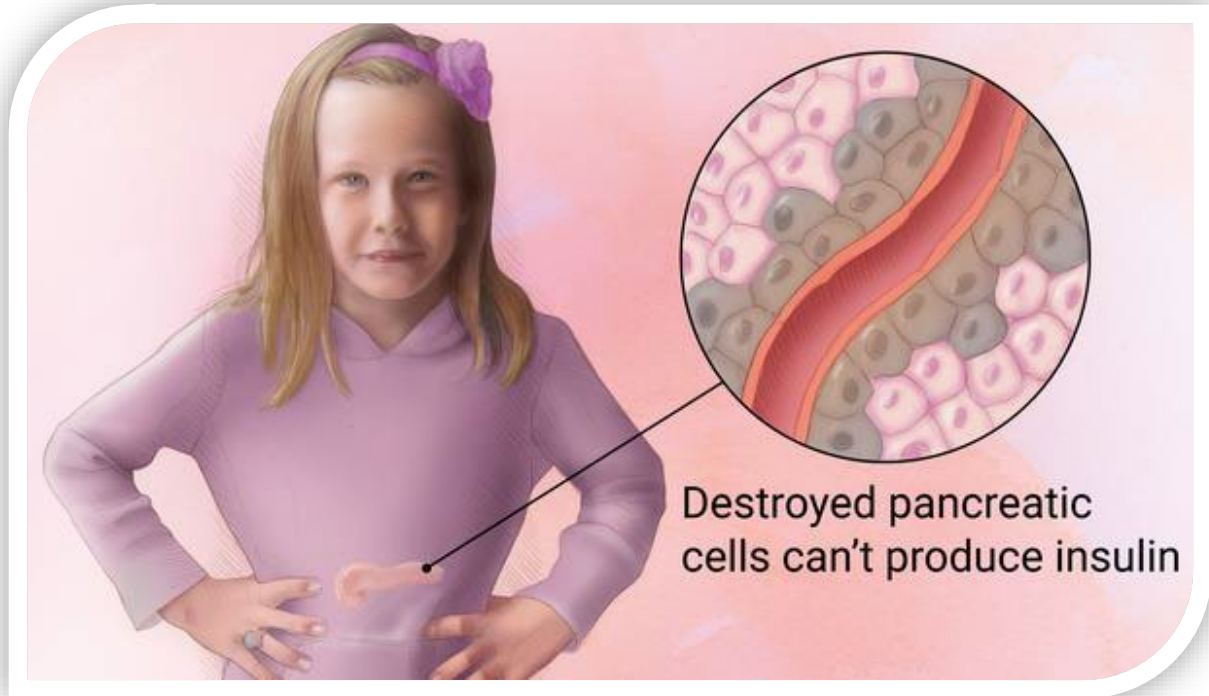
■ Current Studies  
▨ Potential future anticipated studies

# **SAB-142:**

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



# What is Type 1 Diabetes?



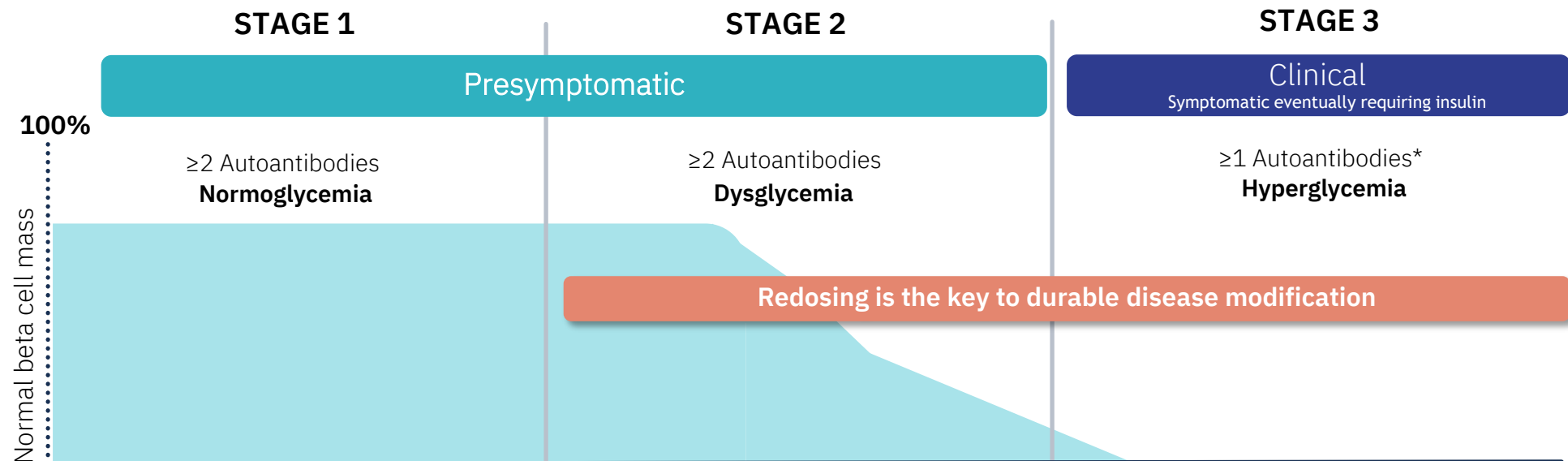
- ❖ **Type 1 diabetes is an autoimmune disorder** and caused by destruction of insulin producing beta-cells in the pancreas from the patient's own immune system
- ❖ Anyone can get it, but it is most often diagnosed in young children with an **average age at diagnosis of 13 years old** with increased 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 Potential to Control or Prevent T1D Across the Continuum of the Disease



In 2015, the ADA, Breakthrough T1D/JDRF, and Endocrine Society reclassified T1D as occurring in 3 progressive stages.

Stages are identified by the presence of multiple autoantibodies and abnormal or increasing glycemic levels.



Serious chronic complications of T1D include nephropathy, neuropathy, retinopathy, heart disease, peripheral arterial disease, cerebrovascular disease, and diabetic foot infections.

These complications exist even when patients are on insulin.

# Disease Modification is Just the Beginning

## Stage 2 T1D Prevention Market



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

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



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

## Stage 3 Recent T1D Onset Market

64k

64k patients are diagnosed with T1D in the US every year<sup>2</sup> **Stage III represents ~90% of total T1D market**

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



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



# SAB-142: The Only Human Polyclonal Disease Modifying Agent



- SAB-142 is a human alternative to rabbit anti-thymocyte globulin (Thymoglobulin)
- 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
- SAB-142, like rabbit ATG, directly targets multiple immune cells involved in destroying pancreatic beta cells
- Most humans treated with rabbit ATG develop serum sickness and anti-drug antibodies from exposure to the rabbit-derived antibody
- SAB-142 is human IgG, and therefore immunogenicity is not expected to occur as it does with animal IgG's

# SAB-142 Offers Distinct Advantages to Rabbit ATG



Thymoglobulin has achieved ~\$500M sales despite use primarily in organ transplant patients

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



Safety

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



Efficacy

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

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

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

**SAB Tc Bovine Human Safety & Immunogenicity Database in >700 Subjects**

**ZERO Subjects with Serum Sickness**

**ZERO Subjects with neutralizing ADA**



# Anti-thymocyte Globulin: Proven Mechanism of Action

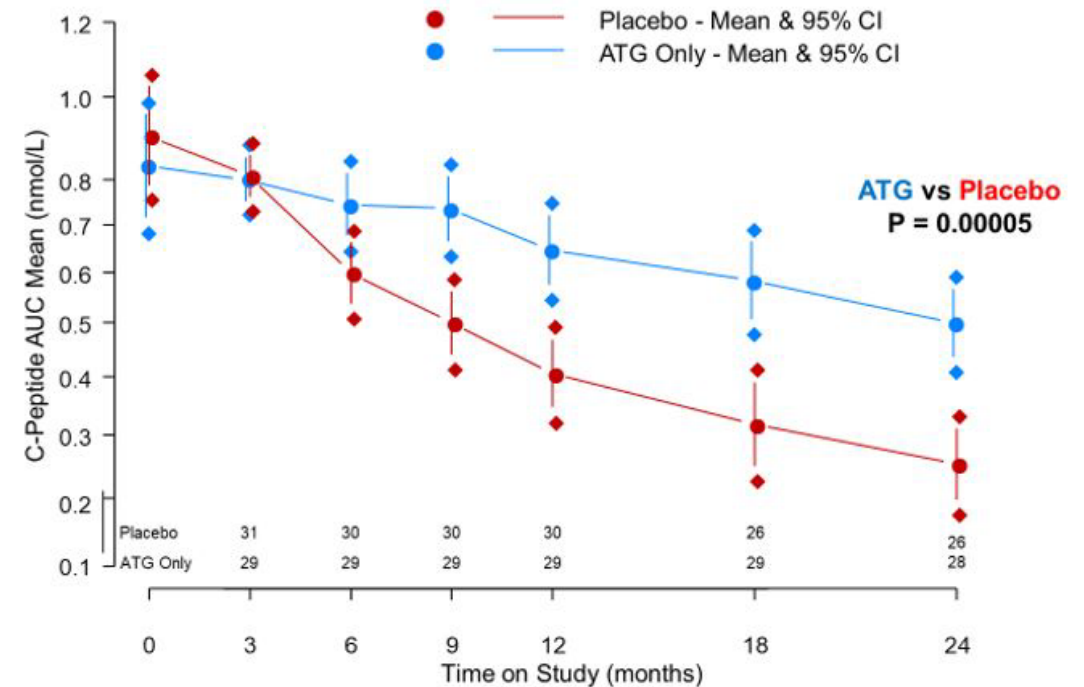


## 2 years: Low-Dose ATG\* Preserved C-Peptide in New Onset T1D



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



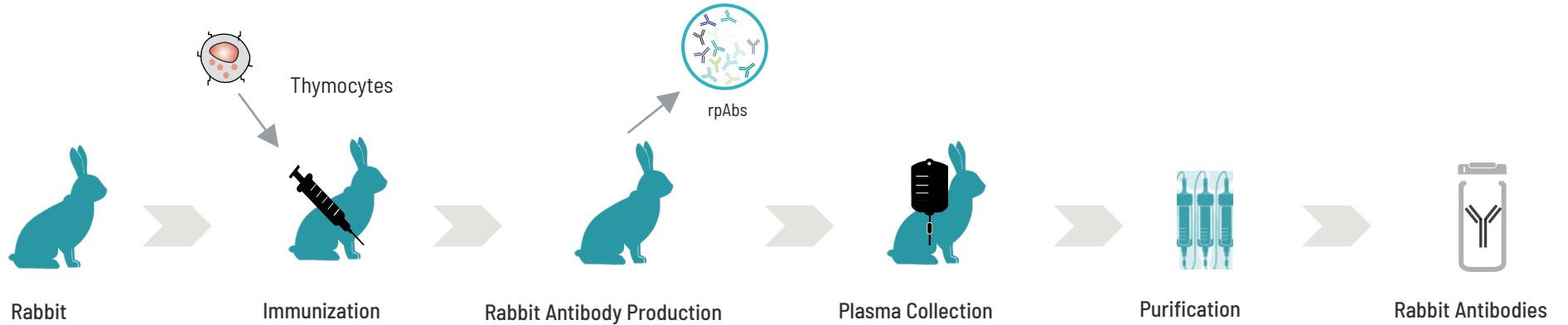
Haller et al. Diabetes. 2019. Jun;68(6):1267-1276

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.

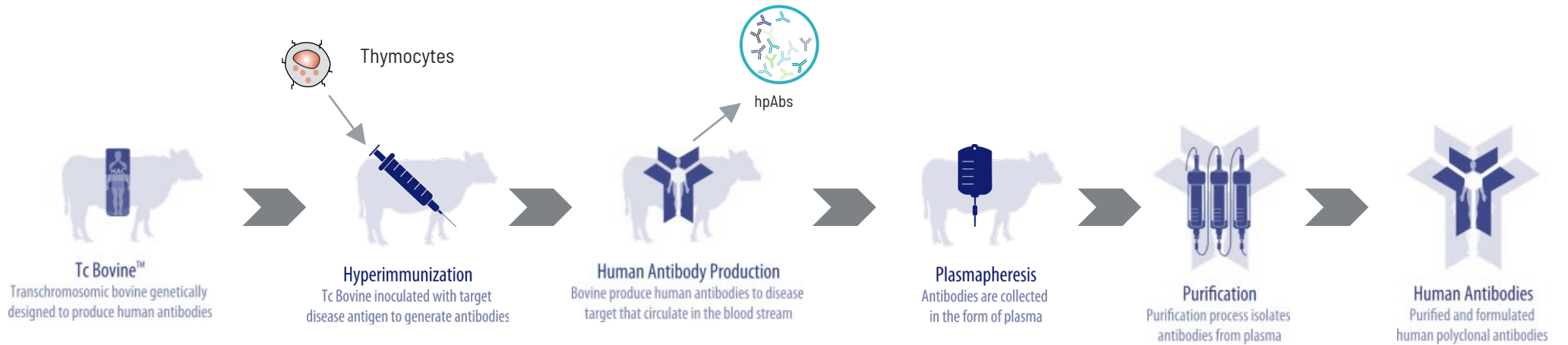
# SAB-142 Production Analogous to FDA-Approved Rabbit ATG



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



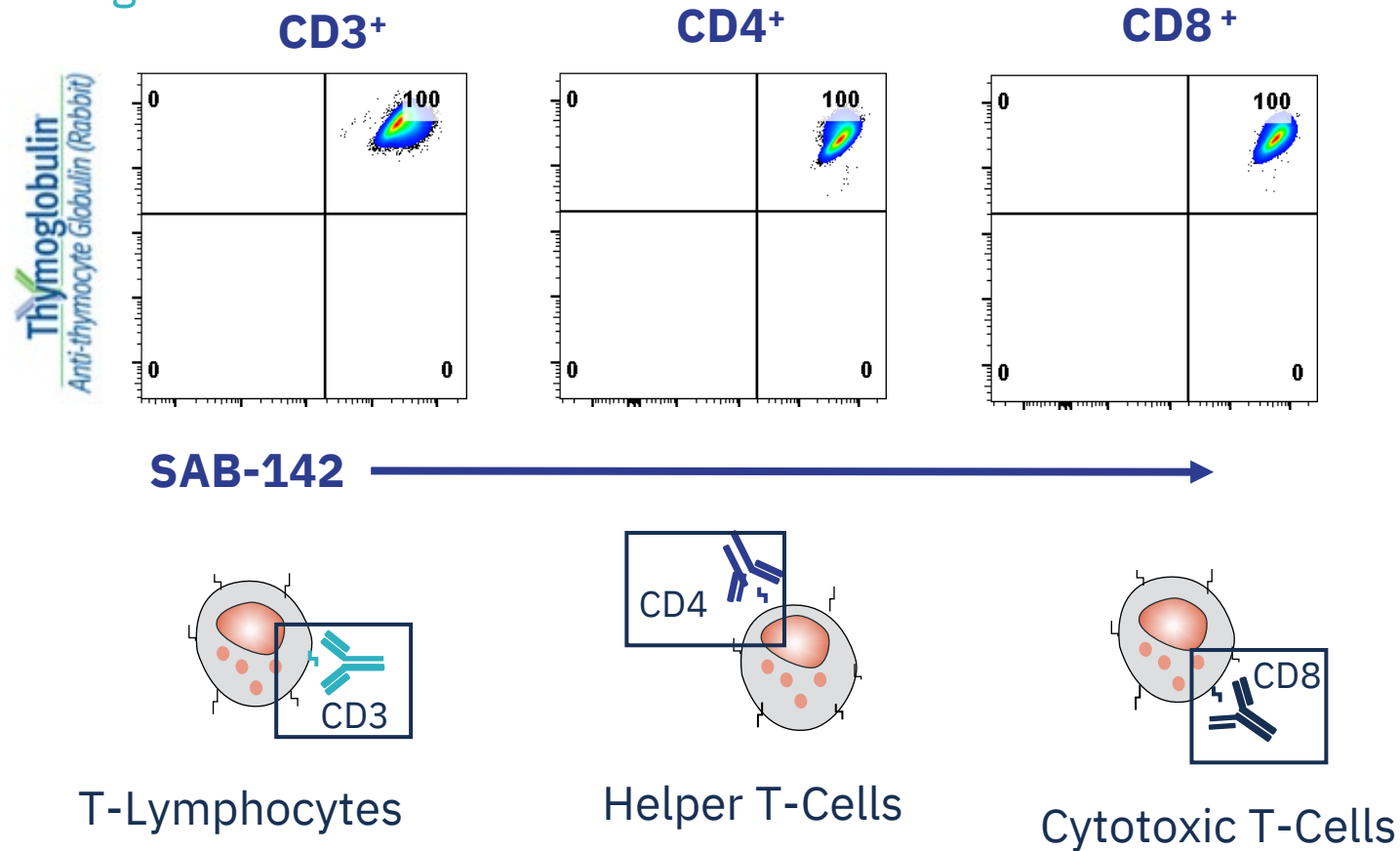
**SAB-142**  
Anti-Thymocyte  
Globulin (Human)



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 Demonstrates Analogous T-Cell Subset Binding Profile as Rabbit ATG

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



# Comparing Teplizumab & Thymoglobulin in Stage 3 T1D



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

**SAB-142:**  
Clinical Development Plan



(**HU**man anti-thymocyte biologic in first-in-**MAN** clinical study)

## Phase 1: Randomized, Single Ascending Dose Trial Assessing Safety, PK and PD

### May 21, 2024: FDA IND acceptance

Design: randomized, double-blind, placebo-controlled, single-ascending dose, adaptive design clinical study

- Healthy volunteers and participants with T1D
- Establish safety, tolerability, pharmacokinetic (PK), immunogenicity and pharmacodynamic (PD) profile for SAB-142

## 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)
- Data generated will enable an upcoming Phase 2b trial

# Case Study: Durable Disease Modification Can Change the Lives of T1D Patients



- An 8-year-old girl, whose father also has type 1 diabetes, tested positive for islet autoantibodies
- Diagnosis of Stage II 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 III T1D. In fact, this patient is no longer experiencing dysglycemia. Her most recent oral glucose tolerance test was normal
- **She does not require insulin 4 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

# SAB-142 Key Milestones

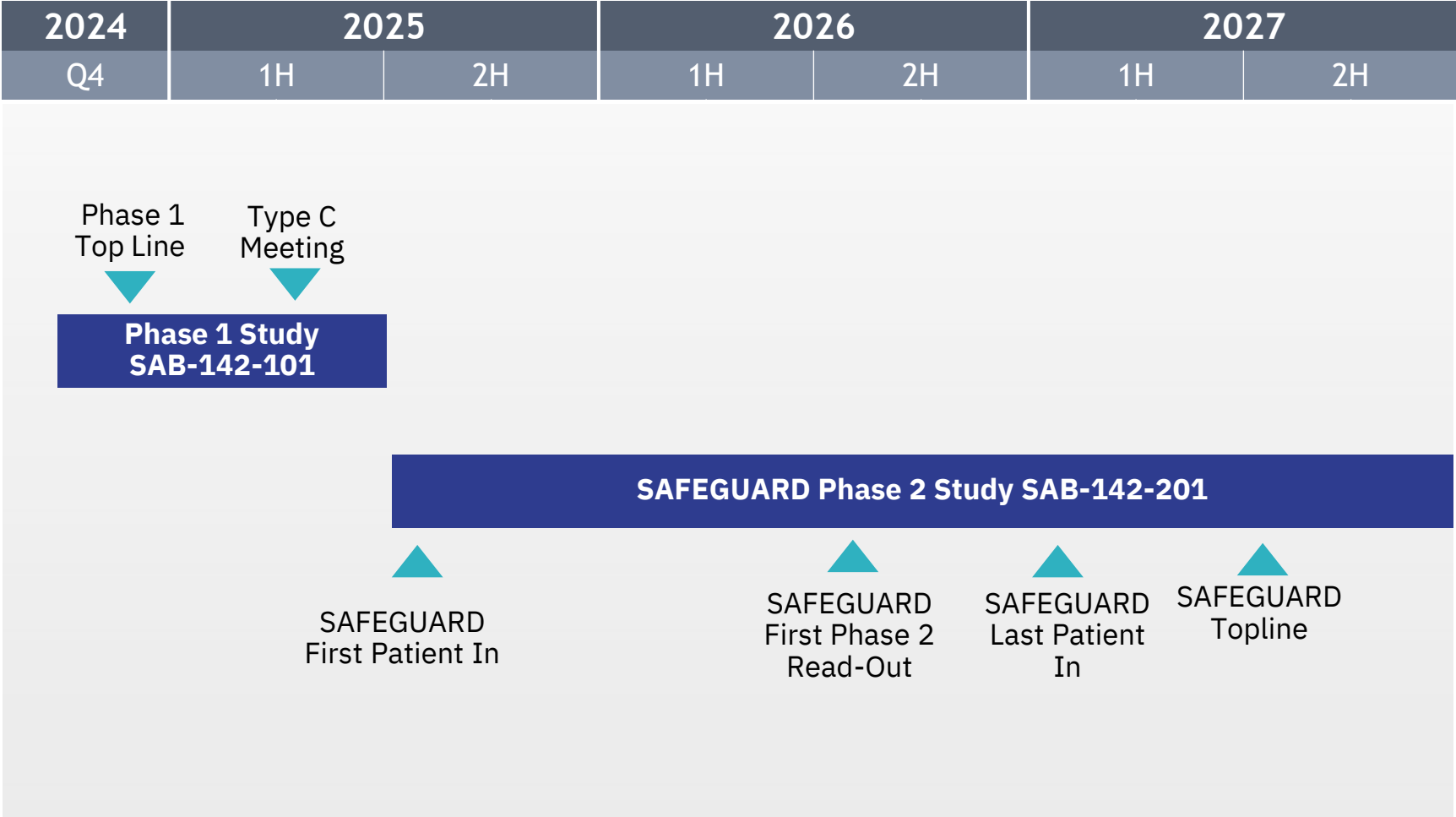


## Phase 1 Objectives

- 0% serum sickness
- 0% Anti-Drug Antibodies
- Proof of biological activity

## Phase 2 Objectives

- Competitive C-peptide efficacy vs TZIELD (cross-study)
- Competitive glycemic control vs TZIELD (cross-study)





# Financial Snapshot



Cash\*  
**\$30M**

Cash  
Runway\*  
**Into  
2026**

Shares\*  
**~42M**

| Bank                      | Covering Analyst         |
|---------------------------|--------------------------|
| Brookline Capital Markets | Kumar Raja, PhD          |
| Chardan                   | Keay Nakae, CFA          |
| Craig-Hallum              | Albert Lowe, PhD         |
| H.C. Wainwright           | Edward White             |
| Oppenheimer               | Leland Gershell, MD, PhD |

Source: FactSet

\* As of September 30, 2024; cash runway based on the assumption of the exercise of outstanding warrants; fully diluted shares outstanding SAB Biotherapeutics is followed by the analysts listed. Please note that any opinions, estimates or forecasts regarding SAB Biotherapeutics' performance made by these analysts are theirs alone and do not represent opinions, forecasts or predictions of SAB Biotherapeutics or its management. SAB Biotherapeutics does not by its reference or distribution imply its endorsement of or concurrence with such information, conclusions or recommendations.

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**THANK YOU**



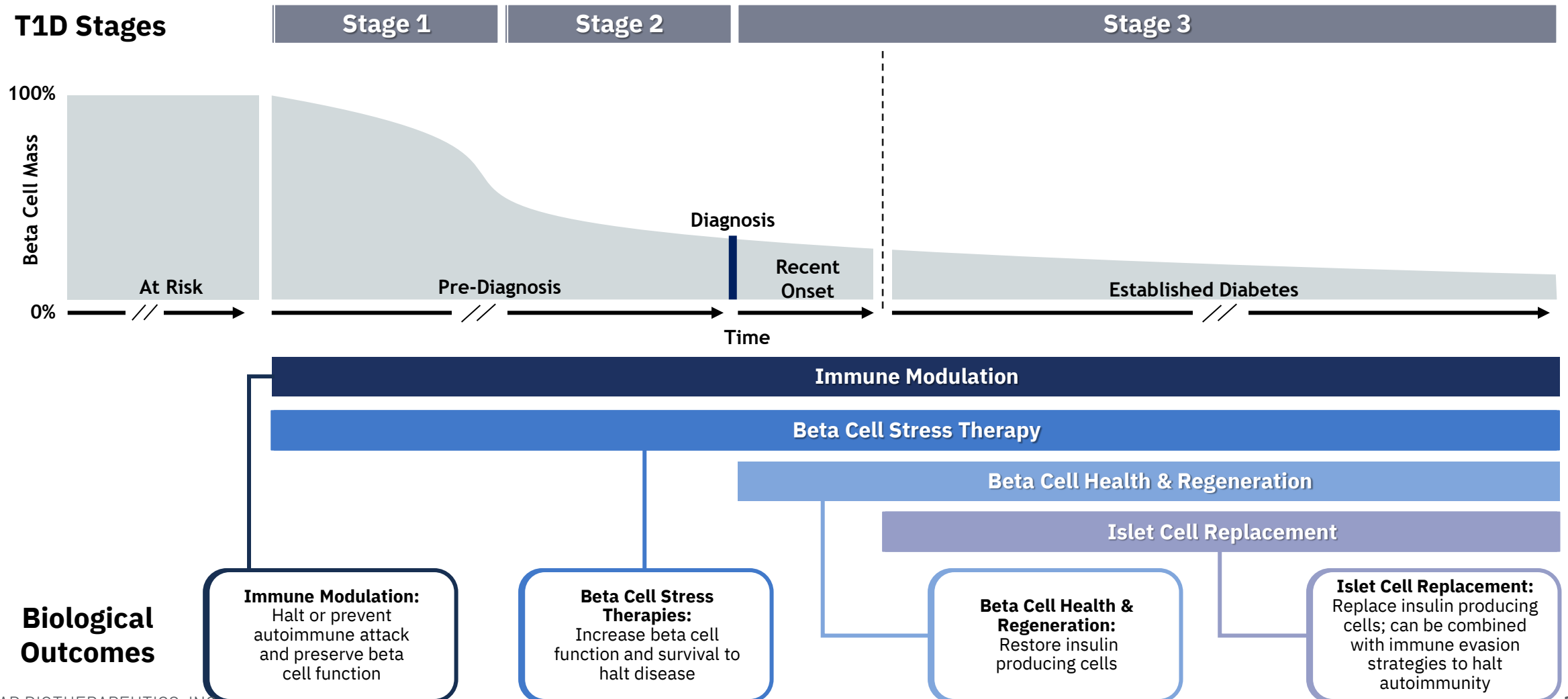
# Appendix



# Type 1 Diabetes Therapeutic Landscape



## Potential therapeutic interventions based on natural history of disease



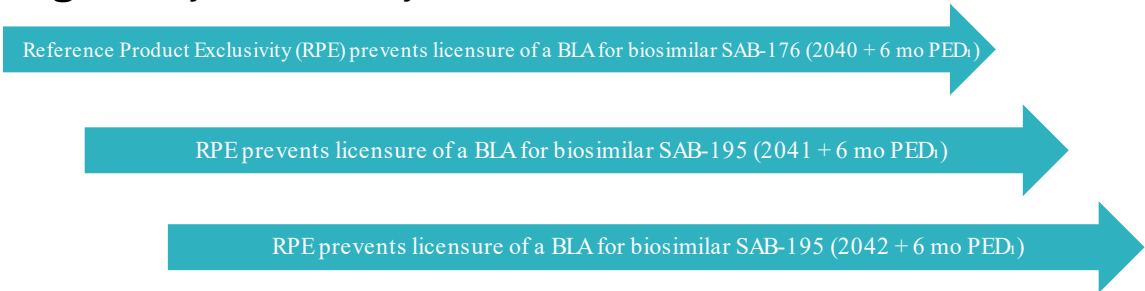
# Significant Space For Innovation Remains



|  | Beta Cell Health & Regeneration   | Islet Cell Replacement / Substitution   | Immune Modulation   |
|--|---|---|---|
| Where we are today (examples) <sup>(1)</sup> | <p>Verapamil<br/>DFMO</p> <p>GLP-1<br/>Imatinib</p> <p> </p>  | <p> </p> <p> </p> <p> </p>  | <p> </p> <p> </p>   |
| Evidence available                           | <ul style="list-style-type: none"> <li>Demonstrated mechanistic rationale across various academic studies                             <ul style="list-style-type: none"> <li>Clinical efficacy observed in select studies on preservation of C-peptide AUC levels</li> </ul> </li> </ul>            | <ul style="list-style-type: none"> <li>Demonstrated clinical benefit in VX-880 Phase 1/2 trial                             <ul style="list-style-type: none"> <li>Met primary endpoint of elimination of severe hypoglycemic events with HbA1c &lt;7.0%</li> </ul> </li> </ul>  | <ul style="list-style-type: none"> <li>Tzield was first disease-modifying drug approved T1D in Nov. 2022                             <ul style="list-style-type: none"> <li>Statistically significant delay in the onset of Stage 3 T1D, 50 months in treatment group vs. 25 months in placebo</li> </ul> </li> </ul> |
| Space for innovation                         | <ul style="list-style-type: none"> <li>Therapies to improve beta cell health that have robust IP protection</li> <li>Proliferative agents with low oncogenic risk and ability to proliferate human beta cells</li> <li>Trans-differentiation approaches with validated delivery strategy</li> </ul> | <ul style="list-style-type: none"> <li>Strategies to eliminate immunosuppression                             <ul style="list-style-type: none"> <li>Hypoimmune gene edits</li> <li>Encapsulation</li> </ul> </li> <li>Improving engraftment                             <ul style="list-style-type: none"> <li>Reducing hypoxia</li> <li>Shutting down inflammatory cytokines</li> <li>Promoting vascularization</li> </ul> </li> <li>New and improved immunosuppression regimen</li> </ul> | <ul style="list-style-type: none"> <li>Significant space for immuno-modulatory therapies</li> <li>The only approved therapy is for Stage 2 patients 8 years or older</li> <li>Unmet need for tolerogenic therapies to truly halt autoimmunity</li> </ul>  |

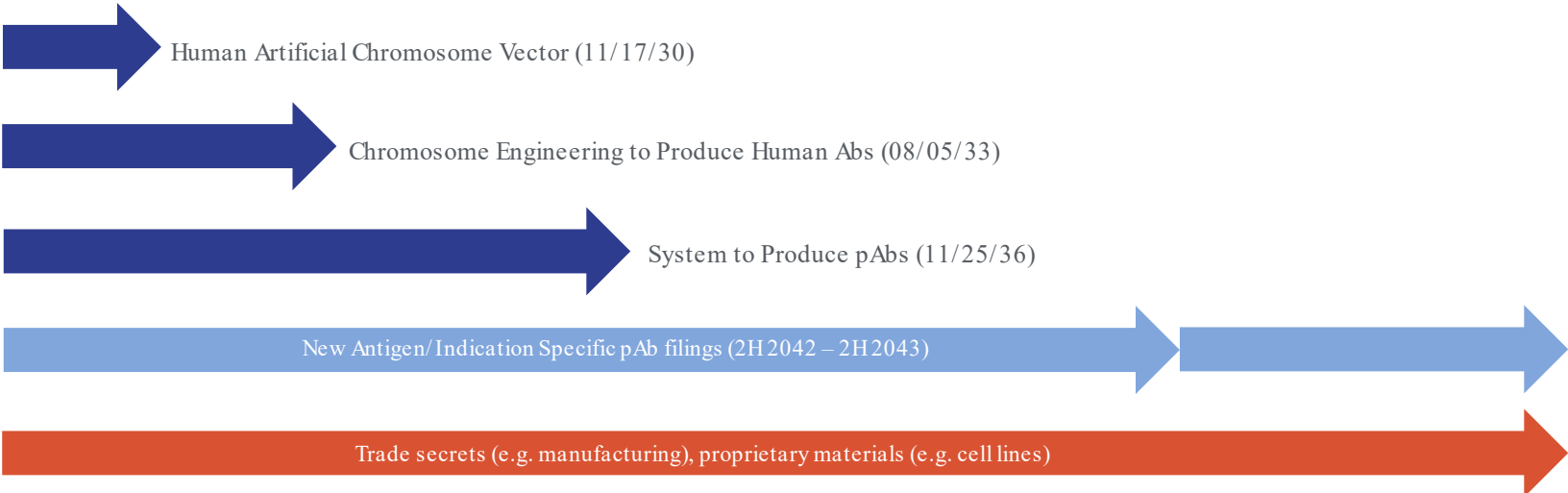
Note: (1) Examples provided are for illustrative purposes only and are not intended to be comprehensive.

## Regulatory Exclusivity



**No regulatory path for biosimilar products to polyclonal immunoglobulins**

## Patent Exclusivity



*Assumptions: licensure of BLA for (i) SAB-176 for C.diff in 2029; and (iii) SAB-142 for type 1 diabetes in 2030*

*<sub>1</sub>Potential pediatric exclusivity + 6 months*

