



Save All Beta Cells: Sustained Autoimmune Balance with SAB-142 Induction and Maintenance Dosing

October 10, 2026



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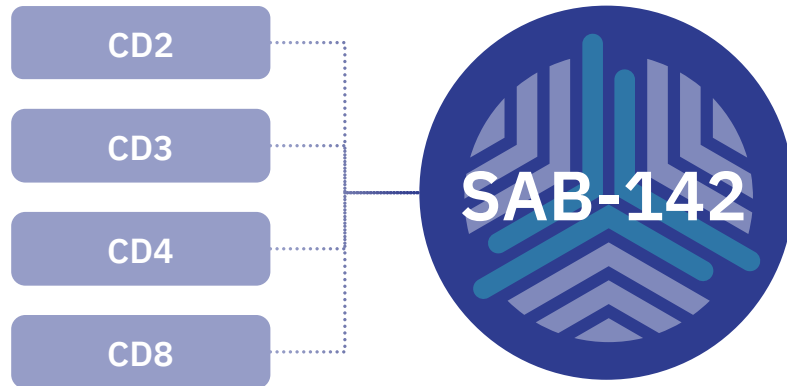
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SAB-142 is a Fully Human, Multi-Specific, Targeted Anti-Thymocyte Globulin (hATG) for Delaying Onset and Progression of T1D

Multi-specific Immunotherapy

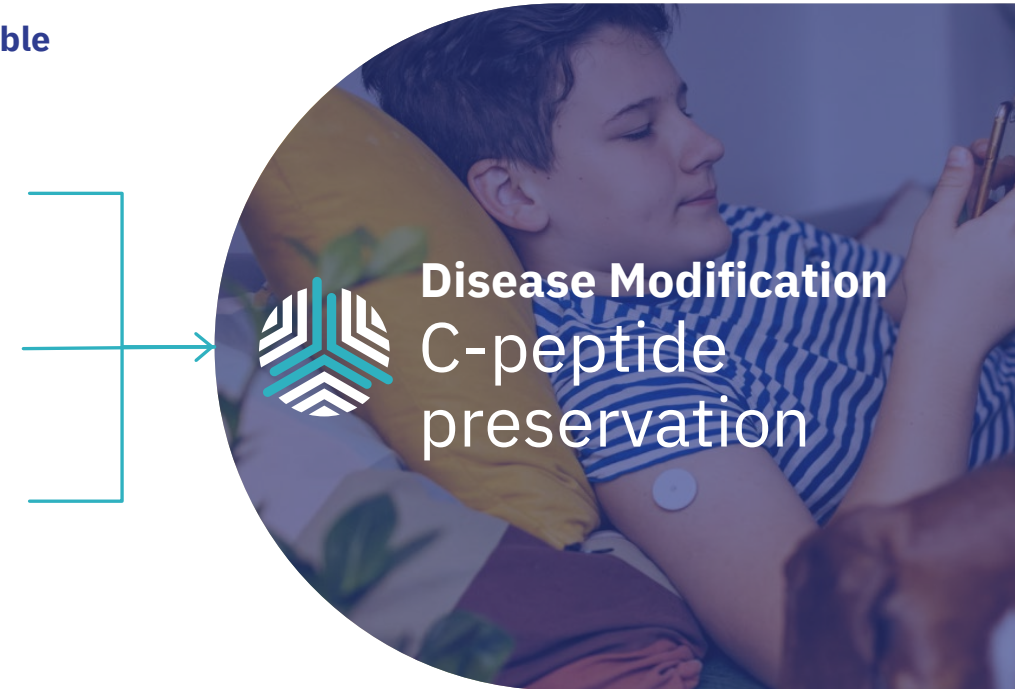
Targets Multiple CD Markers on Multiple Lymphocytes



Pharmacodynamic profile

makes lifelong redosing possible

- ✓ Exhaustion induced
re-established after
maintenance dosing
- ✓ Tregs preserved
after induction and
maintenance doses
- ✓ No lymphodepletion
transient margination only



Disease Modification
C-peptide
preservation

PHASE 1 EVIDENCE

Clinically validated MOA with **improved safety and immunogenicity profile vs. rATG and teplizumab**

PROGRAM STATUS

Phase 2b pivotal **SAFEGUARD**, FDA-designated, in new onset T1D patients ages 5–40

A profile that makes immunomodulation through redosing a lifelong possibility

The Opportunity To Treat T1D Across The Entire Disease Continuum

A potentially differentiated approach to immunomodulation, safe 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

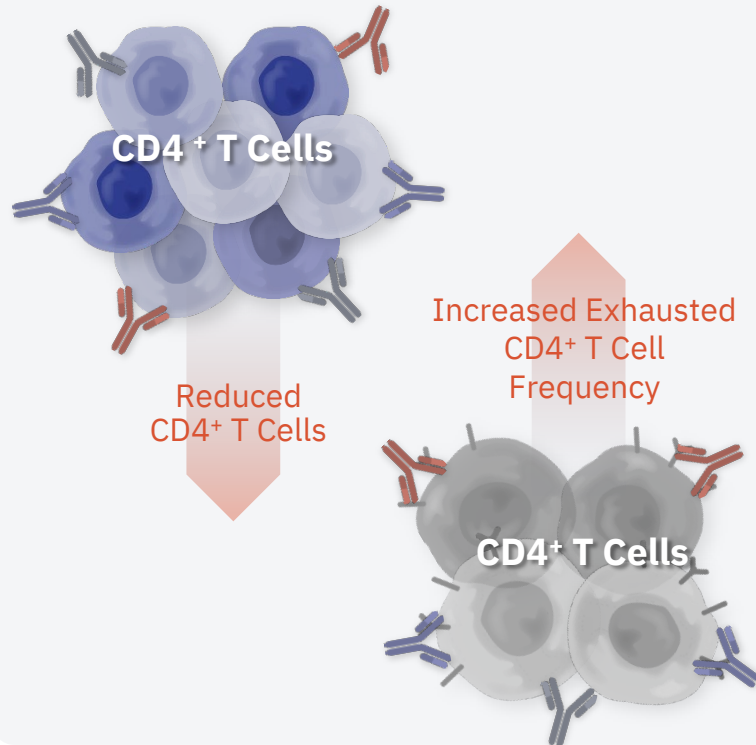
Hyperglycemia
≥1 Autoantibodies²

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.

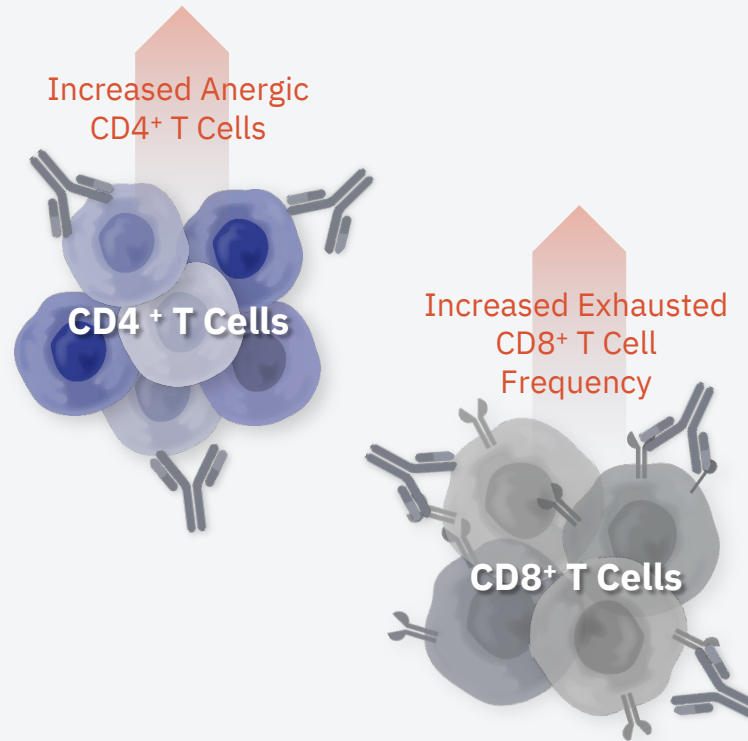
rATG

(rabbit Anti-Thymocyte Globulin)



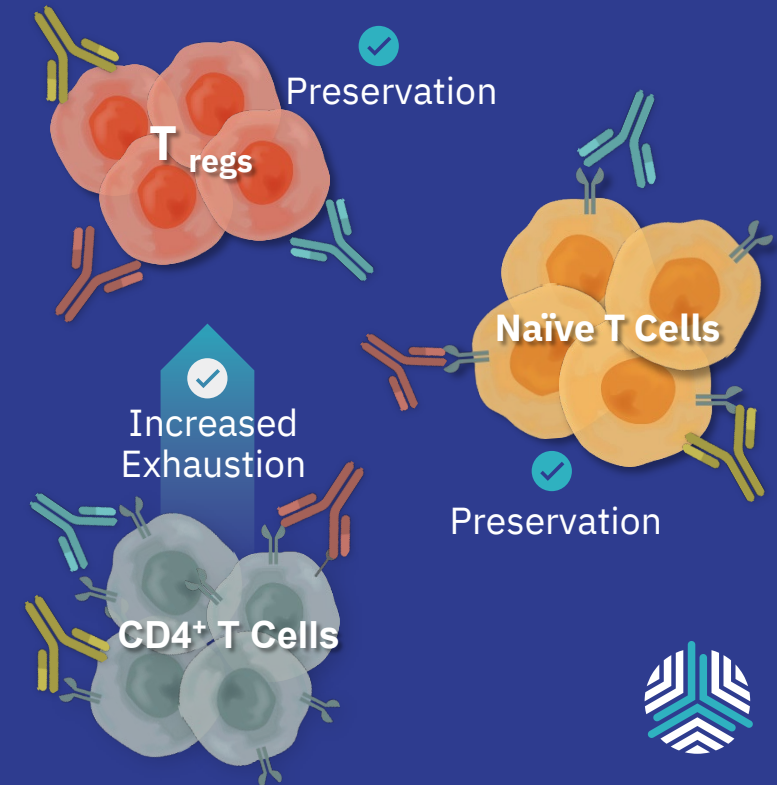
Teplizumab

(Anti-CD3 mAb)



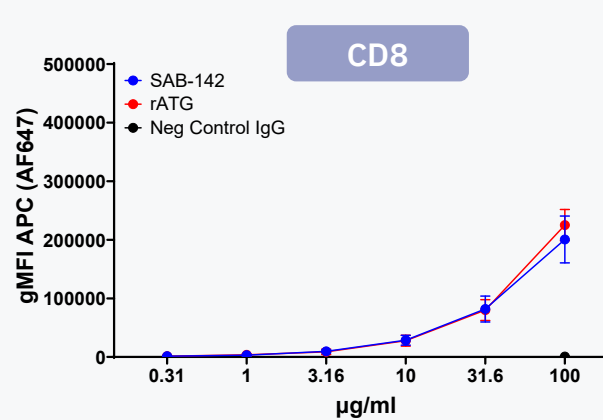
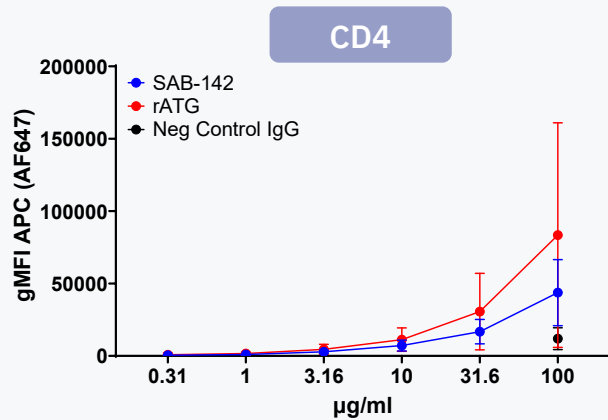
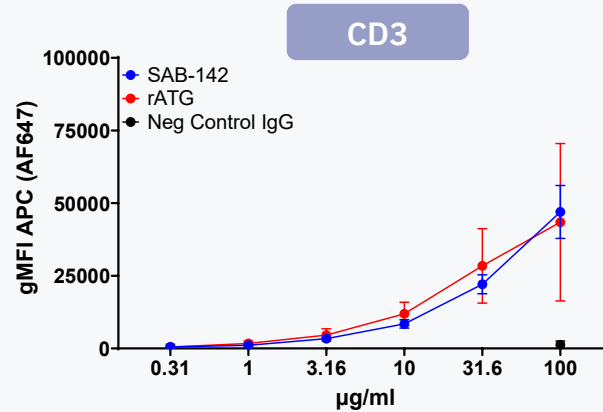
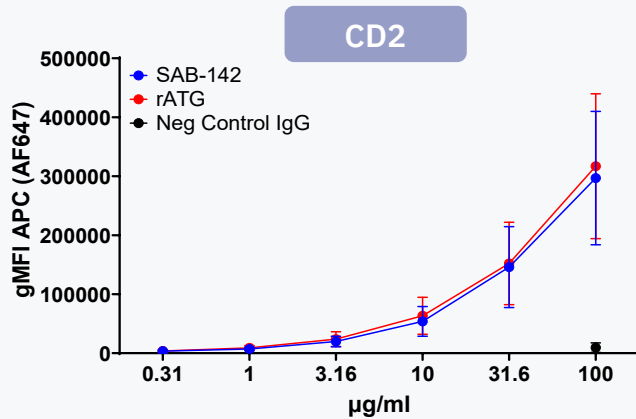
SAB-142

(Human Multi-Specific Anti-Thymocyte Globulin)



SAB-142 Binds to the Same T Cell Surface Receptors as rATG

Binding of Directly Labeled SAB-142 and rATG to CD2, CD3, CD4, and CD8 Cell Lines



SAB-142 binds to CD2, CD3, CD4, and CD8 receptor surface markers **similar to rATG**

Data generated with SAB-142 by Judith Leitner, laboratory of Peter Steinberger based on published methodology.

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doi: 10.1111/ajt.12514

A Comprehensive and Quantitative Analysis of the Major Specificities in Rabbit Antithymocyte Globulin Preparations



SAB-142 is a Fully Human Biologic: T regs are preserved while exhausted T cells enhanced

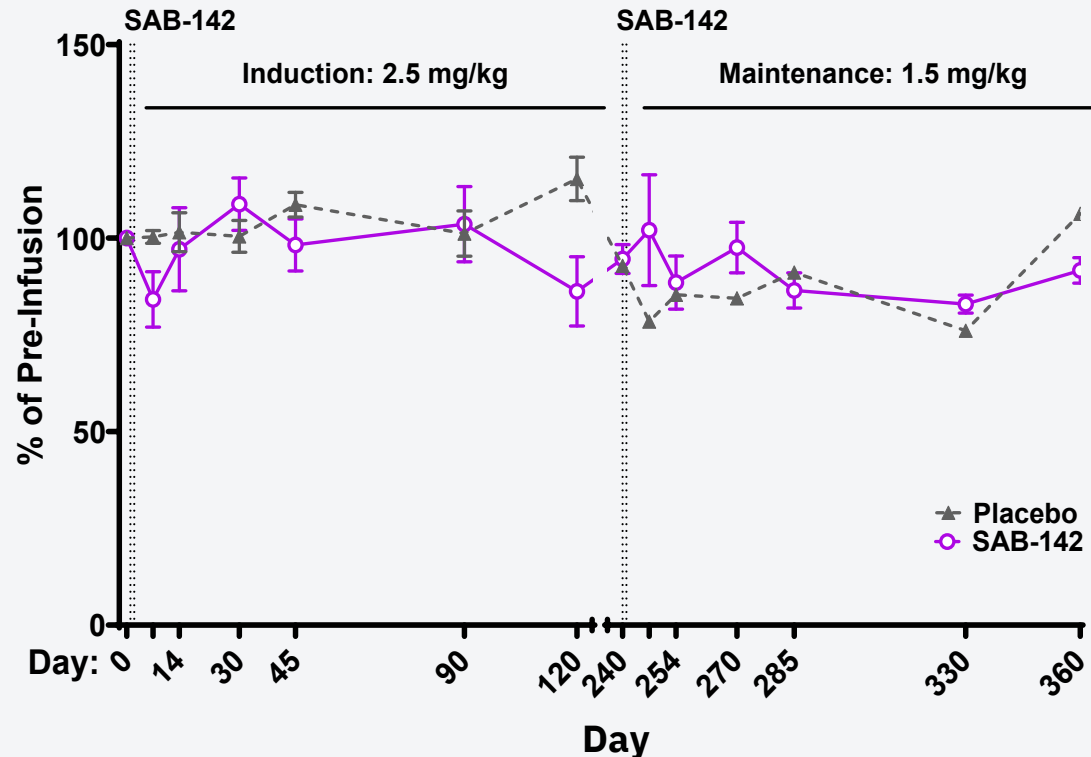


PD

Regulatory T cell Preservation

✓ Tregs preserved following induction and maintenance dosing

CD4+ Treg $\pm$ SEM



Teplizumab PUBLISHED DATA

Teplizumab depletes T regs upon redosing

Remodeling T cell compartments during anti-CD3 immunotherapy of type 1 diabetes

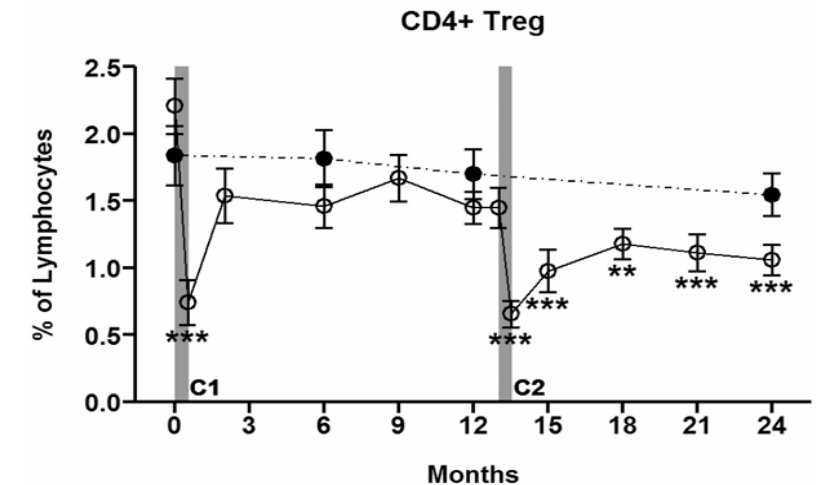
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SAB-142 is a Fully Human Biologic: CD4 exhaustion increased after induction and reestablished post maintenance dose

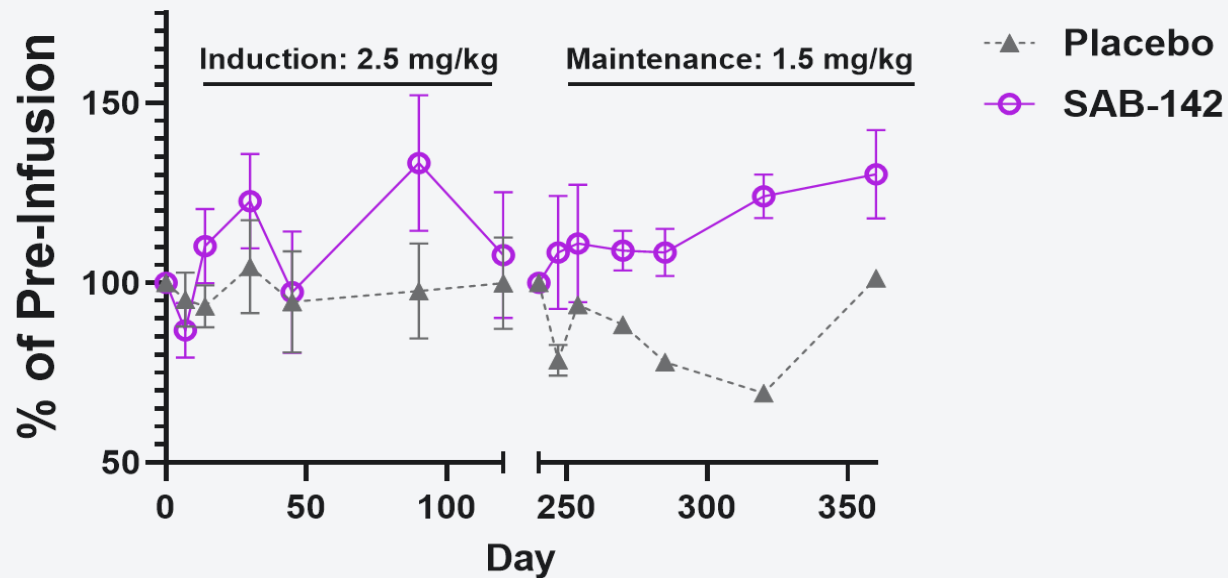


PD

Increased exhaustion markers

- ✓ Increased frequency of PD-1⁺ and TIGIT⁺ T cells
- ✓ Exhaustion maintained upon redosing

PD-1⁺ CD4 Normalized Mean



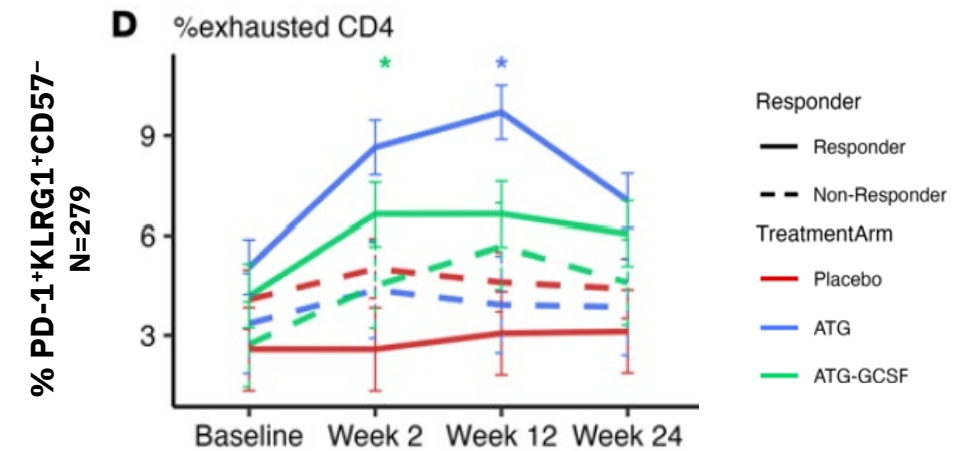
rATG PUBLISHED DATA

CD4 exhaustion is an efficacy correlate post rATG

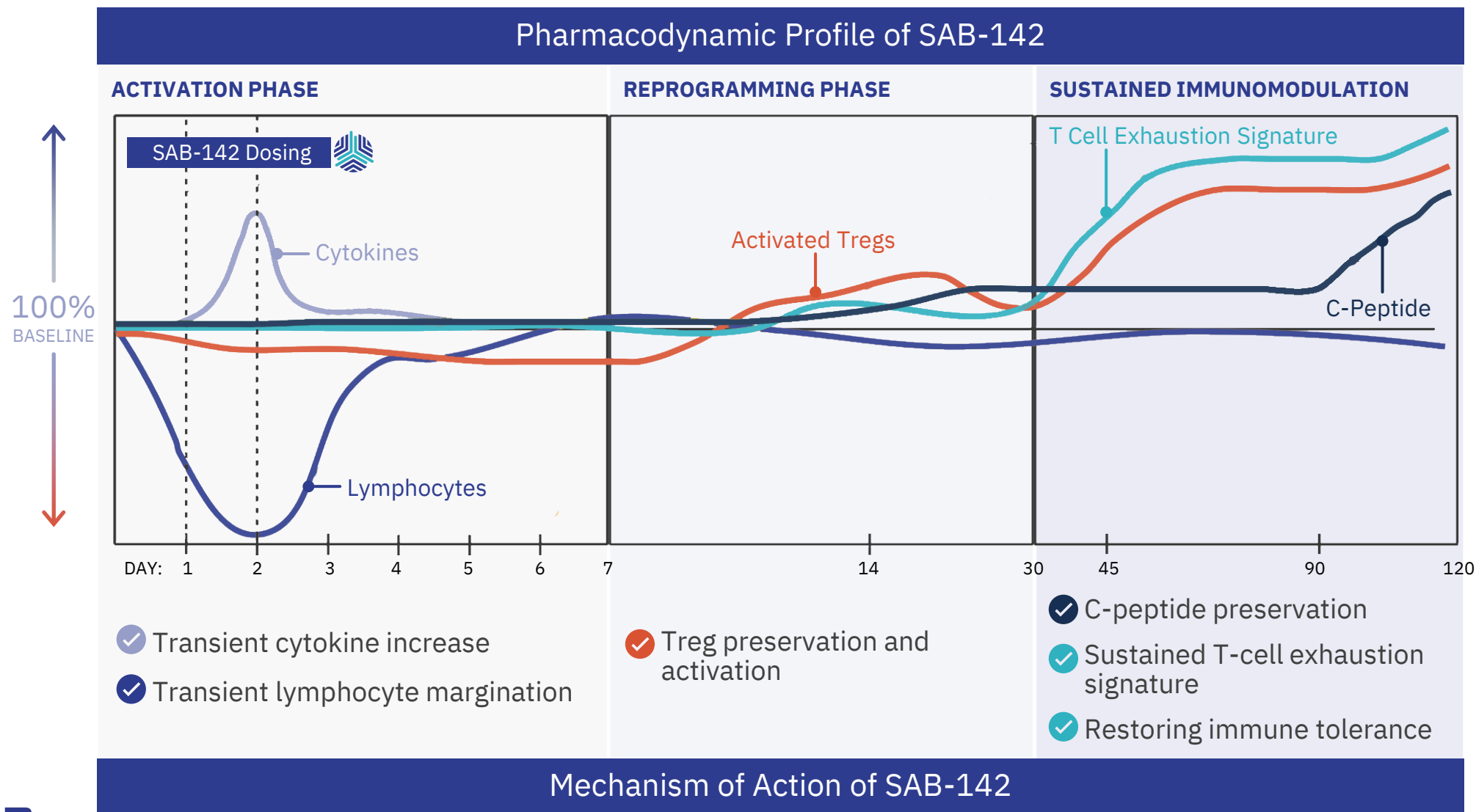
JCI insight

CLINICAL MEDICINE

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



Multi-Specific MoA of SAB-142: A symphony of immunomodulation without lymphodepletion resulting in an early efficacy signal



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 SAB-142 has low immunogenicity

- ✓ Low/no immunogenicity on single and repeat dosing
- ✓ Enables safe and reliable redosing

PK/PD T cell preservation with enhanced “exhaustion” signature

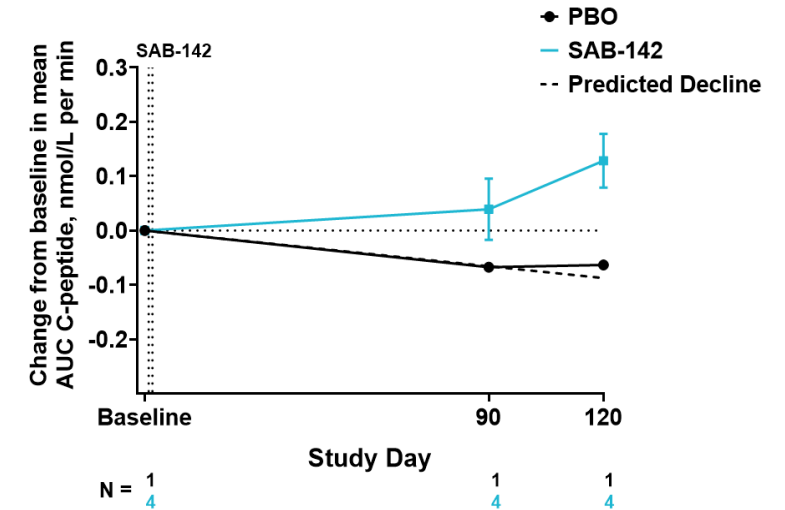
- ✓ Tregs preserved, increased T cell “exhaustion” signature repeated upon redosing
- ✓ Predictable PK upon redosing

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

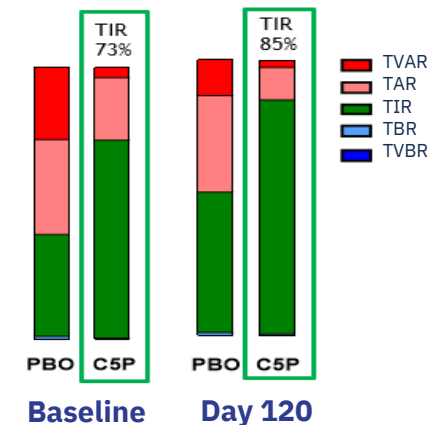
- ✓ No lymphodepletion; no neutropenia, thrombocytopenia, decrease in WBC or RBCs on single and repeat dosing
- ✓ No serum sickness; Grade 1/mild CRS only

C-Peptide Preservation

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

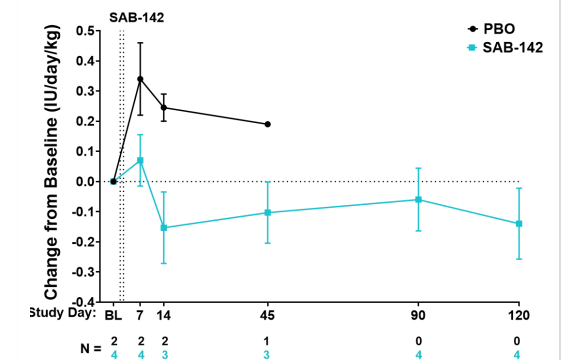


Improved Glycemic Control



Reduced Exogenous Insulin Use

Mean Total Insulin Use Per Day $\pm$ SEM



SAB-142 Safety Profile Enables Induction Dose and Redose (Maintenance dosing) in an Ambulatory Setting

Majority of adverse events (AEs) are mild, associated with Day 1-2 infusions, and resolved by the end of the first week

Safety profile enables ambulatory dosing

Most Frequent TEAEs:

- Headaches: typical for all T-cell-engaging therapies
- Transient lymphopenia (margination):
 - Anticipated PD effect; **self-resolves within 1-3 days**
 - Accounts for 100% of Grade 3 & 4 drug related TEAEs** and not associated with clinical symptoms
- Infusion-related reactions (IRRs):
 - CRS: flu-like symptoms, Grade 1 (mild) only, temporarily associated with SAB-142 infusions with onset up to 24 hours
 - 1.5 mg/kg induction and maintenance dose had no CRS**
 - Infusion-site reactions (ISR): erythema, tenderness, phlebitis
- No serum sickness, no AEs associated with ADAs
- No decrease in RBCs, no neutropenia, no lymphopenia, or thrombocytopenia from Day 7 onward
- No drug related SAEs

Overall summary of treatment emergent adverse events (safety analysis set)

Category	Part A: Induction Dose				Part B: Maintenance Dose			
	Day 1 to 7		Day 8 to 180		Day 1 to 7		Day 8 to 180	
	Pooled Placebo HV+T1D	Pooled SAB-142 HV+T1D	Pooled Placebo HV	Pooled SAB-142 HV	Pooled Placebo HV	Pooled SAB-142 HV	Pooled Placebo HV	Pooled SAB-142 HV
N [n (%)]	18	50	18	50	1	7	1	7
Number of participants with any:								
TEAEs	12 (66.7%)	46 (92.0%)	11 (61.1%)	27 (54.0%)	1 (100.0%)	7 (100.0%)	0	4 (57.1%)
TEAEs by Severity:								
Grade 1	8 (44.4%)	2 (4.0%)	5 (27.8%)	17 (34.0%)	1 (100.0%)	0	0	2 (28.6%)
Grade 2	4 (22.2%)	3 (6.0%)	5 (27.8%)	9 (18.0%)	0	0	0	1 (14.3%)
Grade 3	0	16 (32.0%)	1 (5.6%)	1 (2.0%)	0	5 (71.4%)	0	1 (14.3%)
Grade 4	0	25 (50.0%)	0	0	0	2 (28.6%)	0	0
Grade 5	0	0	0	0	0	0	0	0
Treatment-related TEAEs by Severity:								
Grade 1	4 (22.2%)	1 (2.0%)	0	6 (12.0%)	0	0	0	2 (28.6%)
Grade 2	2 (11.1%)	3 (6.0%)	1 (5.6%)	2 (4.0%)	0	0	0	0
Grade 3	0	16 (32.0%)	0	0	0	5 (71.4%)	0	0
Grade 4	0	25 (50.0%)	0	0	0	2 (28.6%)	0	0
Grade 5	0	0	0	0	0	0	0	0

SAB-142 is a Fully Human Biologic: Low Immunogenicity, Predictable PK



Immunogenicity

Confirmed: SAB-142 has low immunogenicity

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

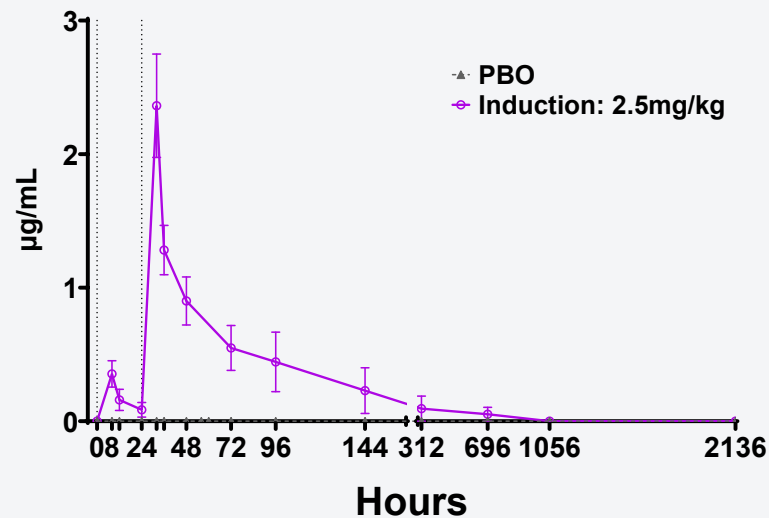


PK

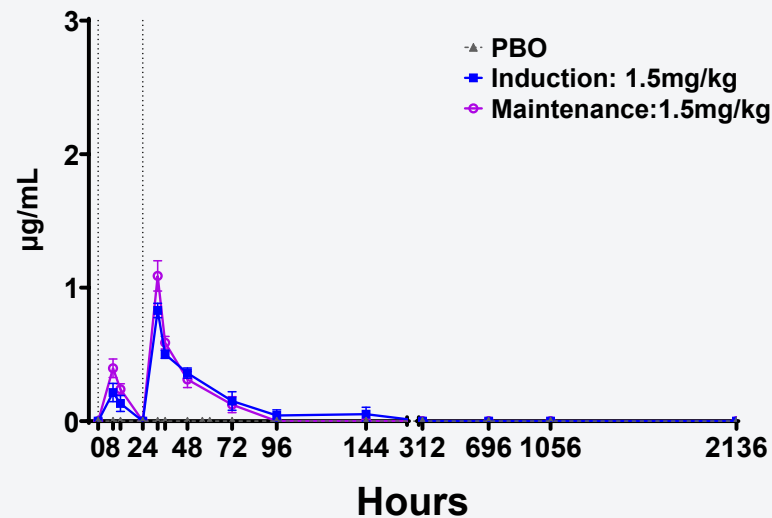
Dose dependent & predictable

- ✓ Dose dependent PK
- ✓ Induction and maintenance PK profile indistinguishable

Serum PK SAB-142 $\pm$ SEM



Serum PK SAB-142 $\pm$ SEM



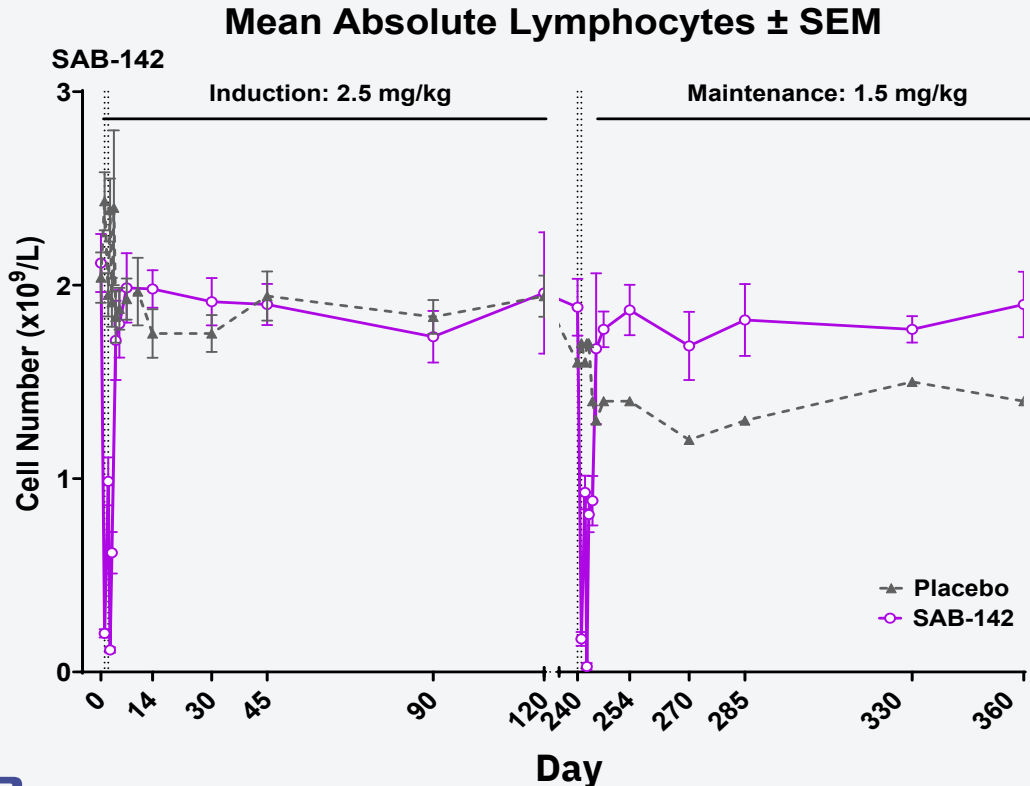
SAB-142 is a Fully Human Biologic: No lymphodepletion following induction or maintenance dosing



PD

No Lymphodepletion

- ✓ No lymphodepletion on single and repeat dosing
- ✓ Transient lymphopenia due to margination with lymphocytes returning to baseline in ≤ 5 days



rATG PUBLISHED DATA

Rabbit ATG causes sustained lymphodepletion up to 2 years

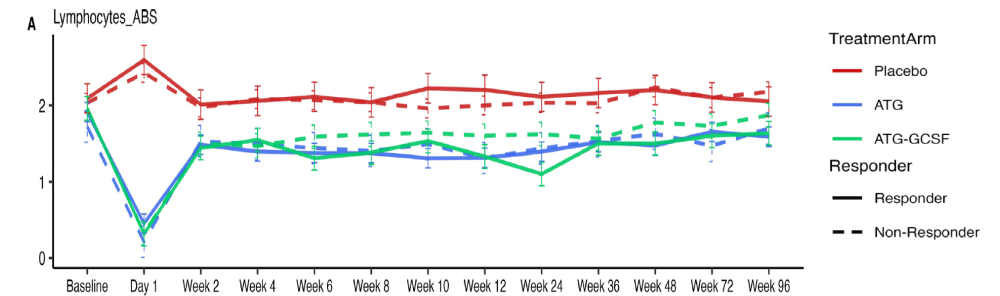
JCI insight

CLINICAL MEDICINE

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

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SAFEGUARD Is the First Study for a New T1D Treatment Paradigm

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



SAFEGUARD

Phase 2b Study

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
(MDSAFE)

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

Part A (n=12)

	Induction	Maintenance
Stage 3 T1D Randomized 1:1	1.5 mg/kg	1.5 mg/kg
	2.5 mg/kg	1.5 mg/kg

Part B (n=147)

	Induction	Maintenance
Stage 3 T1D Randomized 1:1:1	1.5 mg/kg	1.5 mg/kg
	2.5 mg/kg	1.5 mg/kg
	Placebo	

Part C

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

Continued Maintenance every 6 months	
1.5 mg/kg	1.5 mg/kg

Part B Placebo Randomized 1:1

Induction	Maintenance
1.5 mg/kg	1.5 mg/kg
2.5 mg/kg	1.5 mg/kg

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



For more information about the study, go to [SAFEGUARDSTUDY.COM](https://safeguardstudy.com) or reach us at 1-844-763-1890 or SAFEGUARD@sab.bio

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. Mike 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**



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Tim Tree
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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 &
E-posters at
Breakthrough T1D!



#495 PRESENTATION



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

Will Quinn, PhD | *Executive Director of Immunology*

SATURDAY, OCTOBER 10TH, 2026 2:50 – 3:00pm

Hall 103AB



#435 E-POSTER

Tracking multiplicity: clinical pharmacokinetic assay for SAB-142, a multi-target therapeutic for T1D

Eric Sandhurst, PhD | *Director of Program Management*



#499 E-POSTER

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

Will Quinn, PhD | *Executive Director of Immunology*



#428 E-POSTER

Profiling the binding specifications of SAB-142, a fully human anti-thymocyte globulin, against T cell surface proteins

Diane Maher, PhD | *Director of Program Management*