



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

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30th September 2026

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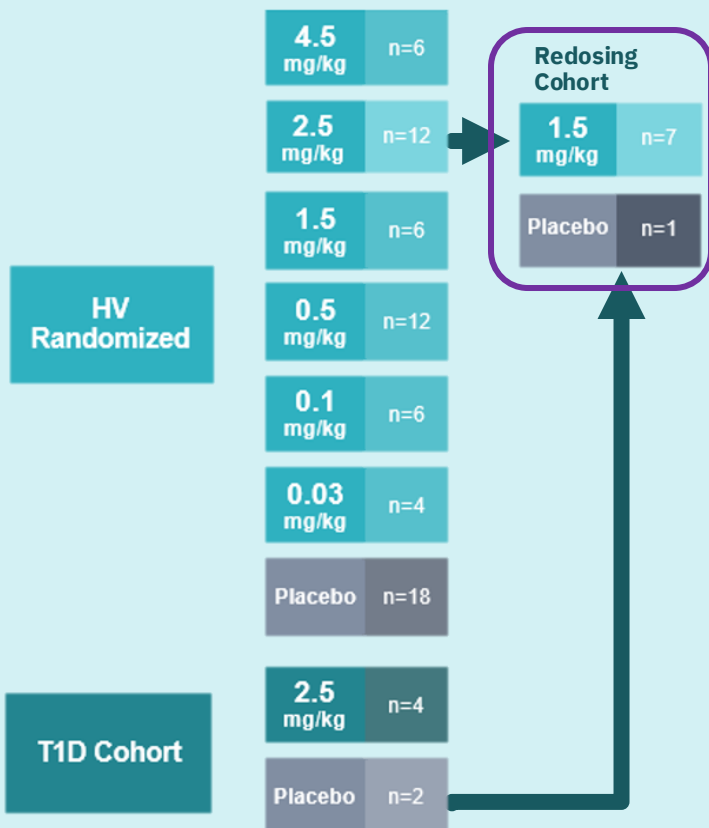
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# SAB-142:

## Redosable Immunomodulating Treatment for Stage 3 T1D

### Study Design

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



### SAB-142 Phase 1 Data: Encouraging Efficacy Signals and Predictable, Safe 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



Enables safe and reliable redosing



#### PK/PD

T cell preservation with enhanced “exhaustion” signature



Predictable PK upon redosing



Tregs preserved, increased T cell “exhaustion” signature



#### Safety and 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

# 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 and reliable redosing

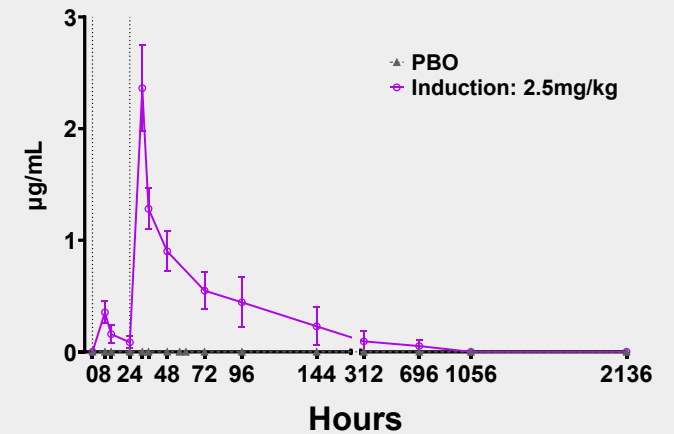


### PK

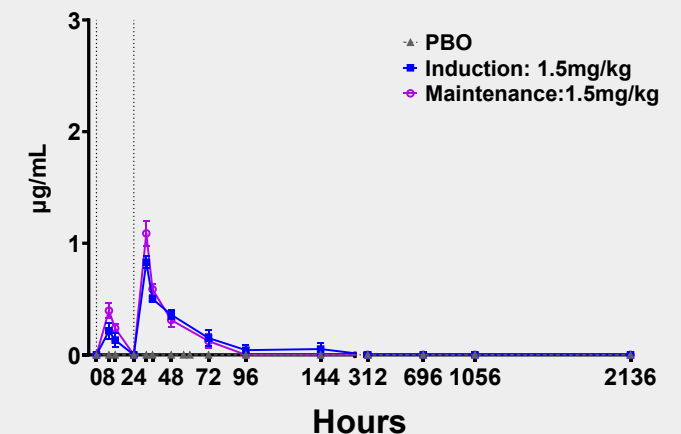
Dose dependent and predictable

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

Serum PK SAB-142  $\pm$  SEM



Serum PK SAB-142  $\pm$  SEM



# SAB-142 is a Fully Human Biologic:

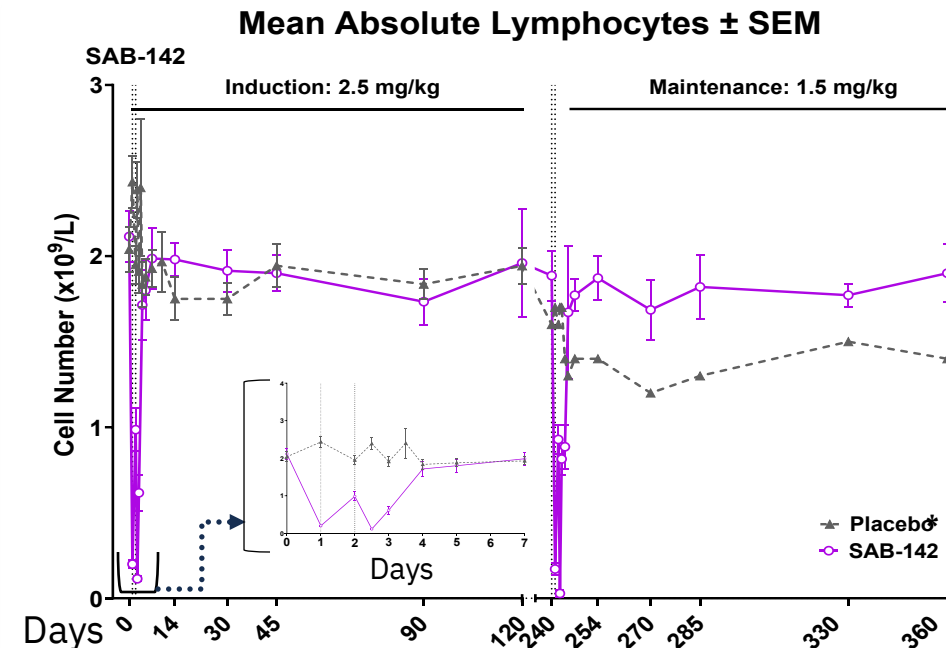
No lymphodepletion following induction or maintenance dosing



PD

No Lymphodepletion

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



rATG Published Data:

*Rabbit ATG causes sustained lymphodepletion up to 2 years*

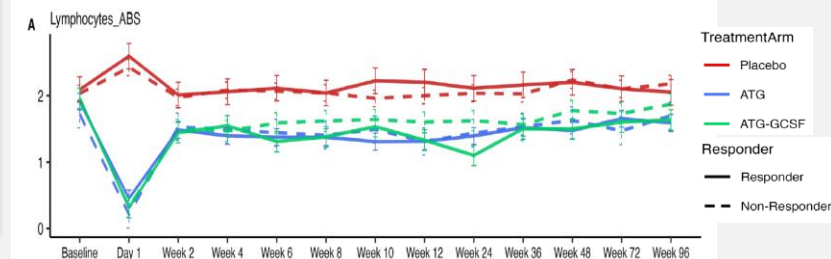
JCI INSIGHT

CLINICAL MEDICINE

## Responders to low-dose ATG induce CD4<sup>+</sup> T cell exhaustion in type 1 diabetes

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

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# SAB-142 is a Fully Human Biologic:

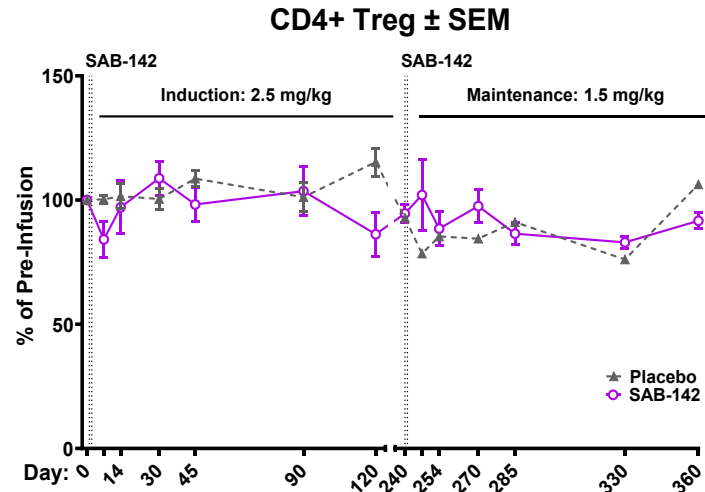
## T regs are preserved while exhausted T cells enhanced



PD

Regulatory T cell Preservation

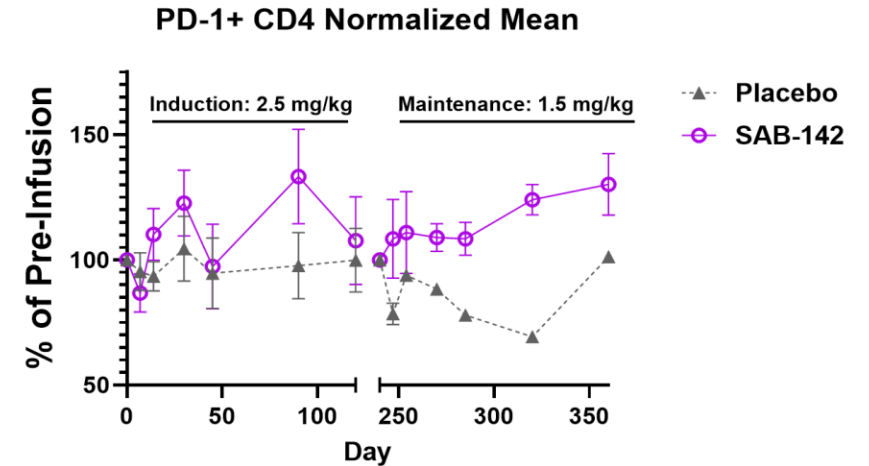
- ✓ T<sub>regs</sub> preserved following induction and maintenance dosing



PD

Increased exhaustion markers

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



*Teplizumab reduces T regs upon redosing*

Research paper

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

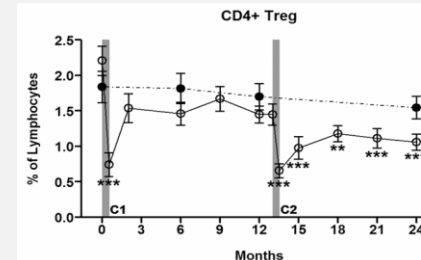
S. Alice Long<sup>a</sup>, Jerill Thorpe<sup>a</sup>, Kevan C. Herold<sup>b</sup>, Mario Ehlers<sup>c</sup>, Srinath Sanda<sup>c</sup>, Noha Lim<sup>d</sup>, Peter S. Linsley<sup>a</sup>, Gerald T. Nepom<sup>a,d</sup>, Kristina M. Harris<sup>a,d</sup>

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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*



Phase 2b  
Study

**SAFEGUARD:** **SAF**ety and **E**fficacy of human anti-thymocyte immuno**GL**ob**UL**in 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**  $\geq 200$  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 (n=12)

|                                  | Induction    | Maintenance  |
|----------------------------------|--------------|--------------|
| Stage 3 T1D<br>Randomized<br>1:1 | 1.5<br>mg/kg | 1.5<br>mg/kg |
|                                  | 2.5<br>mg/kg | 1.5<br>mg/kg |

### Part B (n=147)

|                                    | Induction    | Maintenance  |
|------------------------------------|--------------|--------------|
| Stage 3 T1D<br>Randomized<br>1:1:1 | 1.5<br>mg/kg | 1.5<br>mg/kg |
|                                    | 2.5<br>mg/kg | 1.5<br>mg/kg |
|                                    | Placebo      |              |

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

| Continued Maintenance every<br>6 months |              |
|-----------------------------------------|--------------|
| 1.5<br>mg/kg                            | 1.5<br>mg/kg |

Part B Placebo  
Randomized 1:1

| Induction    | Maintenance  |
|--------------|--------------|
| 1.5<br>mg/kg | 1.5<br>mg/kg |
| 2.5<br>mg/kg | 1.5<br>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**

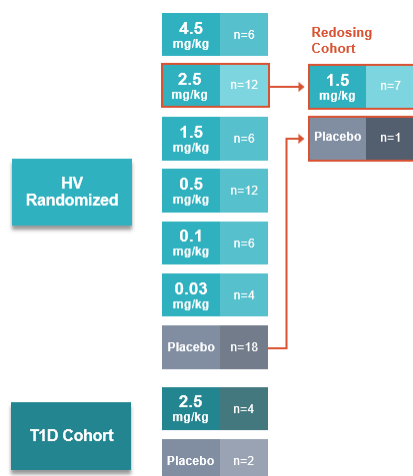
## Other secondary Endpoints:

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

## Introduction

- SAB-142 is a fully human Anti-Thymocyte Globulin (hATG) developed as a multi-specific immunomodulating therapy intended to preserve C-peptide in patients with T1D
- In T1D patients, SAB-142 impact on c-peptide, exogenous insulin use, and glucose time in range was determined.
- As a fully human therapy, SAB-142 was developed to support repeat dosing while reducing limitations associated with heterologous ATG therapies
- The safety, immunogenicity, pharmacokinetic (PK), and pharmacodynamic (PD) profiles of SAB-142 were characterized in a redosing cohort in the SAB-142 Phase 1 clinical trial

## Methods



- A healthy volunteer (HV) redosing cohort was included in the SAB-142 Phase 1 clinical trial to support the anticipated every 6-month dosing regimen.
- Anti-SAB-142 antibodies were assessed using a validated 3-tiered anti-drug antibody (ADA) assay.
- SAB-142 concentrations in participant serum were measured using a validated flow cytometry-based pharmacokinetic (PK) assay.
- Hematologic assessment was performed throughout the study.
- Peripheral blood mononuclear cells (PBMCs) were analyzed by flow cytometry to assess changes in immune cell subsets.

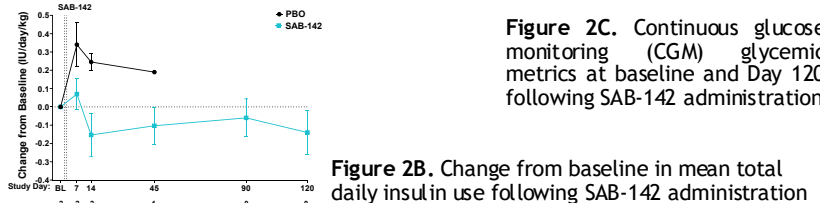
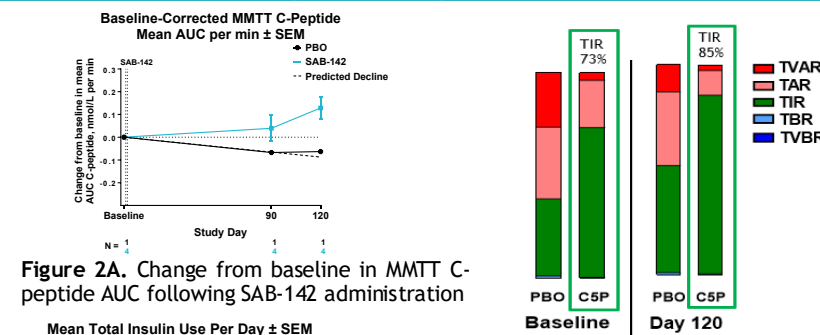
**Figure 1.** Schematic representation of SAB-142-101 phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose adaptive study design including healthy volunteers (HV) and patients with T1D.

## Results

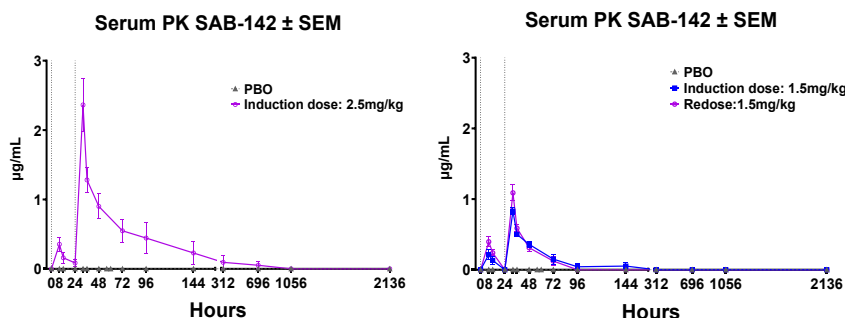
### Safety and Immunogenicity

- No ADAs were detected following redosing of SAB-142 through Day 360, including after the initial administration with no serum sickness.

### C-Peptide and Glycemic Control

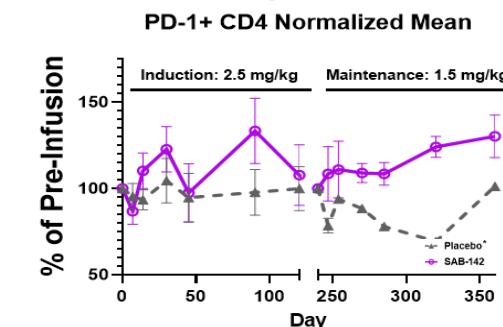
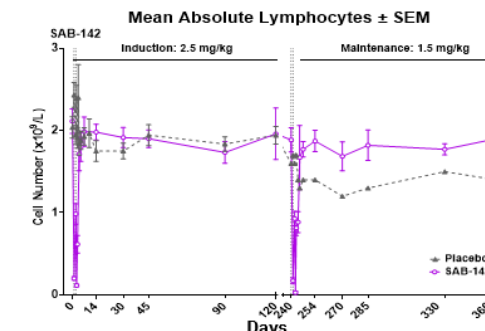


### Pharmacokinetics (PK)



## Results

### Pharmacodynamics (PD)



## Conclusions

- In a cohort of T1D patients >100 days post diagnosis, SAB-142 demonstrated c-peptide preservation, reduced exogenous insulin use, and improved time in range.
- Repeat administration of SAB-142 was safe and well tolerated, with no severe adverse events reported and no detectable ADA following repeat administration.
- SAB-142 demonstrated predictable PK and PD responses, with increased tolerogenic biomarkers and no sustained immunodepletion.
- Findings support the potential for maintenance dosing and sustained immunomodulation in T1D patients