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): January 12, 2026

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 January 12, 2026, SAB Biotherapeutics, Inc. (the "Company") posted an updated corporate presentation set forth as Exhibit 99.1 herein on the Company's official website. The Company undertakes no duty or obligation to update or revise the information contained in this presentation, although it may do so from time to time. Any such updates may be made through the Investor Relations page of the Company's website, the filing of other reports or documents with the U.S. Securities and Exchange Commission, press releases, or other public disclosure. The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 is being furnished and shall not be "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall they be incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Corporate Presentation dated January 12, 2026
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: January 12, 2026

By: */s/ Samuel J. Reich*
Samuel J. Reich

Exhibit 99.1

Modifying Disease
Delaying Progression
Transforming Treatment

Corporate Presentation
January 2026

Forward-Looking Statements

The material in this presentation has been prepared by SAB Biotherapeutics, Inc., doing business as SAB BIO (“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 is for informational purposes only and does not constitute an offer to sell or a solicitation of an offer to buy any securities.

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, the exercise of outstanding warrants for cash, 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 and reports that SAB makes with the SEC.

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

Transforming Treatment for People Living with Autoimmune Diseases through a Unique Disease-modifying Therapy

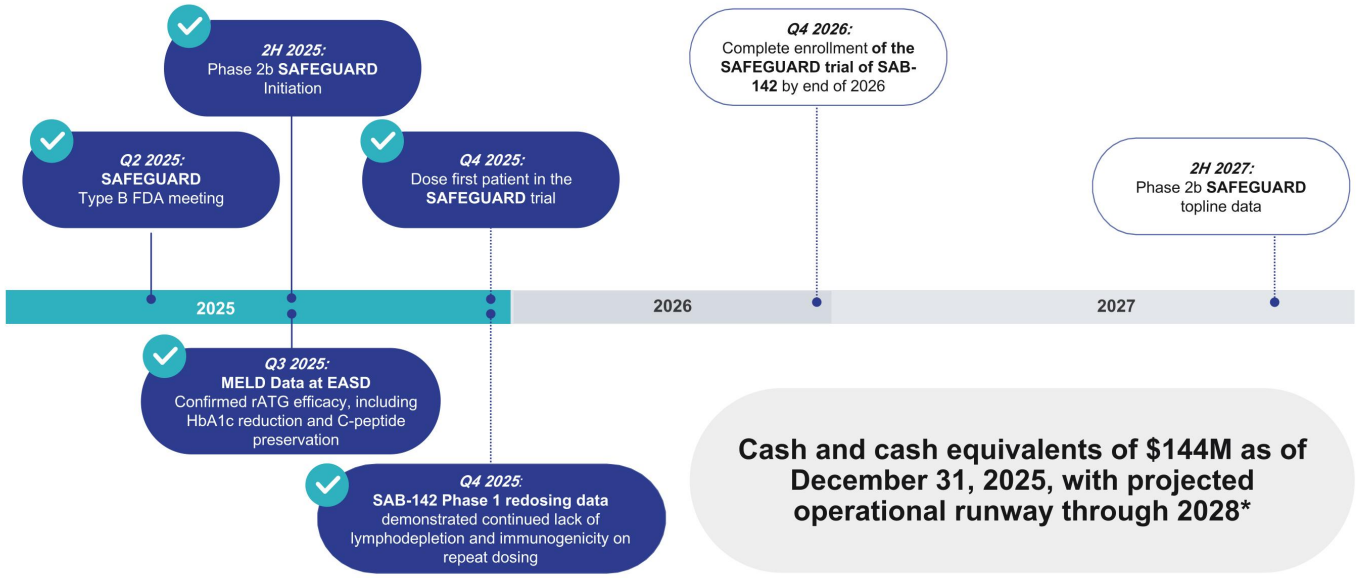
At SAB BIO, our mission is to dramatically redefine what it means to be diagnosed with Type 1 Diabetes by developing a medicine to change the course of disease, not just treat symptoms

SAB BIO Investment Highlights
Potential for Significant Value Creation and Patient Impact

Leading Clinical-Stage Company Focused on Autoimmune Type 1 Diabetes

REDEFINING T1D TREATMENT LANDSCAPE	SAB-142, our lead product candidate, is a potentially best-in-class, disease-modifying therapy with a de-risked mechanism of action Currently conducting a registrational Phase 2b SAFEGUARD study for newly diagnosed Stage 3 autoimmune type 1 diabetes (T1D)
LARGE MARKET OPPORTUNITY WITH ESTABLISHED REGULATORY PATHWAY	T1D is a multi-billion market opportunity with a global prevalence of ~9.5M SAB-142 is initially focused on Stage 3 T1D (U.S. incidence of 64K) where the treatment landscape is expanding towards disease-modifying therapies along a clear regulatory pathway established by Tzield
UNIQUE MULTI-SPECIFIC ANTIBODY PLATFORM WITH HIGH BARRIERS TO ENTRY	First-ever, wholly-owned, discovered in-house platform capable of generating a diverse repertoire of multi-specific, targeted, fully human immunoglobulins (hIgG) This unique platform leverages a multi-level IP strategy with no biosimilar pathway creating high barriers to entry
WELL CAPITALIZED WITH TOP-TIER INVESTORS	Backed by a syndicate of life science specialist investors Current cash position will fully fund SAB-142's SAFEGUARD study, with data expected 2H 2027
EXPERIENCED LEADERSHIP TEAM	Led by management team and board of directors with deep, proven biopharma experience spanning global clinical development, regulatory strategy, and commercialization

Strong 2025 Execution with Significant Catalysts in 2026-2027



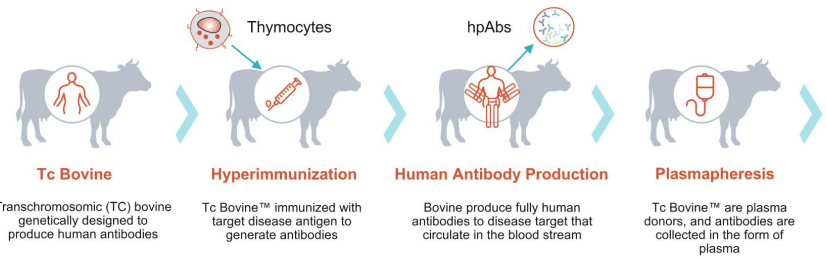
Cash and cash equivalents of $144M as of December 31, 2025, with projected operational runway through 2028*

*Note: Cash and cash equivalents based on unaudited preliminary estimates.

Revolutionary Antibody Technology: Human Immunoglobulin G (hIgG) to Treat and Prevent Autoimmune Disorders

SAB is the only company that can produce targeted, fully human, multi-specific polyclonal antibodies without the need for human donors through its Tc Bovine™ platform

Upstream at SAB's Biosecure Pharm Facility



Tc Bovine

Transchromosomic (TC) bovine genetically designed to produce human antibodies

Hyperimmunization

Tc Bovine™ immunized with target disease antigen to generate antibodies

Human Antibody Production

Bovine produce fully human antibodies to disease target that circulate in the blood stream

Plasmapheresis

Tc Bovine™ are plasma donors, and antibodies are collected in the form of plasma

Downstream at SAB's cGMP Facility

Purification

Purification process isolates antibodies from plasma

Human Antibodies

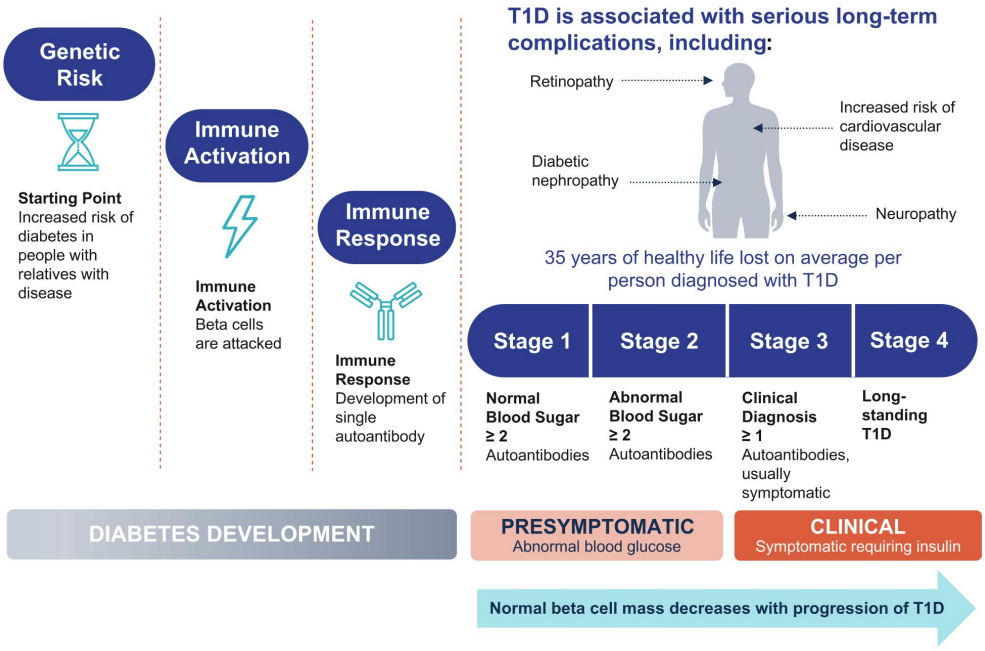
Purified and formulated human multi-specific polyclonal antibodies

T1D: Progressive Autoimmune Disease with Significant Long-term Burden

What is T1D and the SOC?

- T1D is an autoimmune disease characterized by destruction of insulin producing beta-cells in the pancreas by the patient's own immune system
- Affects all ages with an average age of diagnosis at 13 years old
- There is an increased risk if a first-degree relative has been diagnosed with the disease
- Current standard of care (SOC) is insulin – has been transformative but is a chronic symptomatic treatment, not curative or disease-modifying
- Lifelong disease with no current cures and many life-altering implications significantly reducing quality of life

T1D Disease Continuum



Significant Unmet Need in Type 1 Diabetes

An evolving treatment landscape with a clear regulatory pathway established by Tzield

Stage 2 (Delay Onset) Market

Tzield (teplizumab-mzwv)

Approved in Stage 2 patients to delay the onset of T1D

sanofi

$2.9B Sanofi acquisition of Provention Bio

(Tzield in Phase 3 for Stage 3 at time of acquisition)

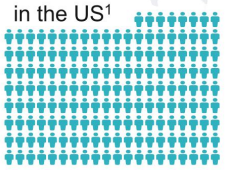
Stage 3 (Newly Diagnosed) Market

Tzield sBLA accepted with CNPV supported by PROTECT data

64,000 U.S. Patients Diagnosed Annually[2]

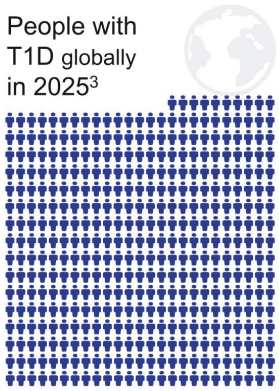
1.4M

People with T1D cases in the US[1]



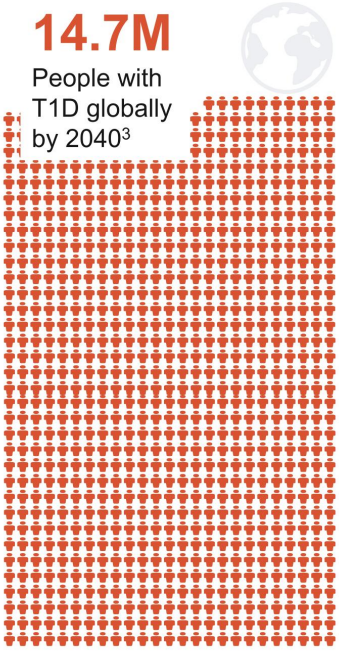
9.5M

People with T1D globally in 2025[3]



14.7M

People with T1D globally by 2040[3]



Source [1] https://www.breakthrought1d.org/explore-research/research-strategy/ [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 [3] https://www.t1dindex.org/

SAB-142: Potential Disease-modifying Immunotherapy Being Developed to Delay the Onset and Progression of Type 1 Diabetes

Goal: develop a T1D therapy that immunomodulates T cells to preserve C-peptide while avoiding immunosuppression

SAB-142
Anti-Thymocyte Globulin (Human)

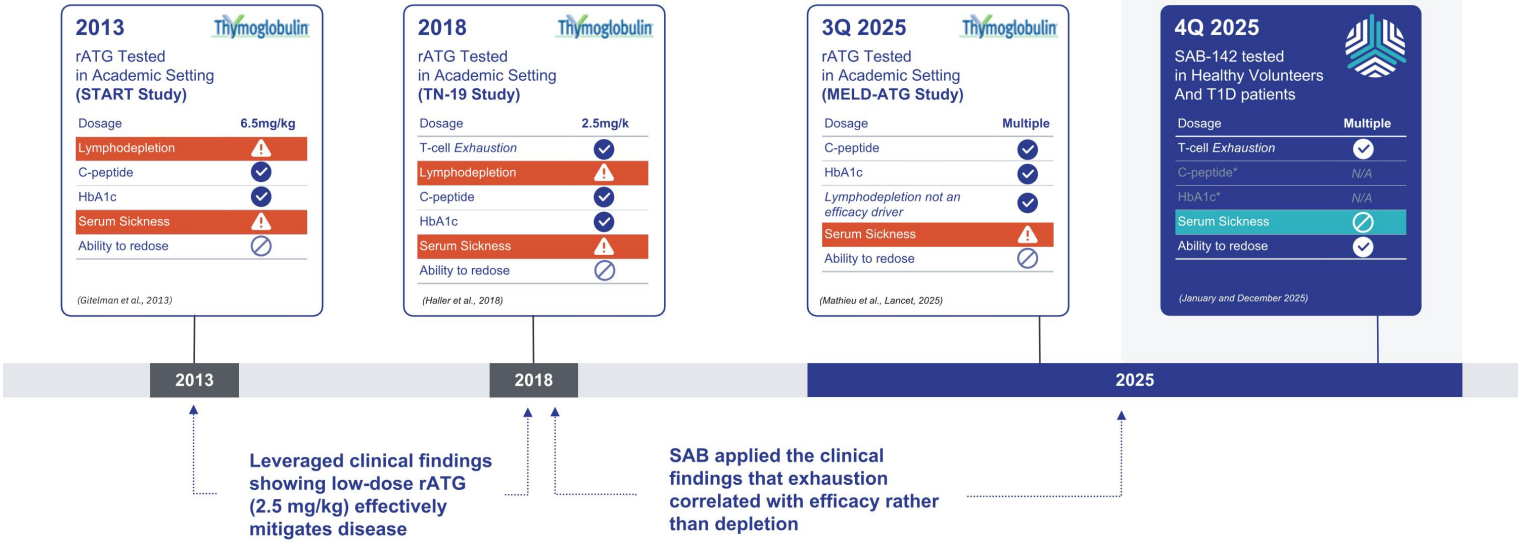
- **SAB-142 is a multi-specific, fully human anti-thymocyte globulin** (hATG) disease-modifying immunotherapy to delay the onset and progression of T1D
- SAB-142 works by directly **targeting multiple immune cells** involved in destroying pancreatic beta cells, including the modulation of "bad acting" T-lymphocytes
  - Mechanism of action, analogous to rabbit ATG (rATG), directly modulates multiple immune cells involved in destroying pancreatic beta cells
  - **SAB-142 provides a better safety profile** resulting in no serum sickness and low/no immunogenicity – this offers the potential for life-long disease modification through redosing safely, preserving C-peptide, and delaying the onset or progression of T1D
  - By stopping immune cells from attacking beta cells, this treatment has the **potential to preserve insulin-producing beta cells**
  - **C-peptide** is a stable marker of endogenous insulin production
  - Preserving beta cell function and thus insulin production as measured by C-peptide is **key to delaying progression of T1D**

Early intervention is essential and life-long disease modification is possible with effective, safe, and reliable redosing

SAB-142: A Clinically-validated De-risked Mechanism of Action

rATG has been tested across multiple studies in T1D patients

SAB-142: hATG tested in healthy volunteers and T1D patients



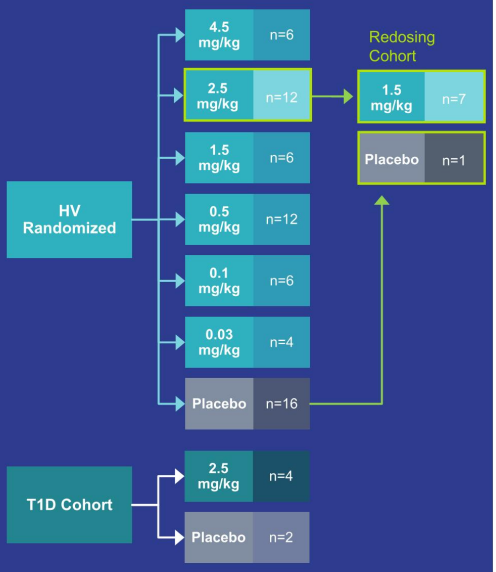
Leveraged clinical findings showing low-dose rATG (2.5 mg/kg) effectively mitigates disease

SAB applied the clinical findings that exhaustion correlated with efficacy rather than depletion

*Not measurable in healthy volunteers.

Phase 1: HUMAN* Trial Study Design

Randomized, double-blind, placebo-controlled, single- and multiple- ascending dose, adaptive design clinical study



SAB-142's Phase 1 Data Demonstrated Clinically-validated, Multi-specific MOA with Sustained Immunomodulation

Immunogenicity — Data confirm SAB-142 not immunogenic

- Does not cause anti-drug antibodies
- Enables safe and reliable redosing

PK/PD — Data demonstrate sustained "T-cell exhaustion" signature

- Clinically validated by rATG and other T1D T-cell targeting biologics
- Demonstrated correlation with C-peptide preservation based on precedent rATG studies and natural course of T1D

Safety and Tolerability — Data position SAB-142 for a convenient, potentially twice a year dosing regimen

- No sustained lymphodepletion leading to immuno-suppression; no neutropenia
- No serum sickness

*HUman anti-thymocyte biologic in first-in-MAN clinical study

SAB-142's Complete Phase 1 Data Confirmed Superior Safety Profile Enabling Outpatient Dosing and Chronic Treatment Potential

Phase 1 data confirmed advancement into a registrational Phase 2b study in newly diagnosed adult, adolescents, and pediatric T1D patients (age 5-40)

Key Safety Outcomes

- No serum sickness (0%, N=0/68)
- No ADA-related AEs at any dose or cohort (0%, N=0/68)
- No drug-related SAEs

Observed AEs

- Headaches, a typical AE for T-cell modifying therapies
- Mild CRS (Grade 1 only)
- Transient infusion-site reactions (erythema, pruritus, tenderness, phlebitis)

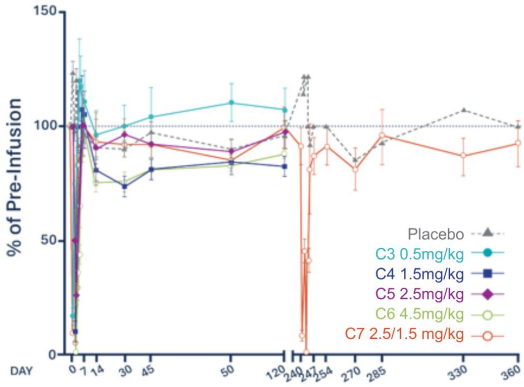
Transient On-Target PD Effects

- Transient lymphopenia indicative of target engagement, a desired PD effect
- Lymphopenia self-resolves in 1–3 days
- No lymphocyte killing/sustained lymphodepletion, a key risk factor of immuno-suppression – supports chronic redosing potential

Hematologic Safety

- No reductions in RBCs, neutrophils, lymphopenia, or thrombocytopenia from Day 7 onward

Mean Absolute Lymphocytes +/- SEM Normalized to Original Pre-SOI



Lymphocytes fully recover to baseline across all doses including 4.5mg/kg and after repeat dosing

Note: AE = Adverse Events; SAE = Serious Adverse Events; CRS = Cytokine Release Syndrome; PD = Pharmacodynamics; RBCs = Red Blood Cells SEM = Standard Error of Means; SOI = Start of Infusion

SAB-142: Potential for Broadest Use with Superior Safety, Efficacy, and Patient Convenience in a Broad Age Range of T1D Patients

	Tzield (teplizumab-mzwv)	Thymoglobulin Anti-thymocyte Globulin (Rabbit)	SAB BIO SAB-142
CD4+ exhaustion signature	✓	✓	✓
Treg preservation	✗	✓	✓
No sustained lymphodepletion (Tconv and/or Tregs)	✗	✗	✓
No anti-drug antibodies (ADAs)	✗	✗	✓
No Serum Sickness	✗	✗	✓
C-peptide Preservation	✓	✓	SAFEGUARD*
HbA1C	✗	✓	SAFEGUARD*
Dosing	12 DAYS	1-2 DAYS	2 DAYS
Infusing timing	1 HOUR	4-12 HOURS	4-6 HOURS
Redosable (with potential for Chronic Dosing without ADAs)	✗	✗	✓
Age Range	8-17	5-45	5-40*

SAB-142 exhibits multi-specific T-cell exhaustion profile and Treg-sparing without sustained lymphodepletion

mimicking immunologic cellular profiles that naturally occur during the initial spontaneous partial remission period ("honeymoon period")

T-cell exhaustion phenotype is universally linked to C-peptide preservation

* Potential benefits on HbA1c and C-peptide are informed by prior rATG outcomes, though this translatability to SAB-142 will be confirmed with the Phase 2b SAFEGUARD study results. Registrational Phase 2b SAFEGUARD trial includes T1D patients ages 5-40.

SAFEGUARD: Multicenter, Global Phase 2b for SAB-142 in Stage 3 Type 1 Diabetes Patients

SAFEGUARD Phase 2b Study

SAFety and Efficacy of human anti-thymocyte immunoGlobUlin SAB-142 ARresting progression of Type 1 Diabetes

Trial design:

- 159 pediatric, adolescent, and adult patients (5-40 years)
  - **Part A:** 12 patients – dose-ranging study for 12 months
  - **Part B:** 147 patients – randomized, double-blind, placebo-controlled, dose-ranging study for 12 months
- All patients, including placebo, eligible for 12-month long-term extension (LTE) study upon completion

Inclusion criteria:

- New onset Stage 3 T1D: within 100 days of diagnosis
- Baseline C-peptide ≥200 pmol/L

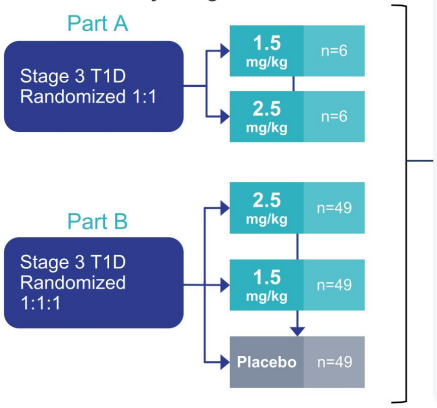
Dosing regimen:

- Intravenous (IV)
- 0.5 mg/kg on Day 1 and remainder of dose Day 2
- 1st dose at study start and 2nd dose at month 6
- Induction dose levels: 1.5 and 2.5mg/kg; Maintenance dose: 1.5mg/kg

Global study initiated with **topline results expected 2H 2027**

United States (FDA) NCT07187531 | **Europe** (EMA) | **United Kingdom** (MHRA) | **Australia** (TGA) | **New Zealand** (MEDSAFE)

Phase 2b Study Design



Primary Endpoint:

Stimulated C-peptide
following 2-hr MMTT at 12 months
(detect at least 40% difference with 80% power)

Secondary Endpoint:

Leading Clinical Endpoint:
HbA1C

Other secondary Endpoints:

- Time in Tight Range, Time in Range, Time Above and Below Range
- Hypoglycemic episodes
- Safety
- Insulin use

Strong Balance Sheet with Committed Strategic Partners

Recent Financing Fully Funds Phase 2b SAFEGUARD Study:

Raised $175 million in July 2025 with the potential for an additional $284 million if milestone-based warrants are exercised in full

T1D Clinical Development Partner:

SAB-142 clinical development plan designed in partnership with Breakthrough T1D (formerly JDRF)

Financial Snapshot:

Cash* $144M

Cash Runway* Through 2028

Key Clinical and Strategic Partners:

AUSTRALASIAN TYPE 1 DIABETES IMMUNOTHERAPY COLLABORATIVE

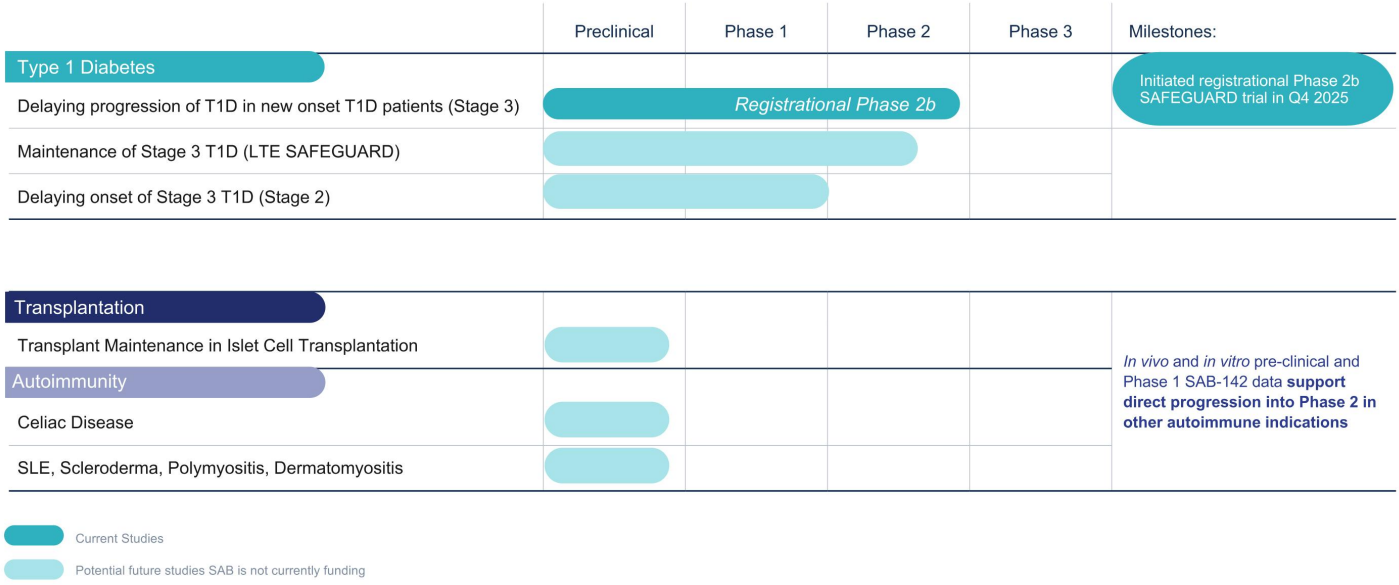
Breakthrough T1D™ Formerly JDRF

INNODIA

sanofi

*Note: Cash and cash equivalents based on unaudited preliminary estimates as of December 31, 2025.

Advancing a Pipeline in Autoimmune Diseases, Led by SAB-142



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Leading Clinical-Stage Company Focused on Autoimmune Type 1 Diabetes

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LARGE MARKET OPPORTUNITY WITH ESTABLISHED REGULATORY PATHWAY	T1D is a multi-billion market opportunity with a global prevalence of ~9.5M SAB-142 is initially focused on Stage 3 T1D (U.S. incidence of 64K) where the treatment landscape is expanding towards disease-modifying therapies along a clear regulatory pathway established by Tzield
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WELL CAPITALIZED WITH TOP-TIER INVESTORS	Backed by a syndicate of life science specialist investors Current cash position will fully fund SAB-142's SAFEGUARD study, with data expected 2H 2027
EXPERIENCED LEADERSHIP TEAM	Led by management team and board of directors with deep, proven biopharma experience spanning global clinical development, regulatory strategy, and commercialization

THANK YOU

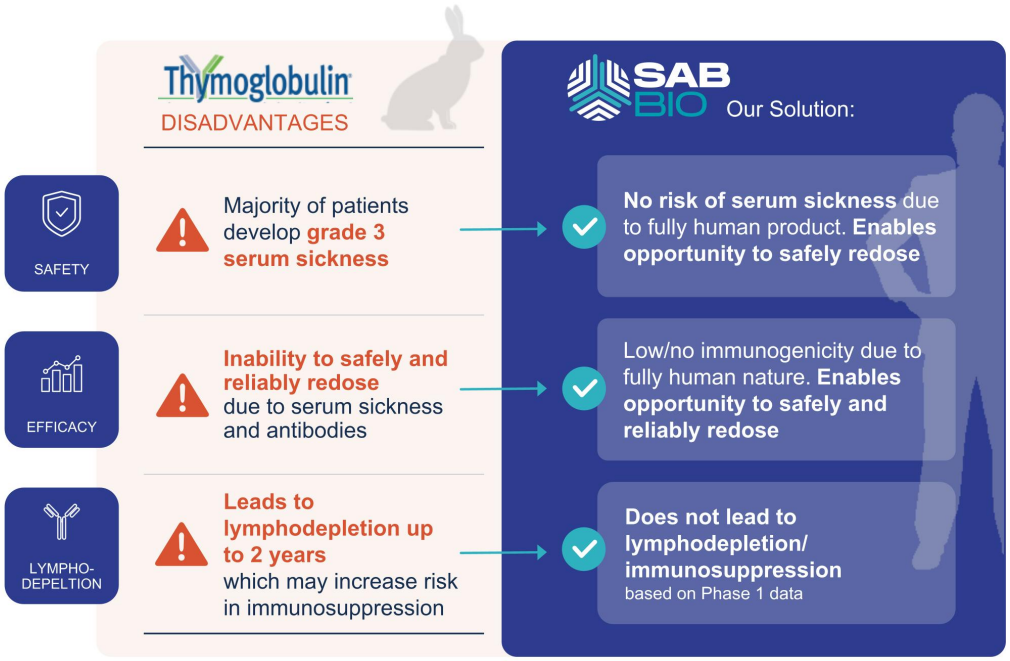
Modifying Disease
Delaying Progression
Transforming Treatment

Appendix

SAB-142 Offers Distinct Advantages Over rATG

SAB-142 / hATG
Mechanism of Action:

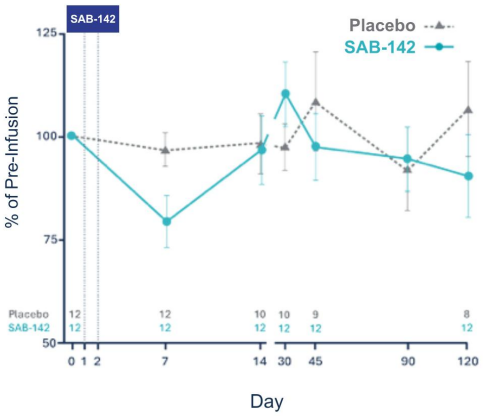
- **SAB-142 is a human alternative** to rATG (Thymoglobulin)
- SAB-142's mechanism of action is comparable to the PD profile of rATG shown to correlate with C-peptide preservation
- SAB-142, like rATG, modulates immune function resulting in sustained exhaustion in T cells likely involved in destroying pancreatic beta cells



SAB-142 Demonstrates a Comparable MOA to rATG, including Induction of Key T-cell Exhaustion Markers that have been Correlated with C-peptide Preservation in Prior rATG Studies

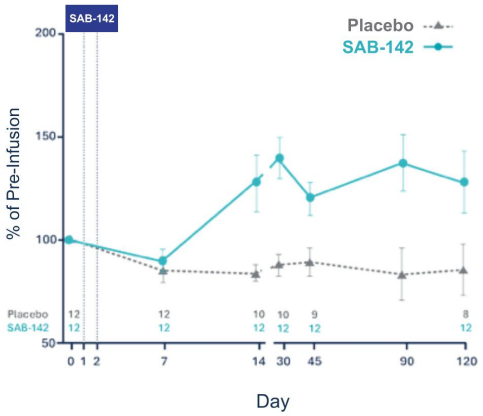
1 Treg preservation

Treg ($CD3^+$ $CD4^+$ $CD127^{lo}$ $CD25^+$ $FoxP3^+$) **± SEM**



2 Dose dependent increase in CD4 exhaustion

Relative $PD\text{-}1^+$ Tconv Cells ± SEM



rATG Published Data:

Responders to low-dose ATG induce CD4+ T-cell exhaustion in type 1 diabetes - PubMed

JCI insight CLINICAL MEDICINE

Responders to low-dose ATG induce CD4⁺ T cell exhaustion in type 1 diabetes

Laura M. Jacobsen,[1,2] Kirsten Diggins,[3] Lori Blanchfield,[3] James McNichols,[2] Daniel J. Perry,[2] Jason Brant,[2] Xiaoru Dong,[2,4] Rhonda Bacher,[4] Vivian H. Gersuk,[3] Desmond A. Schatz,[1] Mark A. Atkinson,[1,2] Clayton E. Mathews,[1,2] Michael J. Haller,[1] S. Alice Long,[3] Peter S. Linsley,[3] and Todd M. Brusko[1,2]

[1]Department of Pediatrics, College of Medicine, University of Florida, Gainesville, Florida, USA. [2]Department of Pathology, Immunology, and Laboratory Medicine, University of Florida Diabetes Institute, Gainesville, Florida, USA. [3]Benaroya Research Institute at Virginia Mason, Seattle, Washington, USA. [4]Department of Biostatistics, University of Florida, Gainesville, Florida, USA.

RESULTS. Treatment with low-dose ATG preserved regulatory T cells (Tregs), as measured by stable methylation of *FOXP3* Treg-specific demethylation region (*TSDR*) and increased proportions of $CD4^+FOXP3^+$ Tregs ($P < 0.001$) identified by flow cytometry. While treatment effects were consistent across participants, not all maintained C-peptide. Responders exhibited a transient rise in IL-6, IP-10, and TNF-α ($P < 0.05$ for all) 2 weeks after treatment and a durable $CD4^+$ exhaustion phenotype (increased $PD\text{-}1^+KLRG1^+CD57^-$ on $CD4^+$ T cells [$P = 0.011$] and $PD1^+CD4^+$ Temra MFI [$P < 0.001$] at 12 weeks, following ATG and ATG/G-CSF, respectively). ATG nonresponders displayed higher proportions of senescent T cells (at baseline and after treatment) and increased methylation of *EOMES* (i.e., less expression of this exhaustion marker).

CONCLUSION. Altogether in these exploratory analyses, Th1 inflammation-associated serum and $CD4^+$ exhaustion transcript and cellular phenotyping profiles may be useful for identifying signatures of clinical response to ATG in T1D.

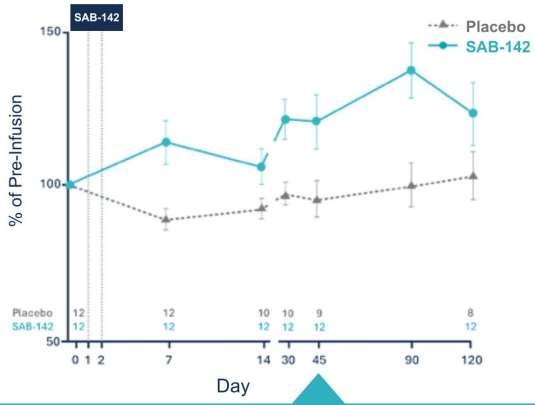
Note: SAB-142: combined 1.5mg/kg and 2.5mg/kg dosed cohorts.

SAB-142 Induces Operational Tolerance as Indicated by Single and Dual-Exhaustion Markers

SAB-142 Phase 1 Top-Line Data:

1 SAB-142 CD4+ T Conv Cell Single Exhaustion Markers

Relative TIGIT⁺ Tconv Cells ± SEM



SAB-142 induced sustained expression of inhibitory receptors (TIGIT+) on CD4+ T conv cells indicative of an exhausted phenotype

2 SAB-142 CD4+ T conv Cell Dual Exhaustion Markers

Tconv Median % Change from Baseline

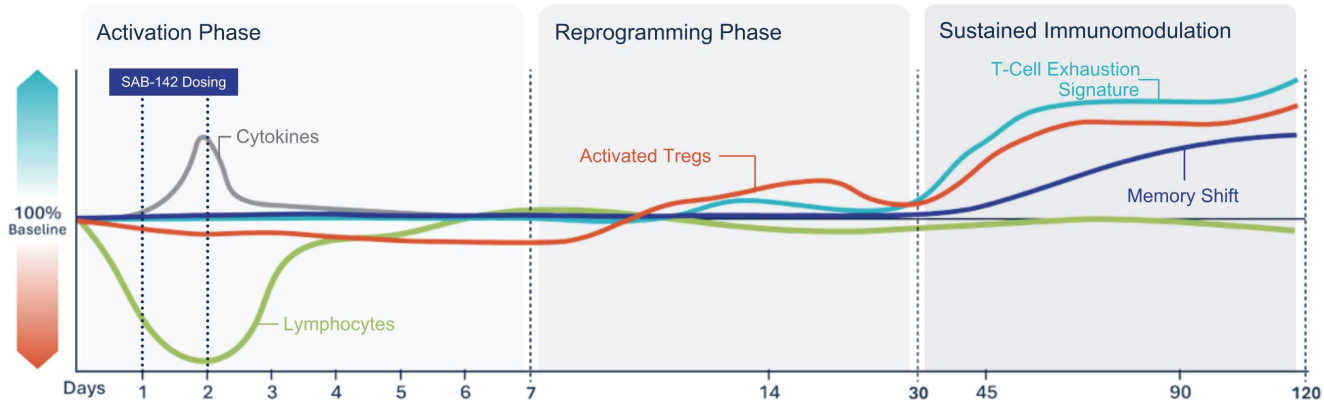
SAB-142 induced persistent expression of co-inhibitory receptors on CD4+ Tconv cells

Note: SAB-142: combined 1.5mg/kg and 2.5mg/kg dosed cohorts.

SAB-142: The Next Generation of Beta Cell Guardians

Sustained Immunomodulation without Lymphodepletion

Pharmacodynamic Profile of SAB-142:



Mechanism of Action of SAB-142:

- Transient Cytokine Increase
- Transient Lymphocyte Margination
- Treg preservation & activation
- Initiation of memory phenotype shift
- Sustained T-cell exhaustion signature
- Supporting restoration of immune tolerance

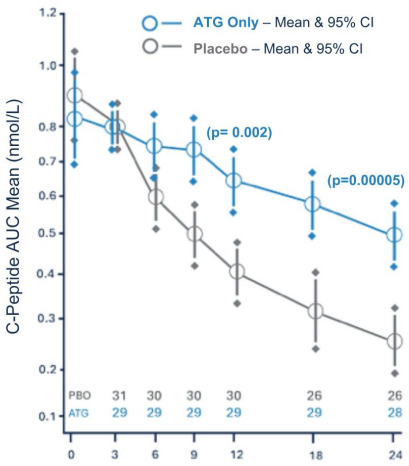
Rabbit ATG: De-Risked Mechanism of Action

TN-19: Low-Dose rATG* Preserved C-peptide in New Onset T1D 1 and 2 years post-treatment

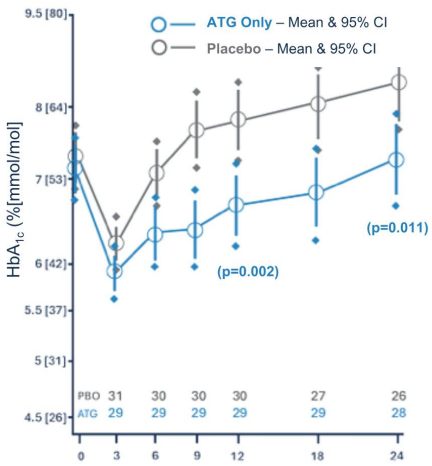
C-peptide, the cleavage product of proinsulin, released in equal amounts with insulin, reflects a person's ability to produce endogenous insulin and is the standard biomarker of pancreatic β-cell function

Thymoglobulin® Anti-thymocyte Globulin (Rabbit)

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



HbA_{1c} Over Time
by Treatment Group



Time on Study (months)

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_{1c}, 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.

Rabbit ATG: De-Risked Mechanism of Action

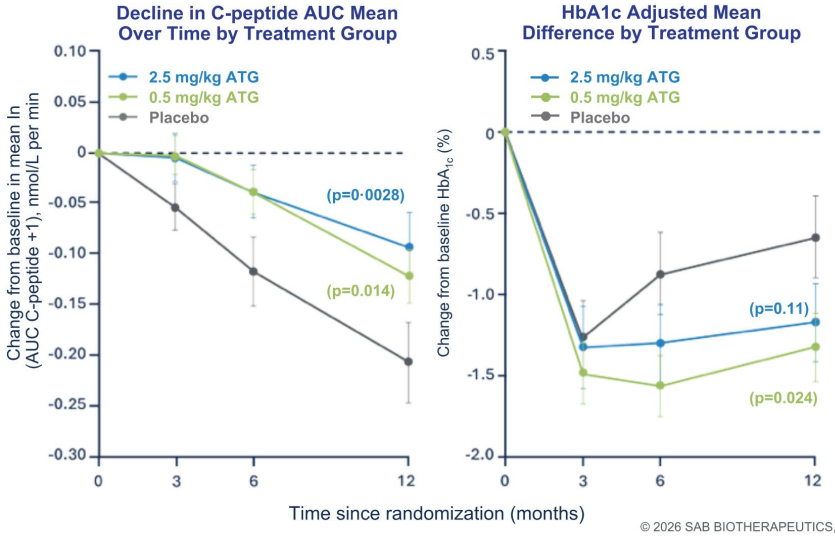
MELD-ATG: Minimal Effective Low Dose of rATG* Preserved C-peptide in New Onset T1D 1 year post-treatment

MELD-ATG replicated results from Haller's TN19 study with ≤2.5 mg/kg with statistically significant C-peptide preservation and glycemic control

Thymoglobulin® Anti-thymocyte Globulin (Rabbit)

ATG is the only mechanism of action that has consistently reproduced clinical data demonstrating preservation of C-peptide and improvements in glycemic control

(Mathieu et al., Lancet. 2025 Sep 18:S0140-6736(25)01674-5)



*Mathieu C, Wych J, Hendriks AEJ, Van Ryckeghem L, Tree T, Chmura P, Möller C, Casteels K, Danne T, Reschke F, Šmigoc Schweiger D, Battelino T, Johannesen J, Rami-Merhar B, Pieber T, De Block C, Evans M, Hilbrands R, Bosi E, Willemsen RH, Basu S, Pulkkinen MA, Knip M, Cnop M, Nitsche A, Schulte AM, Niemöller E, Peakman M, Wilhelm-Benartzi C, Gillespie D, Overbergh L, Mander AP, Marcovecchio ML; INNODIA. Minimum effective low dose of antithymocyte globulin in people aged 5-25 years with recent-onset stage 3 type 1 diabetes (MELD-ATG): a phase 2, multicentre, double-blind, randomised, placebo-controlled, adaptive dose-ranging trial. Lancet. 2025 Sep 18:S0140-6736(25)01674-5. doi: 10.1016/S0140-6736(25)01674-5. Epub ahead of print. PMID: 40976248.

Thymoglobulin's Therapeutic and Dosing Profile is Superior to Tzield in Stage 3 T1D Patients

	Tzield PHASE 3 (PROTECT) DATA	Thymoglobulin PHASE 2 TN-19 and MELD DATA
C-peptide	Primary end point of C-peptide levels **met at Month 18**	Primary end point of C-peptide AUC **met at Month 12**
HbA1c	**Missed statistical significance**	**Statistically significant** at Month 12
Dosing	**Two courses of IV therapy:** **Each course is** 12 days of consecutive IV therapy administered at Randomization and at Month 6	**A single dose of IV** administered over 2 days
Patient Population	Children and adolescents **8-17 years**	Adolescents and adults **12-45 years (TN-19)** **5-25 years (MELD-ATG)**
Study Period	**18 months**	**12 months**
Sample Size n =	200 on Tzield vs. 100 on placebo	29-34 on Thymoglobulin (per dose level) vs. 29-31 on placebo

Thymoglobulin ADVANTAGES

- **Statistically significant on C-peptide** like Tzield
- **Statistically significant on HbA1C** where Tzield missed
- **More Convenient Dosing**
- Shown to work in **Broader range of patients**
- **Required one course and less time** to primary endpoint
- **Superior statistically significant efficacy** with smaller sample size