



SAB-142: Setting a New Standard for Beta-Cell Preservation

A differentiated, repeat-dose approach to
preserving beta-cell function across the T1D
continuum



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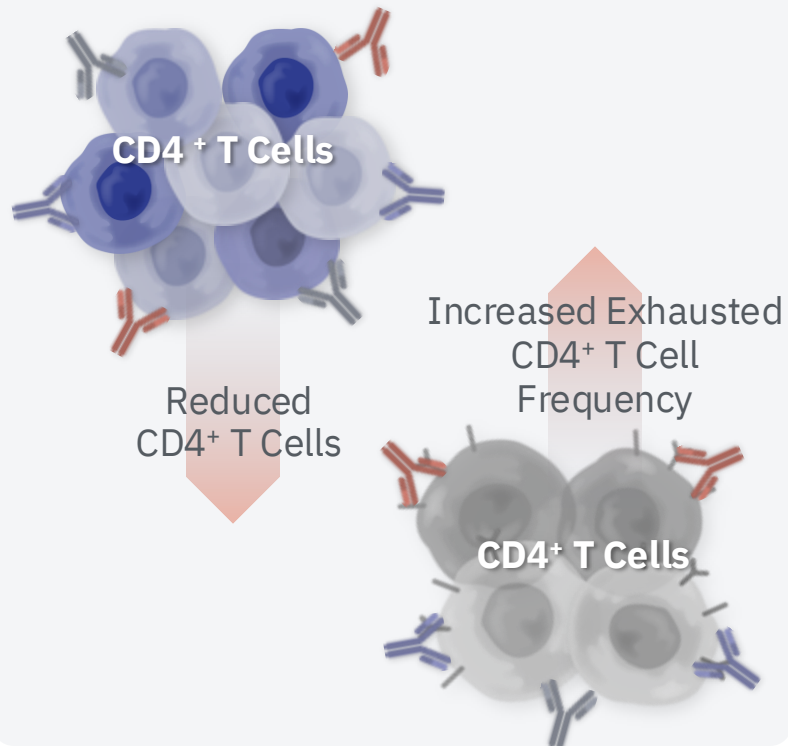
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SAB-142 is a Novel Fully Human Multi-specific IgG Immunomodulator Designed to Set a New Standard in Type 1 Diabetes

Not All Immune Modulation Is Created Equal: Unlike broad depletion or single-target exhaustion, SAB-142 is designed to preserve regulatory T cells and target the immune cells most relevant to beta-cell destruction.

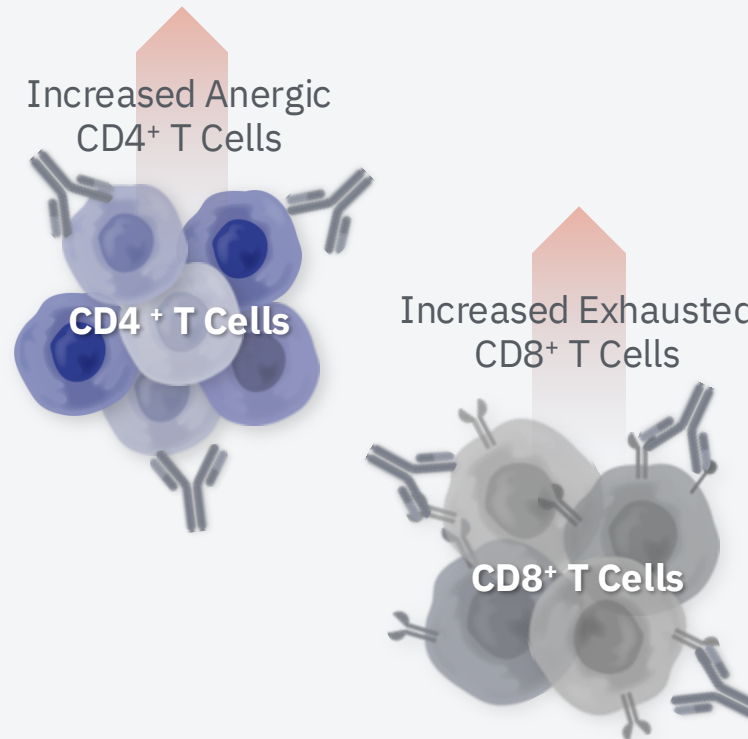
rATG

(rabbit Anti-Thymocyte Globulin)



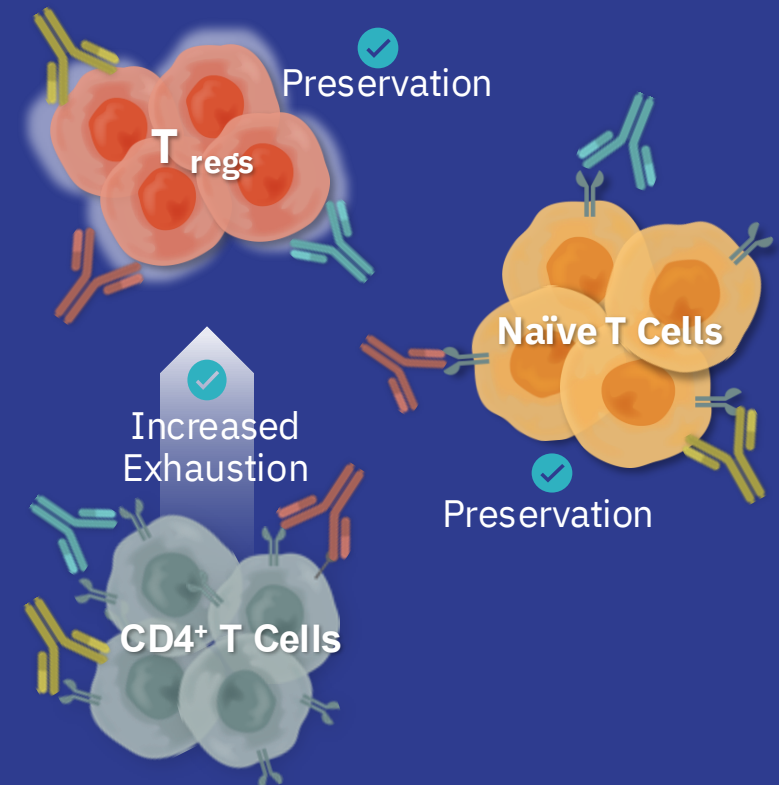
Teplizumab

(Anti-CD3 mAb)



SAB-142

(Human Multi-Specific Anti-Thymocyte Globulin)



Early Clinical Data Show the Hallmarks of a Repeat-Dose Disease Modifier

The clinical goal is not a one-time transient immune reset. It is sustainable beta-cell preservation enabled by safe, predictable redosing



Efficacy

Encouraging early signals of C-peptide preservation in T1D patients >2 yrs from diagnosis

- ✓ Early C-peptide signal consistent with beta cell preservation



Immunogenicity

Confirmed: SAB-142 has low immunogenicity

- ✓ Low immunogenicity on single and repeat dosing
- ✓ Enables safe and reliable redosing



PK/PD

T cell preservation with enhanced “exhaustion” signature

- ✓ Tregs preserved, increased T cell “exhaustion” signature repeated upon redosing
- ✓ Predictable PK upon redosing



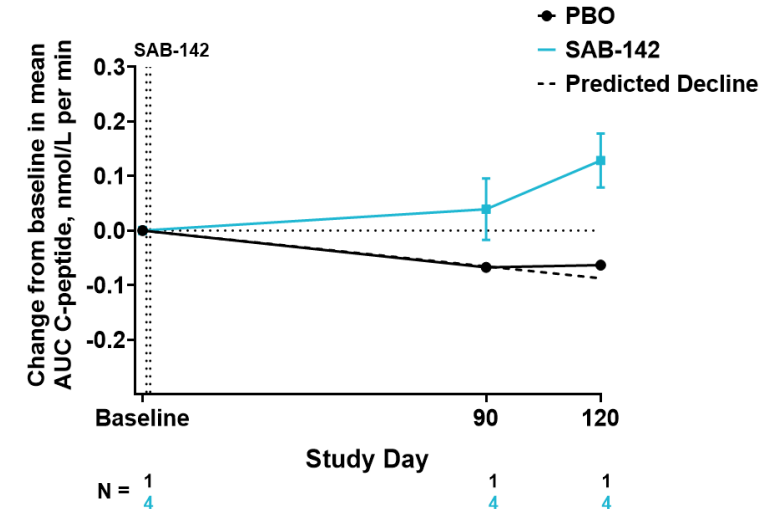
Safety & Tolerability

Positions SAB-142 for a convenient, potentially twice a year dosing regimen

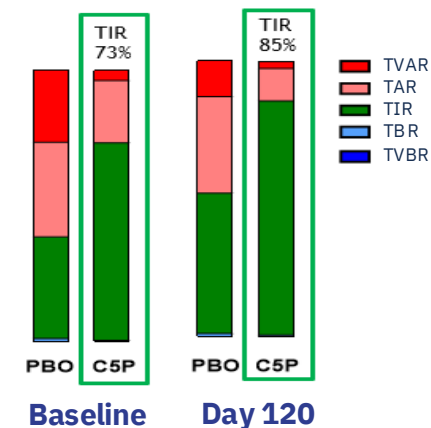
- ✓ No lymphodepletion; no neutropenia, thrombocytopenia, decrease in WBC or RBCs on single and repeat dosing
- ✓ No serum sickness; Grade 1/mild CRS only

C-Peptide Preservation

Baseline-corrected MMTT C-peptide Mean AUC per min $\pm$ SEM

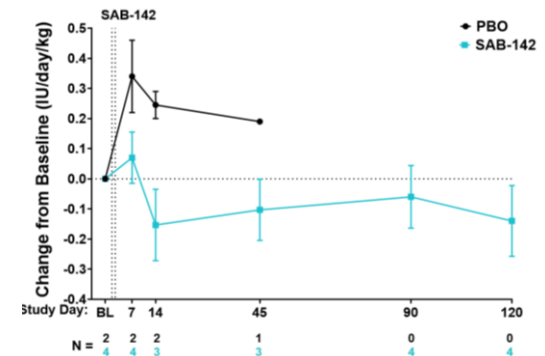


Improved Glycemic Control



Reduced Exogenous Insulin Use

Mean Total Insulin Use Per Day $\pm$ SEM



The Opportunity Is Not One Moment in T1D - It Is the Entire Continuum

A potentially differentiated approach to immunomodulation, redosing, and lifelong T1D care

Early intervention is essential.

Life-long disease modification is possible with safe and reliable redosing

Under development

Stage 1

Stage 2

Intervention enables potentially delayed onset

PRESYMPTOMATIC

Normoglycemia
≥2 Autoantibodies

Dysglycemia
≥2 Autoantibodies

Normal Beta
Cell Mass

Normal beta cell mass decreases with progression of T1D



SAFEGUARD

Stage 3

New Onset

Intervention enables preservation of beta cells and C peptide



PRISE-hATG

Stage 3

Recent & Established Onset

Intervention enables preservation of beta cells and C peptide

CLINICAL

Symptomatic T1D requiring insulin

Hyperglycemia
≥1 Autoantibodies²

Hyperglycemia
≥1 Autoantibodies²

SAFEGUARD Is the First Study for a New T1D Treatment Paradigm

www.safeguardstudy.com

Studying SAB-142 in the new onset window up to 100 days



SAFEGUARD

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

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
- **Part C:** All patients including placebo with preserved beta cells eligible for 12-month long-term extension 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**
- **Induction dose levels:** 1.5 and 2.5 mg/kg
- **Maintenance dose:** 1.5 mg/kg every 6 months

Global study initiated

First patient dosed in December 2025 with **Topline results expected 2H 2027**



United States
(FDA) [NCT07187531](#)



Europe
(EMA)



United Kingdom
(MHRA)



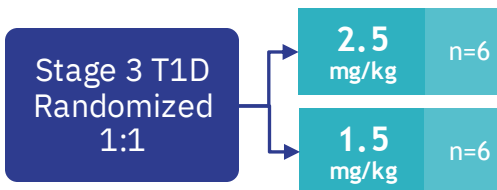
Australia
(TGA)



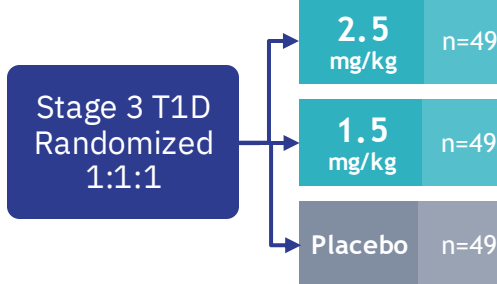
New Zealand
(MEDSAFE)

Randomized, Double-Blind, Placebo-Controlled Safety and Efficacy Study

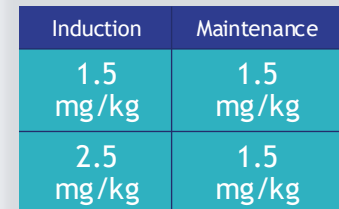
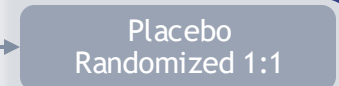
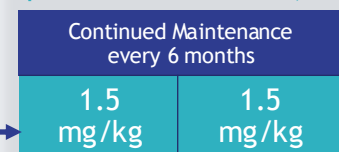
Part A



Part B



Part C (all patients, including placebo, with preserved beta cells)



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

PRISE Expands the Ambition: Disease Modification for More of the T1D Population

By enrolling patients up to two years after diagnosis, PRISE evaluates whether meaningful preservation can extend beyond the newly diagnosed setting



PRISE-hATG

PI: Dr. Haller

PRISE: Personalized Response and Immunologic Surveillance of Endogenous C-Peptide Preservation in New, Recent, and Established Onset Type 1 Diabetes Treated with Human Anti-Thymocyte Globulin (h-ATG)

TRIAL DESIGN:

- Expanding clinical trial opportunities for patients with Stage 3 T1D and no current treatment options.
- 108 pediatric, adolescent, and adult patients (5-40 yr)
 - Cohort 1 from SAFEGUARD: Less than 100 days from T1D Diagnosis
 - Cohort 2: 100 days to 1 year from T1D Diagnosis
 - Cohort 3: 1 – 2 years from T1D Diagnosis

INCLUSION CRITERIA:

- Baseline C-peptide ≥ 200 pmol/L

DOSING REGIMEN:

- Intravenous (IV)
- 0.5 mg/kg on Day 1 and remainder of dose Day 2
- Induction dose (TP1): 2.5 mg/kg SAB-142 or placebo
- Maintenance dose (TP2): 1.5 mg/kg at 6 months



Breakthrough T1D™
Formerly JDRF

UF UNIVERSITY of FLORIDA



United States
(FDA) NCT07187531



Europe
(EMA)



United Kingdom
(MHRA)

Phase 3 Randomized, Double-Blind, Placebo-Controlled Safety & Efficacy Study

Cohort 1 From SAFEGUARD

Stage 3 T1D (<100 days)
Randomized 2:1

2.5 mg/kg
n=24

Placebo
n=12

Cohort 2

Stage 3 T1D (100 days – 1 yr)
Randomized 2:1

2.5 mg/kg
n=24

Placebo
n=12

Cohort 3

Stage 3 T1D (1-2 yrs)
Randomized 2:1

2.5 mg/kg
n=24

Placebo
n=12

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

The Science Continues

Join SAB BIO for our other presentations at EASD!

Wednesday, September 30th, 2026

1:00 – 2:00pm

Station 03

Session Title: Can We Stop Type 1 Diabetes?



#3258

Mechanism of action of SAB-142 and responsive C-peptide signal in adult patients with type 1 diabetes > 100 days post diagnosis

*Christoph Bausch, PhD
Chief Operating Officer*

#3229

SAB-142, a fully human anti-thymocyte globulin, can be safely readministered, is not immunogenic, and has predictable PK/PD profiles in healthy volunteers

*Will Quinn, PhD
Executive Director of Immunology*

#3308

SAB-142, a fully human anti-thymocyte globulin, demonstrated anticipated PD profiles and early efficacy signals in T1D patients with residual C-peptide

*Will Quinn, PhD
Executive Director of Immunology*