



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

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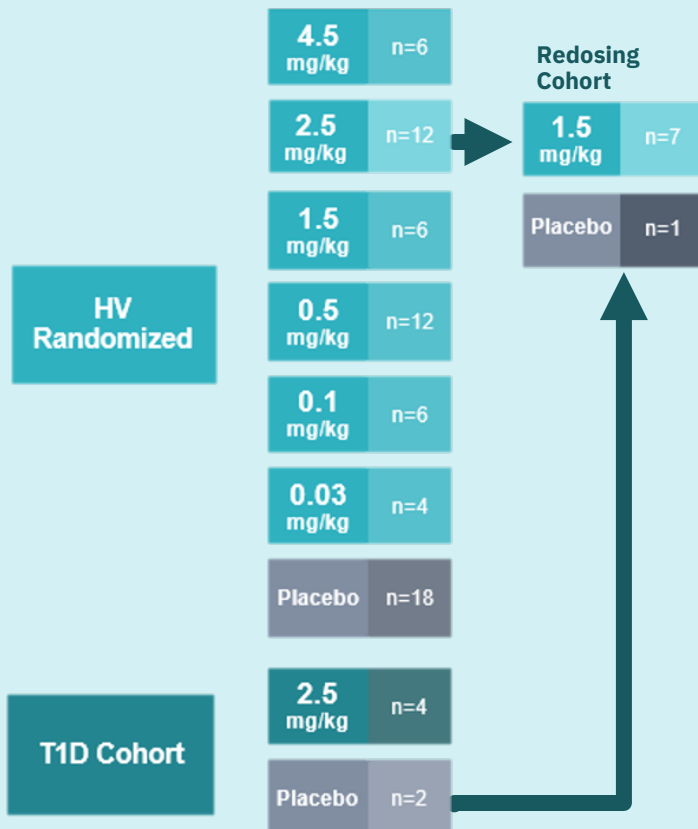
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SAB-142:

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

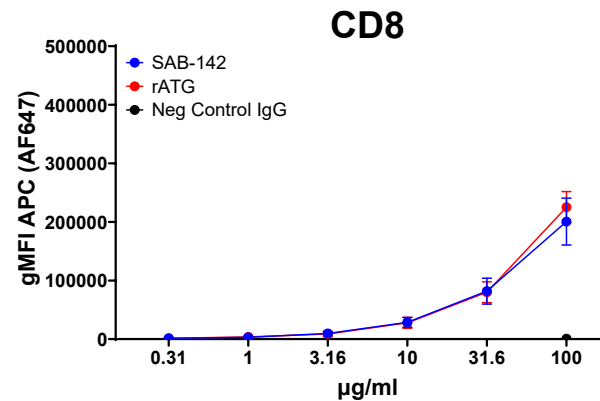
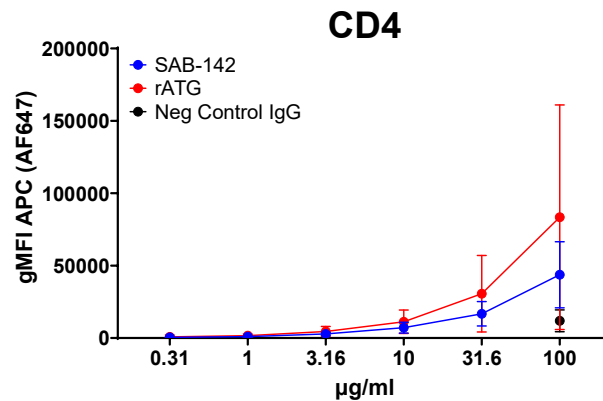
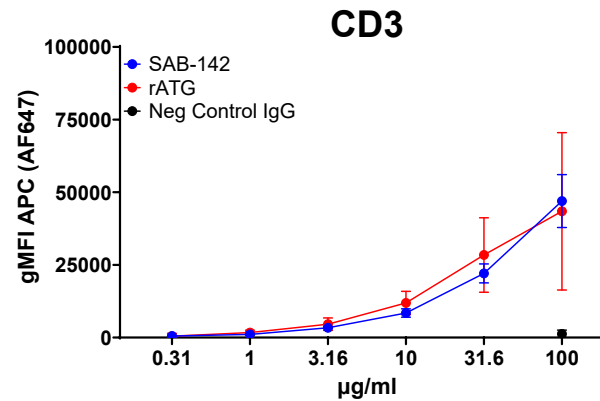
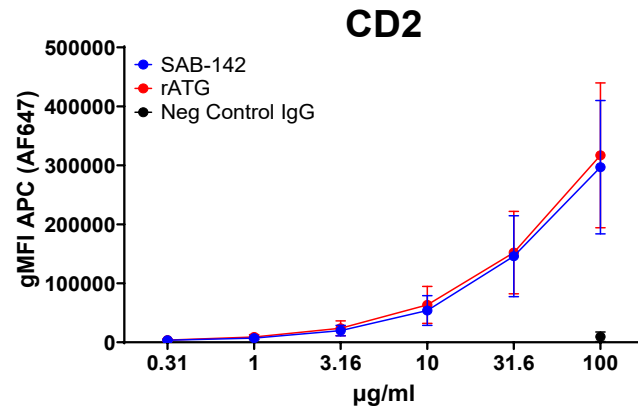


No serum sickness; Grade 1/mild CRS only

SAB-142:

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 Reference:

Judith Leitner, laboratory of Peter Steinberger lab based on published methodology.

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doi: 10.1111/ajt.12514

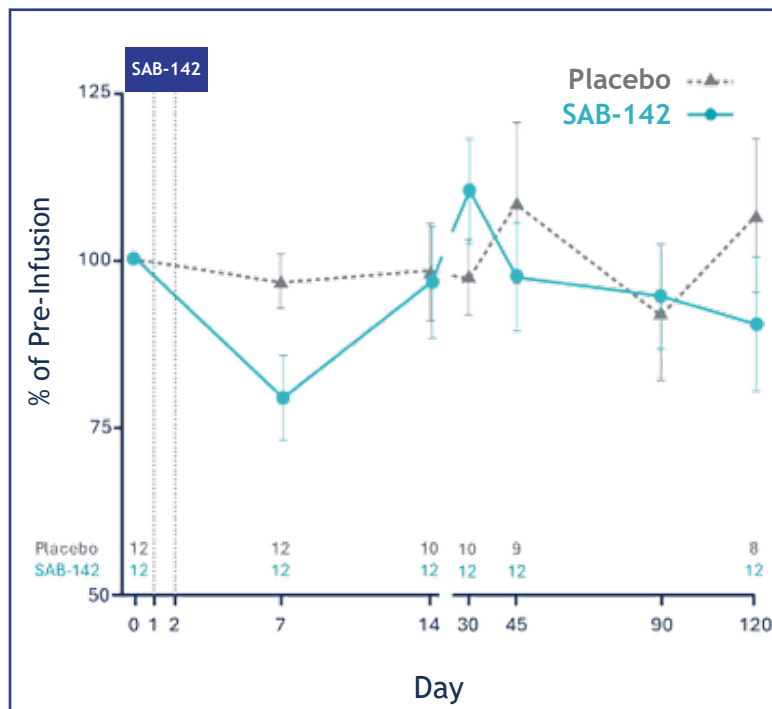
A Comprehensive and Quantitative Analysis of the Major Specificities in Rabbit Antithymocyte Globulin Preparations



SAB-142 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

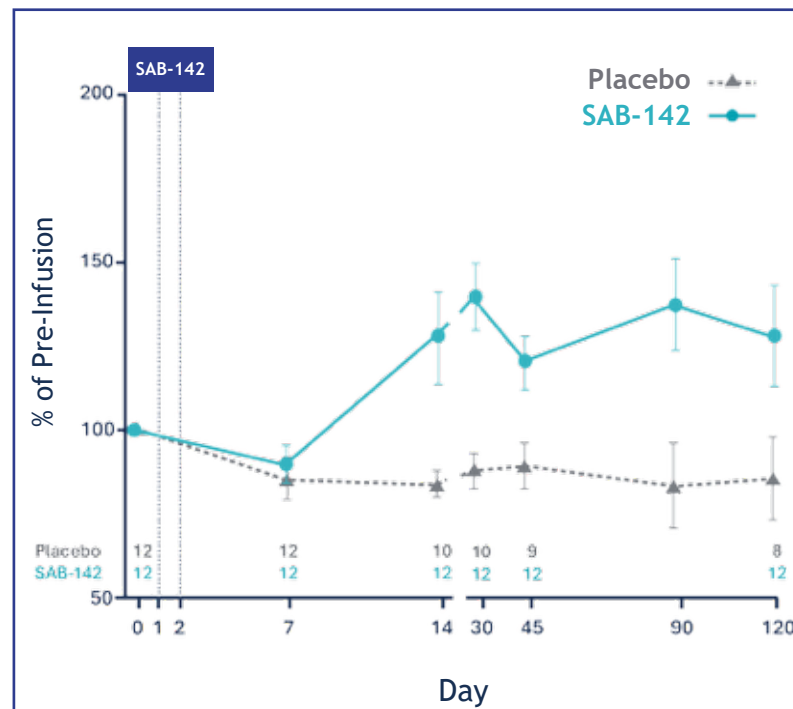
1 Treg preservation

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



2 Increase in CD4 exhaustion

Relative PD-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}

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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-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.

SAB-142 Improved C-Peptide and Glycemic Control

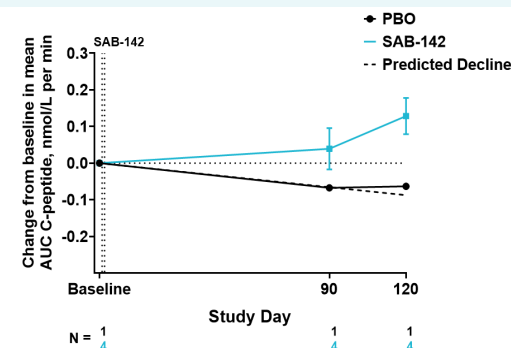
T1D Cohort at 2.5mg/kg

KEY FINDINGS

- ✓ SAB-142 has promising efficacy in an exploratory T1D cohort >2 years from diagnosis
- ✓ 4 of 4 patients showed C-peptide preservation through 120 Days; 3 of 4 had enhanced C-peptide
- ✓ TIR improved from 73% at baseline to 85% by End of Study
- ✓ Insulin doses decreased over time in the SAB-142 group

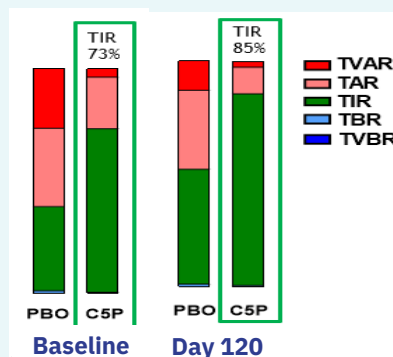
C-Peptide Preservation

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



¹Predicted decline was estimated by first calculating the incremental AUC of TN19 placebo subject C-peptide MMTT data (n=26) for Weeks 48-96 with post-2hr values masked. The linear slope was used to calculate the predicted rate of decline in days: $AUC_{BL} - (-0.6108 \times (\text{Study Day}/7))$. Source: Haller et al. Diabetes. 2019 Jun;68(6):1267–1276. MMTT = Mixed Meal Tolerance Test; AUC = Area Under the Curve; SEM = Standard Error the Mean.

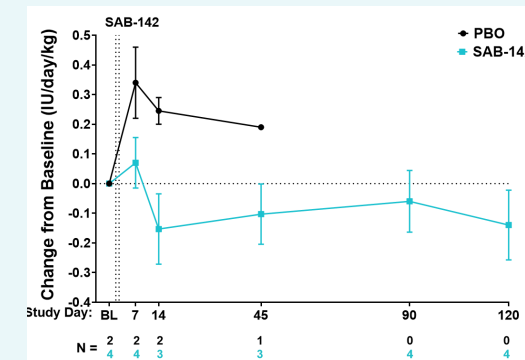
Improved Glycemic Control



*CGM data are based on the patients' individual CGM devices

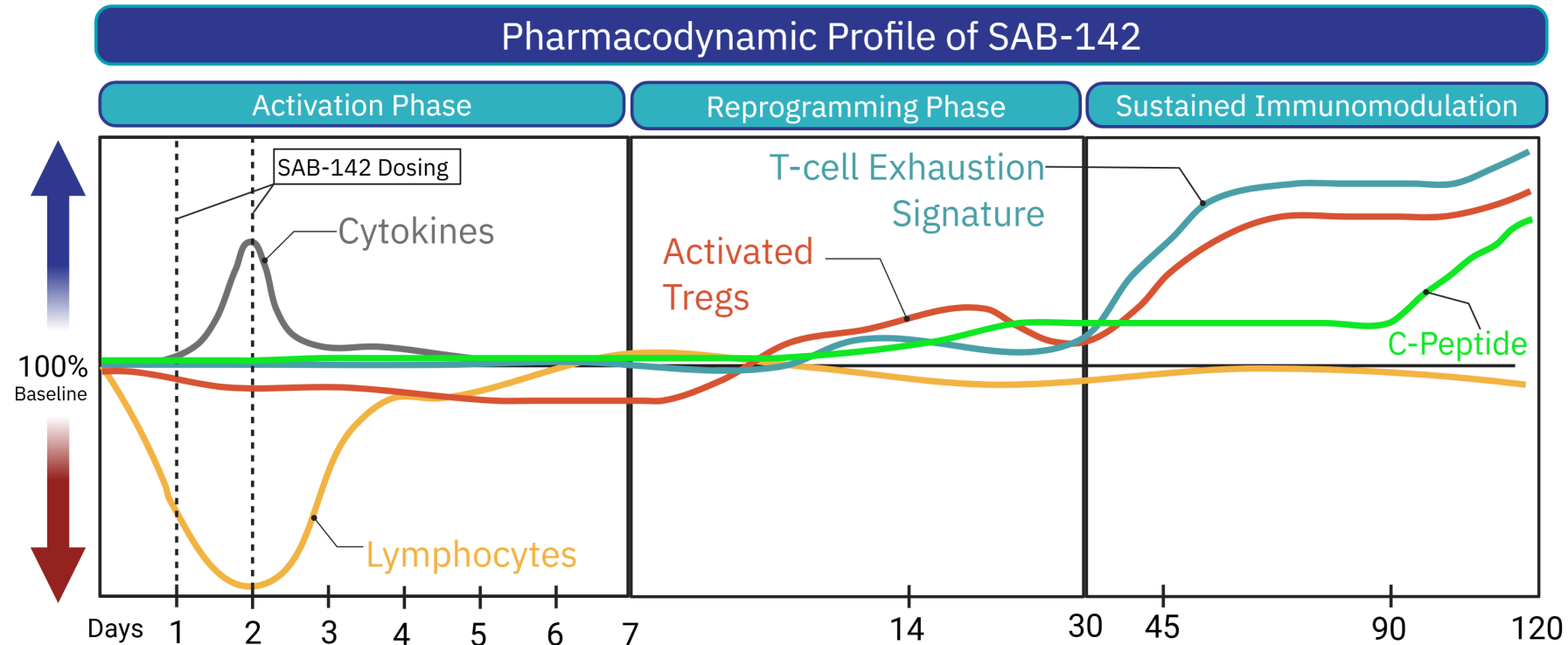
Reduced Exogenous Insulin Use

Mean Total Insulin Use Per Day $\pm$ SEM



Multi-Specific MoA of SAB-142:

A symphony of immunomodulation without lymphodepletion resulting in an early efficacy signal



Mechanism of Action of SAB-142

- Transient Cytokine Increase
- Transient Lymphocyte Margination

- Treg preservation and activation

- C-Peptide Preservation
- Sustained T-cell Exhaustion Signature
- Restoring Immune Tolerance

Introduction

Clinical Need An Effective Therapy That Sustains Beta-Cell Preservation Through Safe, Predictable Redosing — Not Just a One-Time Immune Reset

- ✓ Rabbit anti-thymocyte globulin (rATG) slows the progression of T1D (preserves C-peptide and improves glycemic control).
- ✓ rATG it is limited by serum sickness and the formation of neutralizing antibodies.

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

- ✓ SAB-142 is generated from a unique multi-specific antibody platform.
- ✓ SAB-142 binds to multiple T cell surface proteins, similar to rATG.
- ✓ Low immunogenicity with potential for redosing.
- ✓ No Serum Sickness.

Aim of Study The aim of this study was to characterize SAB-142's pharmacodynamic mechanism of action through immunoprofiling in a first-in-human clinical study.

Study Design

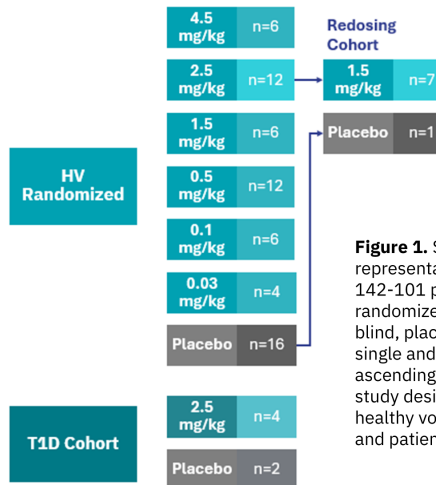
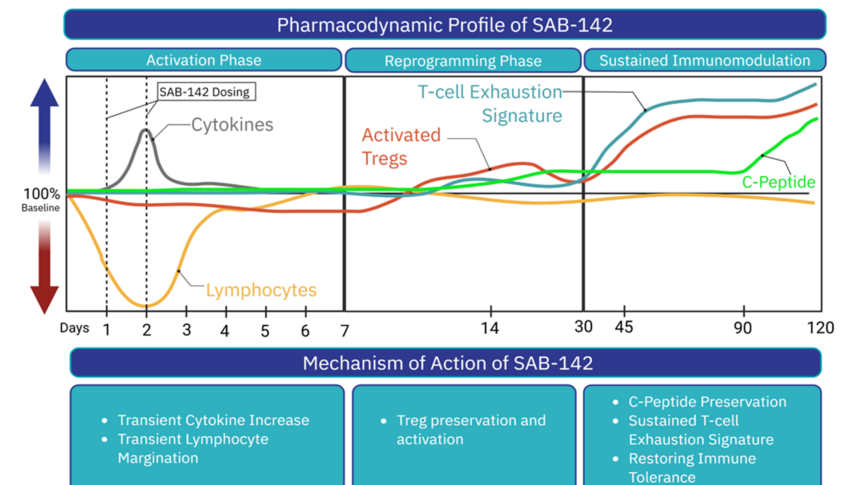


Figure 1. Schematic representation of SAB-142-101 phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose adaptive study design including healthy volunteers (HV) and patients with T1D

Conclusion



Results

SAB-142 Binds to the Same Receptors as rATG

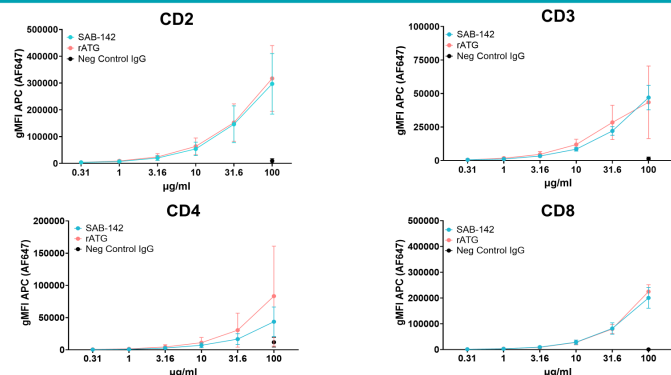


Figure 2. SAB-142 and rATG binding to CD2, CD3, CD4, CD8. Directly labeled SAB-142, rATG or negative control IgG was incubated with Bw cells expressing the indicated T cell surface protein. The cells were analyzed by flow cytometry and data shown is the geometric mean fluorescent intensity with the background from the parental Bw cells subtracted. Error bars show SEM, N=6.

SAB-142 Preserves T Regulatory Cells and Demonstrates Sustained CD4⁺ T Conv Cell Exhaustion analogous to rATG

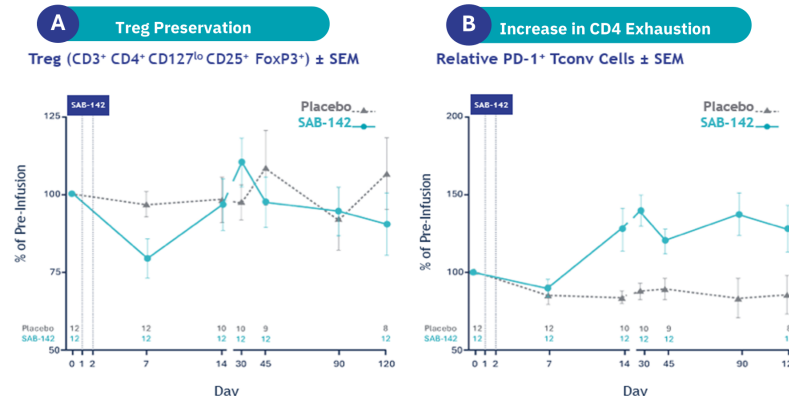


Figure 4. SAB-142 preserves Treg Cells (A) and induced expression of PD-1 (B). PBMCs were isolated from healthy volunteers who received 1.5 mg/kg or 2.5 mg/kg SAB-142 and subjected to immunophenotyping analysis by flow cytometry. Results shown were subject-normalized to pre-infusion data. Error bars indicate SEM. Sample number per time point indicated below the x axis.

SAB-142 Improved C-peptide and Glycemic Control

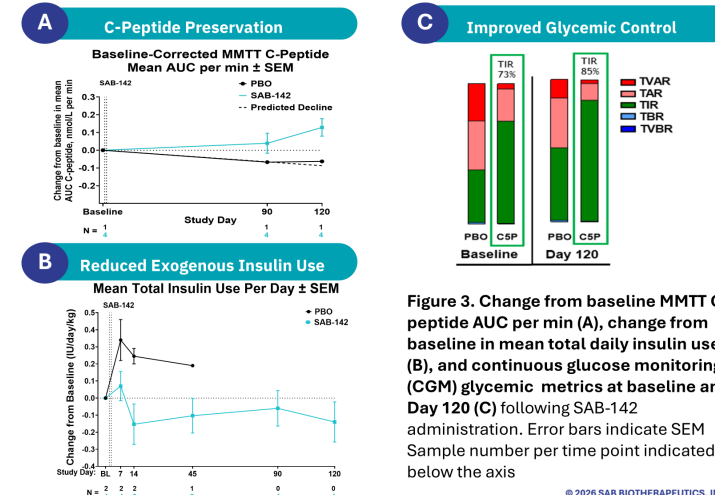


Figure 3. Change from baseline MMTT C-peptide AUC per min (A), change from baseline in mean total daily insulin use (B), and continuous glucose monitoring (CGM) glycemic metrics at baseline and Day 120 (C) following SAB-142 administration. Error bars indicate SEM. Sample number per time point indicated below the axis.