



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

April 22nd, 2026

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



## POSITIVE PHASE 1 DATA SUPPORT DE- RISKED MOA

Phase 1 data show SAB-142 has a clinically validated MOA showing C-peptide preservation, **with improved safety and immunogenicity profile vs. rATG and teplizumab**



## PROGRAM STATUS

SAB-142 is in the Phase 2B Pivotal clinical trial SAFEGUARD designated by the FDA as a **pivotal trial in new onset T1D patients 5-40 years of age**



## MANUFACTURING AND CLINICAL SUPPLIES

SAB-142 is manufactured using a process similar to rATG production. Clinical supplies are available for new trials including trials in **participants in Stage 2**

# SAB-142: Clinically-validated, De-risked Mechanism of Action to Potentially Control or Prevent T1D Over the Entire Life Span

Rabbit anti-thymocyte globulin (rATG) tested in T1D patients across multiple studies

**2013**  
Rabbit ATG tested in Academic Setting (START Study)

|                   |          |
|-------------------|----------|
| Dosage            | 6.5mg/kg |
| Lymphodepletion   | ⚠️       |
| C-peptide         | ✅        |
| HbA1c             | ✅        |
| Serum Sickness    | ⚠️       |
| Ability to redose | 🚫        |

(Gitelman et al., 2013)

**2018**  
Rabbit ATG tested in Academic Setting (TN-19 Study)

|                   |          |
|-------------------|----------|
| Dosage            | 2.5mg/kg |
| T-cell Exhaustion | ✅        |
| Lymphodepletion   | ⚠️       |
| C-peptide         | ✅        |
| HbA1c             | ✅        |
| Serum Sickness    | ⚠️       |
| Ability to redose | 🚫        |

(Haller et al., 2018)

**3Q 2025**  
Rabbit ATG tested in Academic Setting (MELD-ATG Study)

|  |          |
|--|----------|
| Dosage                                 | Multiple |
| C-peptide                              | ✅        |
| HbA1c                                  | ✅        |
| Lymphodepletion not an efficacy driver | ✅        |
| Serum Sickness                         | ⚠️       |
| Ability to redose                      | 🚫        |

(Mathieu et al., Lancet, 2025)

**SAB-142**, a human anti-thymocyte globulin (hATG), tested in healthy volunteers and T1D patients

**4Q 2025**



SAB-142 tested in Healthy Volunteers And T1D patients

|                   |          |
|-------------------|----------|
| Dosage            | Multiple |
| T-cell Exhaustion | ✅        |
| C-peptide*        | N/A      |
| HbA1c*            | N/A      |
| Serum Sickness    | 🚫        |
| Ability to redose | ✅        |

(January and December 2025)

2013

2018

2025

Applied the learning that **high dose rATG (6.5 mg/kg) is ineffective to mitigate disease**

SAB Bio applied the learning that **exhaustion drives efficacy and depletion does not.**  
With low immunogenicity and no serum sickness, SAB-142 profile enables safe and reliable redosing

## Rabbit ATG: De-Risked Mechanism of Action

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

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

\*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.

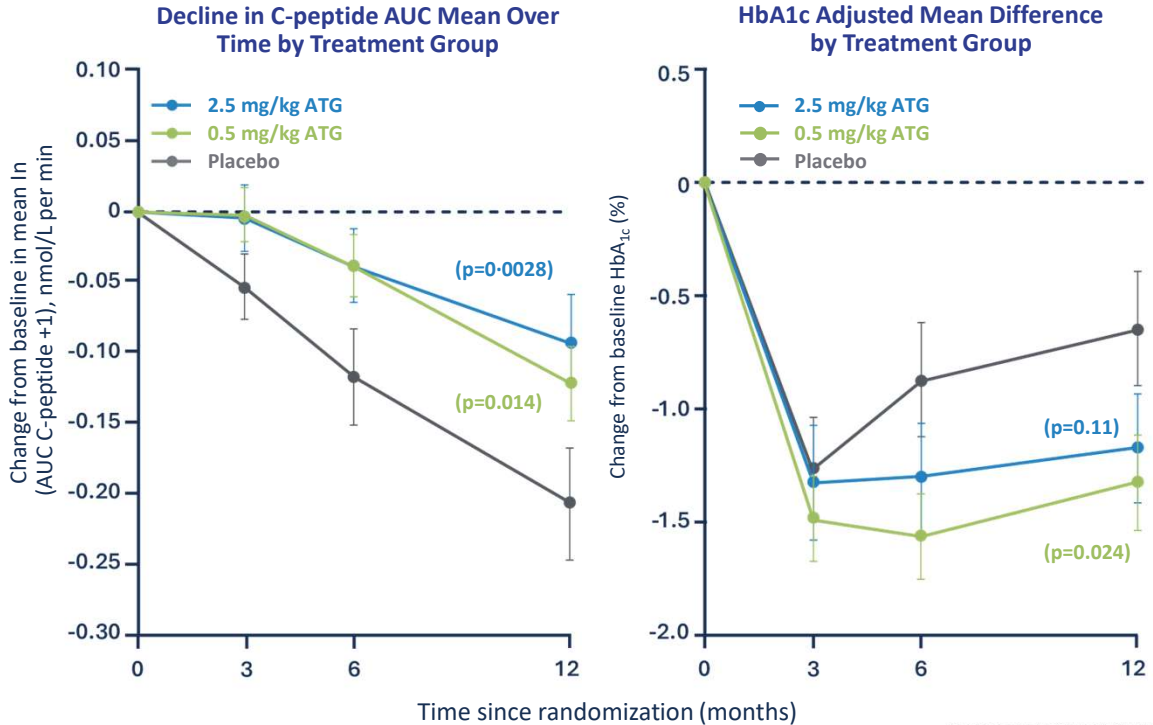


**Thymoglobulin**  
Anti-thymocyte Globulin (Rabbit)

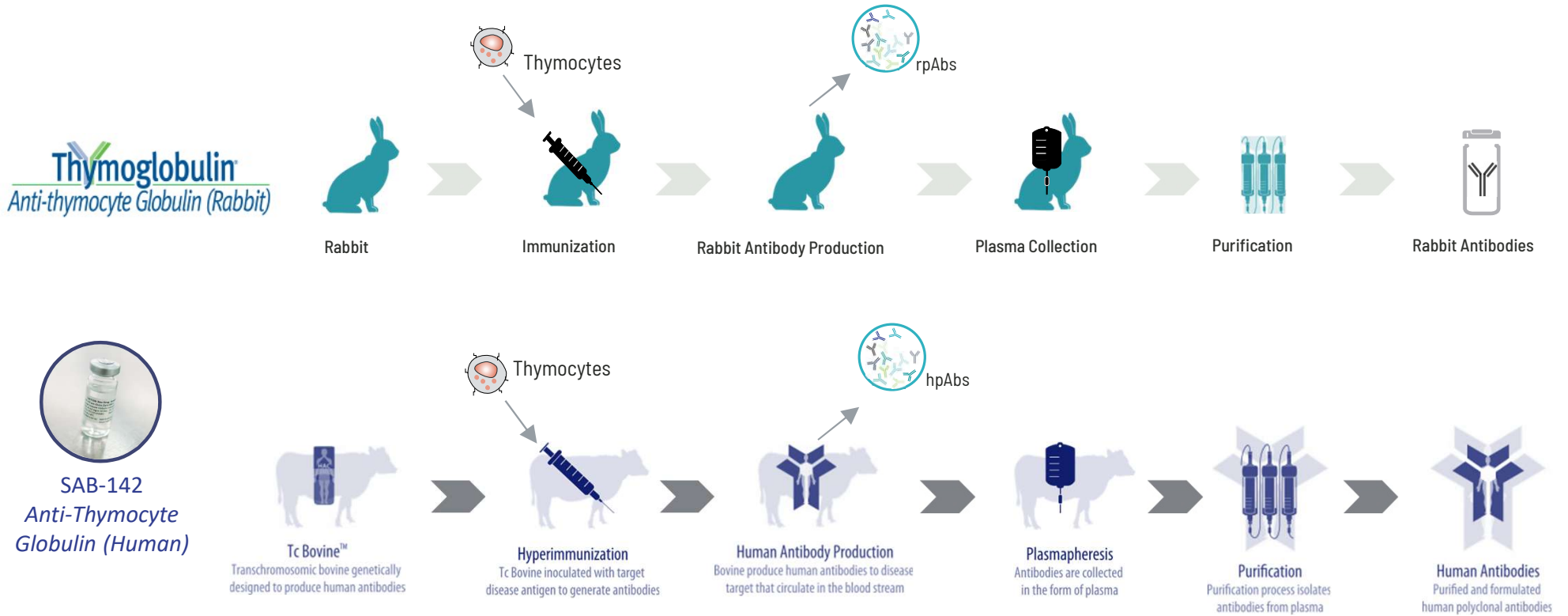
**ATG is the only mechanism of action that has consistently reproduced clinical data demonstrating preservation of C-peptide and improvements in glycemic control**

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

MELD-ATG



# SAB-142 Production Analogous to FDA-Approved Rabbit ATG



# SAB-142

In vitro binding data

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

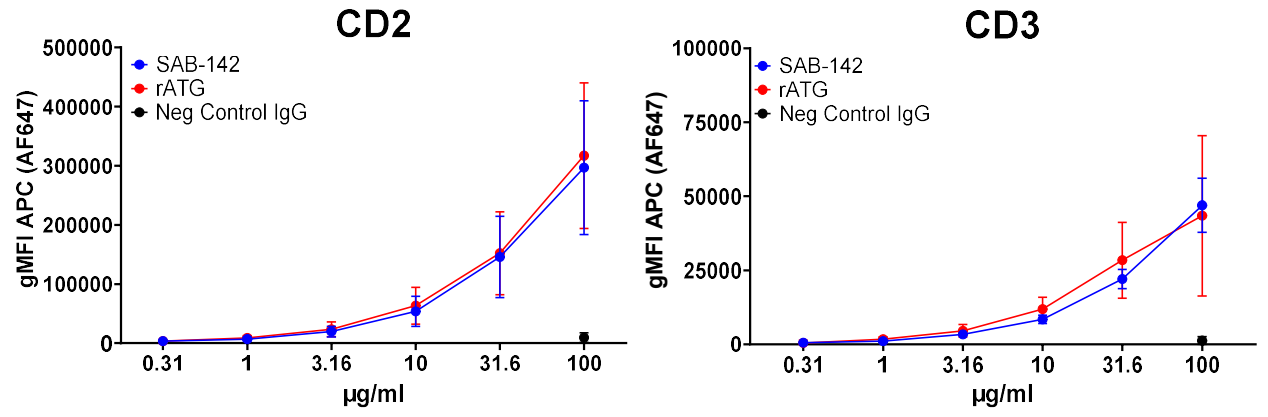
Data generated by Judith Leitner from the laboratory of Peter Steinberger lab based on published methodology.

American Journal of Transplantation 2013; 13: 3103-3113  
Wiley Periodicals Inc. © Copyright 2013 The American Society of Transplantation and the American Society of Transplant Surgeons  
doi: 10.1111/ajt.12514

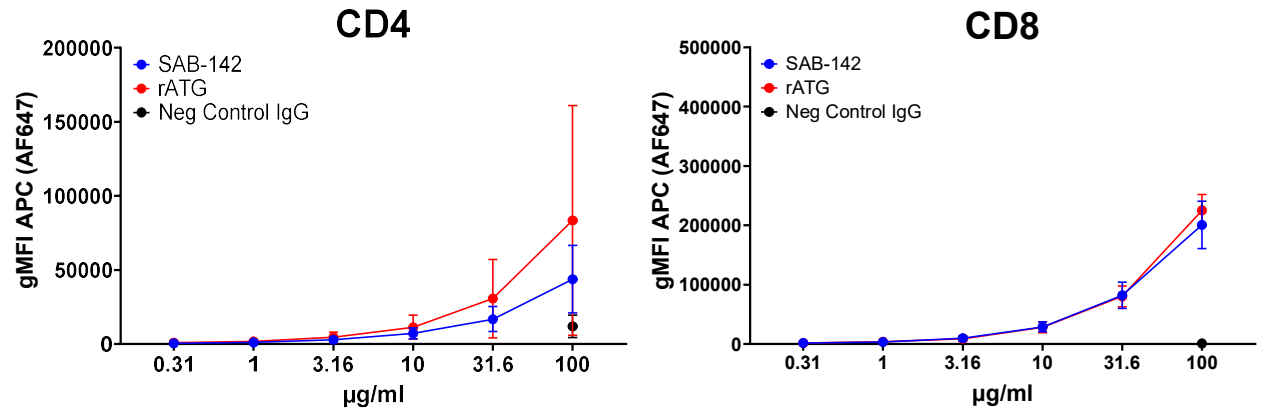
A Comprehensive and Quantitative Analysis of the Major Specificities in Rabbit Antithymocyte Globulin Preparations



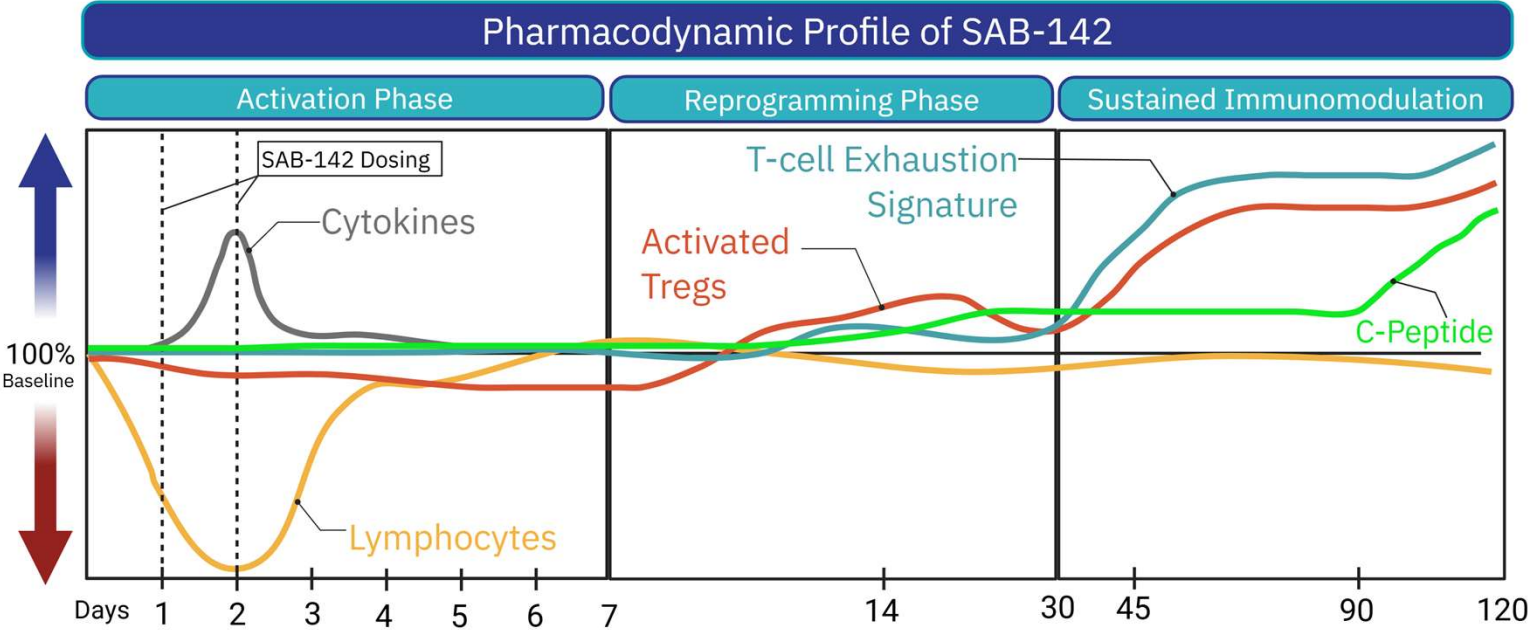
## SAB-142 Binds to the Same Receptors as rATG



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



# SAB-142 has a competitive well-characterized MOA resulting in sustained immunomodulation without liability of lymphodepletion



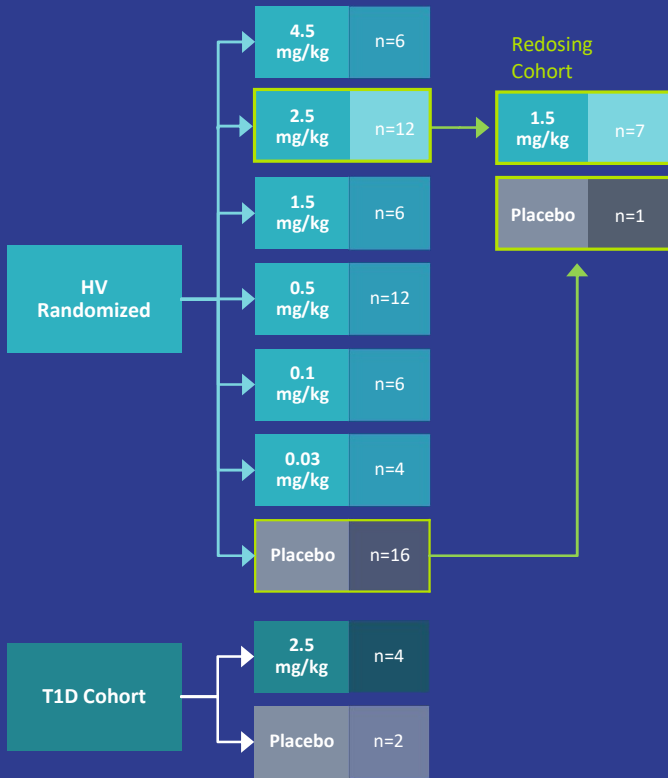
## Mechanism of Action of SAB-142

- Transient Cytokine Increase
- Transient Lymphocyte Margination
- Treg preservation and activation
- C-Peptide Preservation
- Sustained T-cell Exhaustion Signature
- Restoring Immune Tolerance



## 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 Encouraging Efficacy Signals with Clinically Validated, Multi-specific MOA with Sustained Immunomodulation



### Efficacy

Encouraging early signals of C-peptide preservation in established T1D patients



Early C-peptide signal consistent with beta cell preservation



### Immunogenicity

Confirm SAB-142 has low immunogenicity



Low immunogenicity



Enables safe and reliable redosing



### PK/PD

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

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

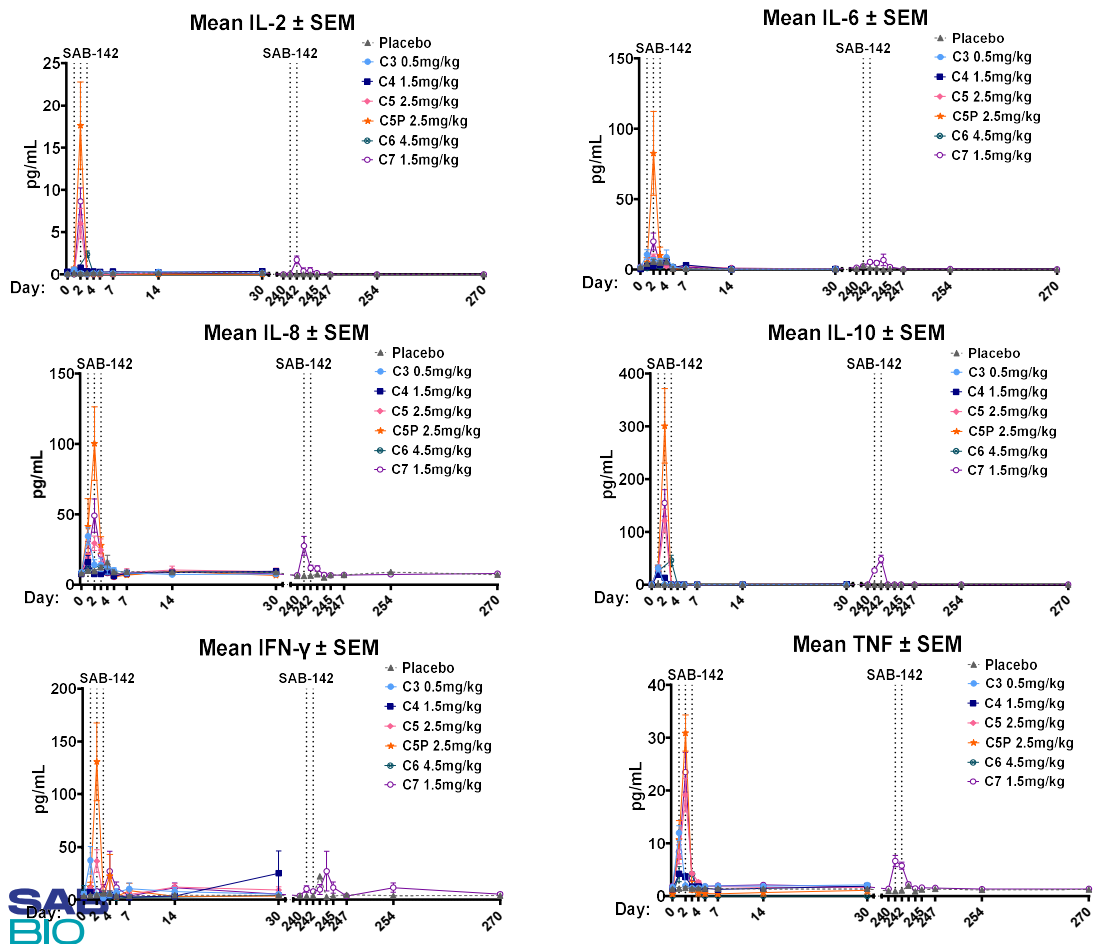


No sustained lymphodepletion leading to immuno-suppression; no neutropenia



No serum sickness

# Cytokine Response following SAB-142 Demonstrates MOA Analogous to Rabbit ATG Correlative to C-peptide Preservation



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>1</sup> James McNichols,<sup>2</sup> Daniel J. Perry,<sup>2</sup> Jason Brant,<sup>2</sup> Xiaoru Dong,<sup>1,4</sup> Rhonda Bacher,<sup>4</sup> Vivian H. Gersuk,<sup>4</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>1</sup> Peter S. Linsley,<sup>1</sup> and Todd M. Brusko<sup>1,2</sup>

<sup>1</sup>Department of Pediatrics, College of Medicine, University of Florida, Gainesville, Florida, USA; <sup>2</sup>Department of Pathology, Immunology, and Laboratory Medicine, University of Florida Diabetes Institute, Gainesville, Florida, USA; <sup>3</sup>Benaroya Research Institute at Virginia Mason, Seattle, Washington, USA; <sup>4</sup>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<sup>+</sup>FOXP3<sup>+</sup> 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- $\alpha$  ( $P < 0.05$  for all) 2 weeks after treatment and a durable CD4<sup>+</sup> exhaustion phenotype (increased PD-1<sup>+</sup>KLRG1<sup>+</sup>CD57<sup>-</sup> on CD4<sup>+</sup> T cells [ $P = 0.01$ ] and PD1<sup>+</sup>CD4<sup>+</sup> 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<sup>+</sup> exhaustion transcript and cellular phenotyping profiles may be useful for identifying signatures of clinical response to ATG in T1D.

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

# SAB-142-101

## Phase 1 Top Line

### SAB-142 CD4<sup>+</sup> T conv Cell Single Exhaustion Markers

SAB-142 induced sustained expression of inhibitory receptor PD-1 on CD4<sup>+</sup> T conv cells indicative of an exhausted phenotype.

### SAB-142 CD4<sup>+</sup> T conv Cell Dual Exhaustion Markers

SAB-142 induced sustained expression of co-inhibitory receptors on CD4<sup>+</sup> T conv cells.

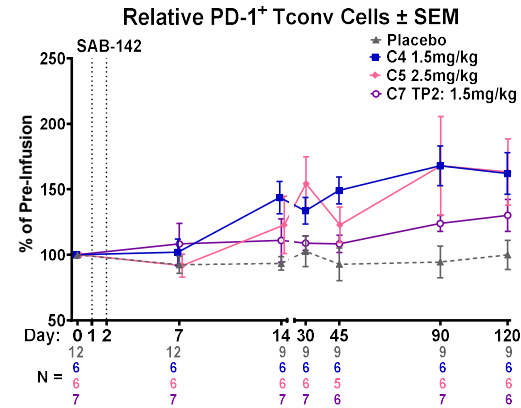
SAB-142: combined 1.5mg/kg and 2.5mg/kg dosed cohorts.

### Rabbit ATG CD4<sup>+</sup> T Cell Dual Exhaustion Markers

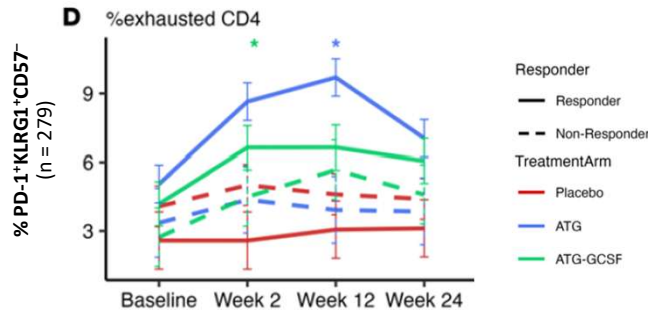
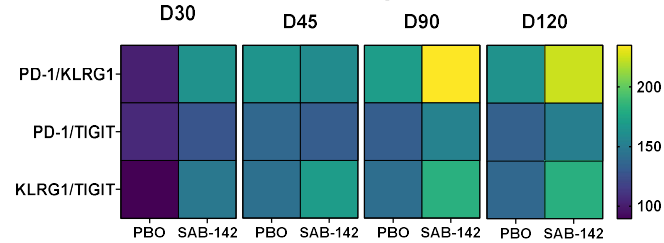
Low-dose ATG induced sustained expression of co-inhibitory receptors (PD-1, KLRG1) on CD4<sup>+</sup> cells indicating exhaustion-like phenotype which correlates with C-Peptide preservation.



# SAB-142 Demonstrates Sustained CD4<sup>+</sup> T Conventional Cell Exhaustion Analogous to rATG



### Tconv Median Percent Change from Pre-Infusion



CLINICAL MEDICINE

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

# SAB-142-101

Phase 1 Top Line



No sustained lymphodepletion



SAB-142: Transient lymphopenia due to lymphocyte margination



Lymphocytes recover back to baseline by Day 7 after Induction and Maintenance Doses of SAB-142

Rabbit ATG causes sustained lymphodepletion up to 2 years

**JCI INSIGHT** CLINICAL MEDICINE

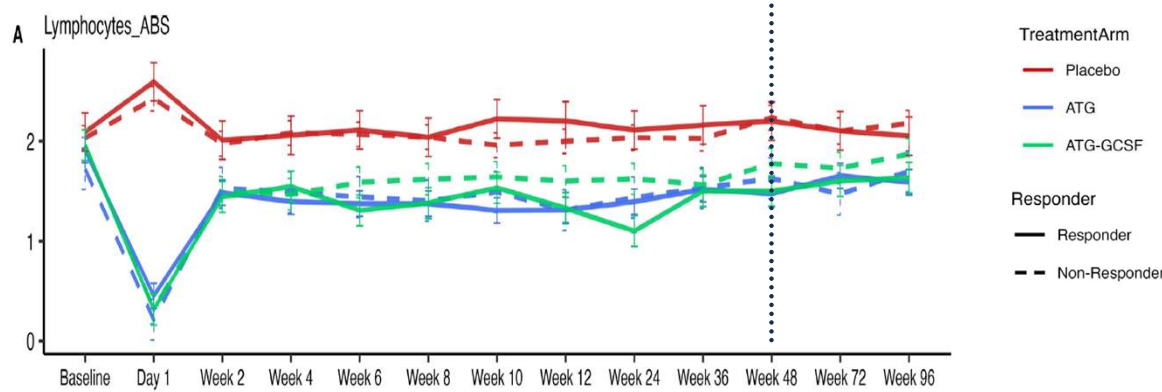
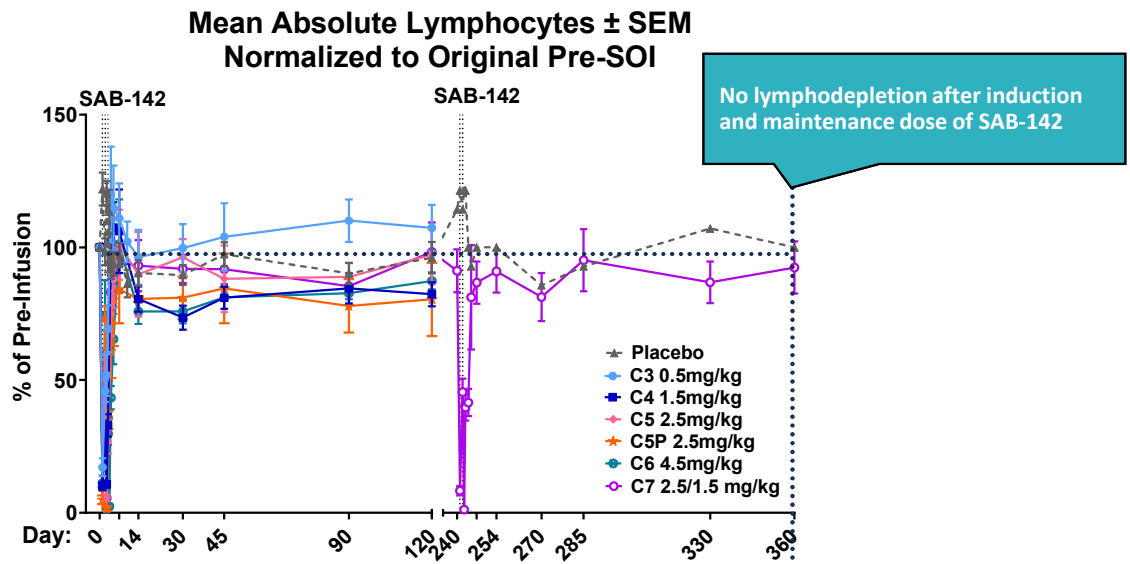
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<sup>1</sup>Department of Pediatrics, College of Medicine, University of Florida, Gainesville, Florida, USA; <sup>2</sup>Department of Pathology, Immunology, and Laboratory Medicine, University of Florida Diabetes Institute, Gainesville, Florida, USA;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



## SAB-142 Does Not Cause Sustained Lymphodepletion





# Induction Dose: SAB-142 Safety Profile Enables Ambulatory Dosing, with Safety Profile Comparable to PBO from Day 8 Onwards

**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

- 9 Cohorts of Healthy Volunteers (HVs) and 1 Cohort of T1D
- Total n=68; 50 on SAB-142 and 18 on Placebo
- Most frequent AEs:
  - Headaches: typical for all T-cell-engaging therapies, associated with infusion; onset within ~24 hours from 1<sup>st</sup> or 2<sup>nd</sup> day of infusion
  - Transient lymphopenia:
    - Anticipated PD effect which rapidly self-resolves within 1-3 days
    - On target effect that accounts for 100% of Grade 4 TEAEs
    - Defined as a lab value change 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 the onset up to 24 hours
    - Infusion-site reactions (ISR): erythema, tenderness, phlebitis
- No drug-related SAEs
- No serum sickness, no AEs associated with ADAs
- No decrease in RBCs, no neutropenia, no lymphopenia, or thrombocytopenia from Day 7 on

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

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

**Transient lymphopenia: On target effect not observed past Day 7**

## Maintenance Dose: SAB-142 Safety Profile of Maintenance Dosing is comparable to Safety of the Induction Dosing

**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

- 1 Cohort of Healthy Volunteers (HVs)
  - Total n=8, 7 on SAB-142 and 1 on Placebo
- Most frequent AEs:
  - Headaches: typical for all T-cell-engaging therapies, associated with Days 1-2
  - Transient lymphopenia:
    - Anticipated PD effect which rapidly self-resolves within 1-3 days
    - On target effect that accounts for 100% of Grade 4 TEAEs
    - Defined as a lab value change and not associated with clinical symptoms
  - Infusion-related reactions (IRRs):
    - No CRS
    - Infusion-site reactions (ISR): phlebitis and pruritus
- No drug-related SAEs
- No serum sickness, no AEs associated with ADAs
- No decrease in RBCs, no neutropenia, no lymphopenia, or thrombocytopenia from Day 7 on

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

| Part B: Maintenance Dose                    | Day 1 to 7                       |                                  | Day 8 to 180                     |                                  |
|---|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
|   | Pooled Placebo HV (N=1)<br>n (%) | Pooled SAB-142 HV (N=7)<br>n (%) | Pooled Placebo HV (N=1)<br>n (%) | Pooled SAB-142 HV (N=7)<br>n (%) |
| <b>Number of participants with any:</b>     |                                  |                                  |                                  |                                  |
| <b>TEAEs</b>                                | 1 (100.0%)                       | 7 (100.0%)                       | 0                                | 4 (57.1%)                        |
| <b>TEAEs by Severity:</b>                   |                                  |                                  |                                  |                                  |
| <b>Grade 1</b>                              | 1 (100.0%)                       | 0                                | 0                                | 2 (28.6%)                        |
| <b>Grade 2</b>                              | 0                                | 0                                | 0                                | 1 (14.3%)                        |
| <b>Grade 3</b>                              | 0                                | 5 (71.4%)                        | 0                                | 1 (14.3%)                        |
| <b>Grade 4</b>                              | 0                                | 2 (28.6%)                        | 0                                | 0                                |
| <b>Grade 5</b>                              | 0                                | 0                                | 0                                | 0                                |
| <b>Treatment-related TEAEs by Severity:</b> |                                  |                                  |                                  |                                  |
| <b>Grade 1</b>                              | 0                                | 0                                | 0                                | 2 (28.6%)                        |
| <b>Grade 2</b>                              | 0                                | 0                                | 0                                | 0                                |
| <b>Grade 3</b>                              | 0                                | 5 (71.4%)                        | 0                                | 0                                |
| <b>Grade 4</b>                              | 0                                | 2 (28.6%)                        | 0                                | 0                                |
| <b>Grade 5</b>                              | 0                                | 0                                | 0                                | 0                                |

**Transient lymphopenia: On target effect not observed past Day 7**

# SAB-142 is a Fully Human Biologic: Low Immunogenicity and Does not Cause Serum Sickness

## SAB-142: Low immunogenicity

- At target doses (1.5 or 2.5mg/kg), SAB-142 did not generate anti-SAB-142 antibodies above background level in HVs and T1Ds out to day 120/End of Treatment.
- This demonstrates that SAB-142 is less immunogenic than rATG

## rATG: Grade 3-4 serum sickness in >50% of subjects following the very first course

| Adverse events                       | ATG only |           | Placebo |          |
|--------------------------------------|----------|-----------|---------|----------|
|                                      | Events   | Patients  | Events  | Patients |
| All immune system disorders          | 38       | 23 (79.3) | 0       | 0 (0)    |
| Serum sickness only                  | 21       | 21 (72.4) | 0       | 0 (0)    |
| <b>Adverse events grades 3 and 4</b> |          |           |         |          |
| Adverse effect category              | ATG only |           | Placebo |          |
|                                      | Events   | Patients  | Events  | Patients |
| All immune system disorders          | 15       | 15 (51.7) | 0       | 0 (0)    |
| Serum sickness only                  | 15       | 15 (51.7) | 0       | 0 (0)    |
| Cytokine release syndrome only       | 0        | 0 (0)     | 0       | 0 (0)    |

Low-Dose ATG Preserves C-Peptide in T1D Diabetes Care Volume 41, September 2018

<https://diabetesjournals.org/care/article/41/9/1917/40730/Low-Dose-Anti-Thymocyte-Globulin-ATG-Preserves>





# T1D Cohort Data

## Adult T1D Cohort >2 Years from Onset: Baseline Characteristics

T1D >2 Years from Onset

All study participants met SAFEGUARD inclusion criteria with residual beta cell function and at least one T1D autoantibody at baseline

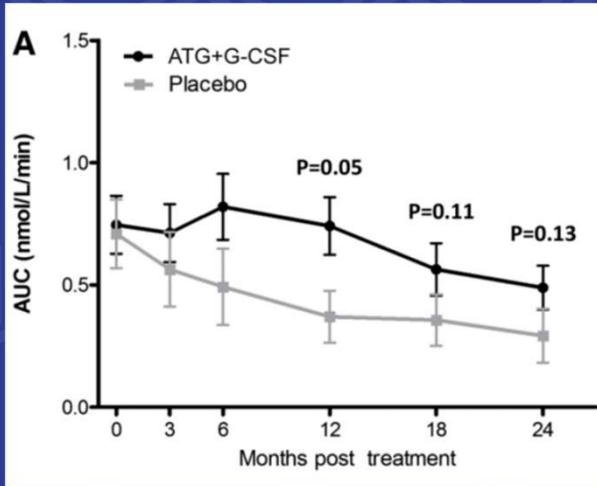
|  | SAB-142 2.5 mg/kg<br>T1D (n=4) | Placebo<br>T1D (n=2)* |
|--|--------------------------------|-----------------------|
| Age range (mean)   | 19-40 (28.75)                  | 19-34 (26.5)          |
| Sex  | 2 Female & 2 Male              | 2 Female              |
| <b>C-peptide AUC for 2-hr MMTT (nmol/L) / min</b>          |                                |                       |
| n  | 4                              | 1*                    |
| Mean (SD)  | 0.302 (0.032)                  | 0.432                 |
| <b>Fasting Glucose (mmol/L)</b>                            |                                |                       |
| n  | 4                              | 2                     |
| Mean (SD)  | 6.53 (1.773)                   | 5.95 (1.344)          |
| <b>Time from T1D diagnosis to randomization (months)</b>   |                                |                       |
| n  | 4                              | 2                     |
| Mean (SD)  | 40.2 (11.39)                   | 28 (9.9)              |
| <b>Average Total Insulin per day by Weight (IU/day/kg)</b> |                                |                       |
| n  | 4                              | 2                     |
| Mean (SD)  | 0.406 (0.287)                  | 0.323 (0.225)         |
| GAD Autoantibodies Positive N (%)                          | 4 (100%)                       | 0 (0%)                |
| IA-2 Autoantibodies Positive N (%)                         | 2 (50%)                        | 2 (100%)              |
| ZNT8 Autoantibodies Positive N (%)                         | 3 (75%)                        | 0 (0%)                |

\*One placebo subject discontinued after Day 45  
Note: SD = Standard deviation

# SAB-142-101:

T1D Cohort at 2.5mg/kg

“Antithymocyte Globulin Plus G-CSF Combination Therapy Leads to Sustained Immunomodulatory and Metabolic Effects in a Subset of Responders With Established Type 1 Diabetes.”

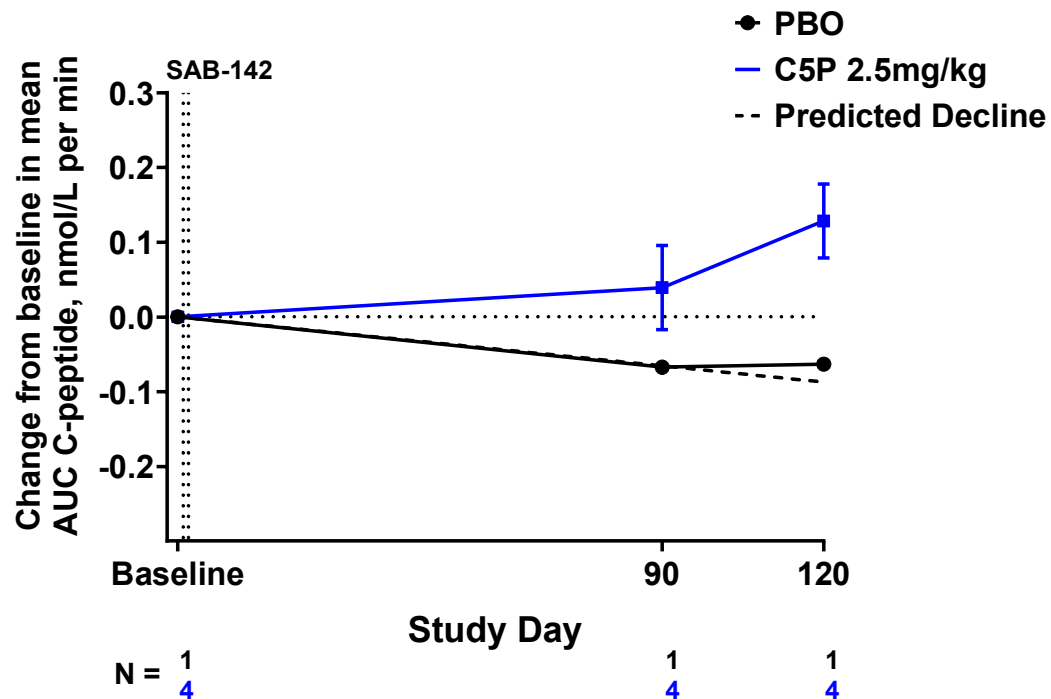


Haller MJ, Gitelman SE, Gottlieb PA, Michels AW, Perry DJ, Schultz AR, Hulme MA, Shuster JJ, Zou B, Wasserfall CH, Posgai AL, Mathews CE, Brusko TM, Atkinson MA, Schatz DA. Antithymocyte Globulin Plus G-CSF Combination Therapy Leads to Sustained Immunomodulatory and Metabolic Effects in a Subset of Responders With Established Type 1 Diabetes. Diabetes. 2016 Dec;65(12):3765-3775. doi: 10.2337/db16-0823. Epub 2016 Sep 26. PMID: 27669730; PMCID: PMC5127248.



## T1D Cohort: C-Peptide Response

### Baseline-Corrected MMTT C-Peptide Mean AUC per min ± SEM



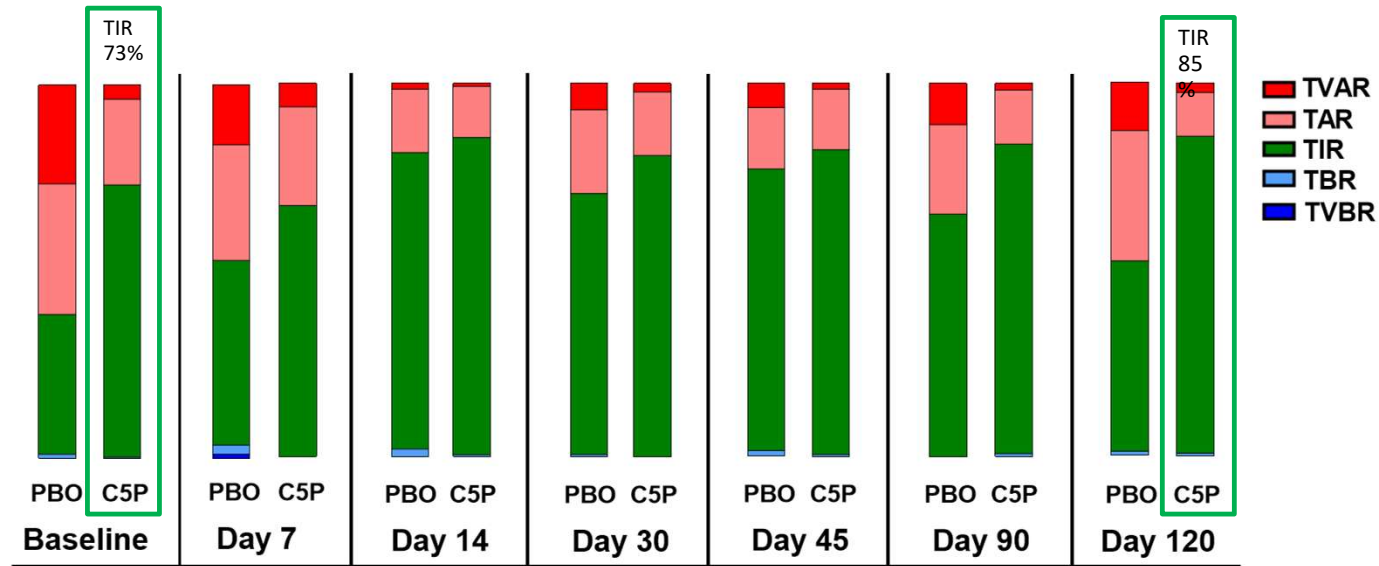
Predicted decline was estimated by first calculating the incremental AUC of TN19 PBO subject C-peptide MMTT data (n=26) for Weeks 48-96 with post-2hr values masked. The linear slope was used to calculate the predicted rate of decline in days:  $AUC_{BL} - (-0.6108 * (Study Day/7))$

# SAB-142-101

T1D Cohort at 2.5mg/kg

SAB-142 effects on glycemic control are consistent with C-peptide response

## Continuous Glucose Monitoring (CGM): SAB-142-treated patients improved glycemic control vs. baseline



Data are based on the patients' individual CGM devices

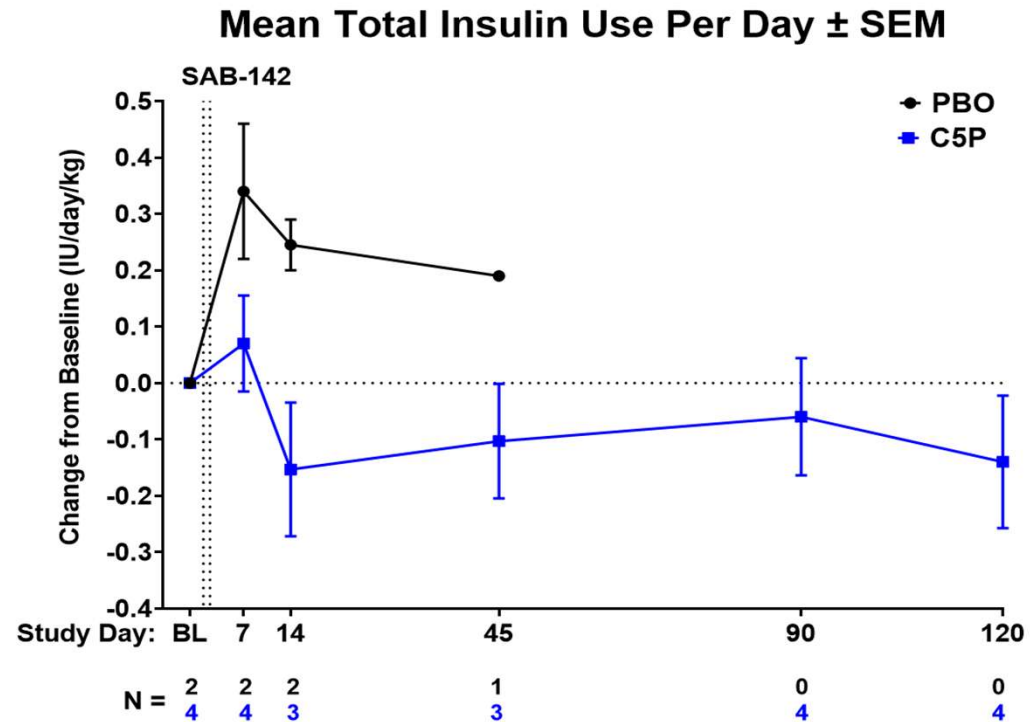
# SAB-142-101

T1D Cohort at 2.5mg/kg

SAB-142 improvements in glycemic control were not driven by increase in insulin doses

Insulin doses decreased over time in SAB-142 group

Total Insulin per day and participant weight (IU/day/kg):  
Insulin use decreased in SAB-142 group



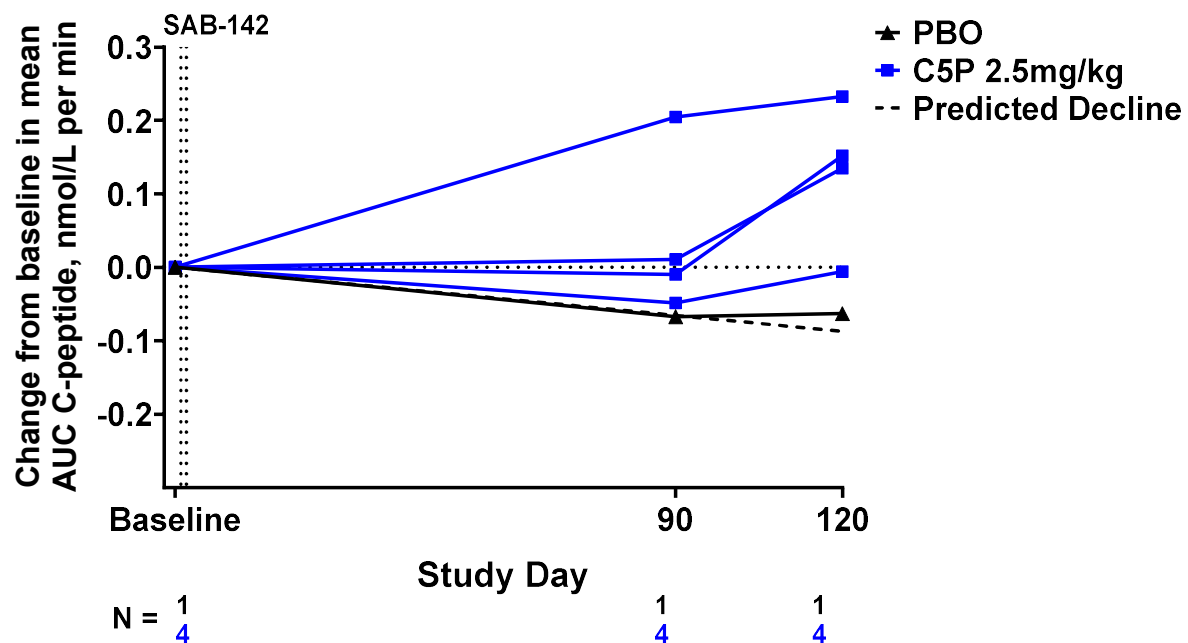
# SAB-142-101

T1D Cohort at 2.5mg/kg

SAB-142 exhibits C-Peptide preservation profile, similar to rATG.

## T1D Cohort: Individual C-Peptide Response

### Baseline-Corrected MMTT C-Peptide Mean AUC $\pm$ SEM

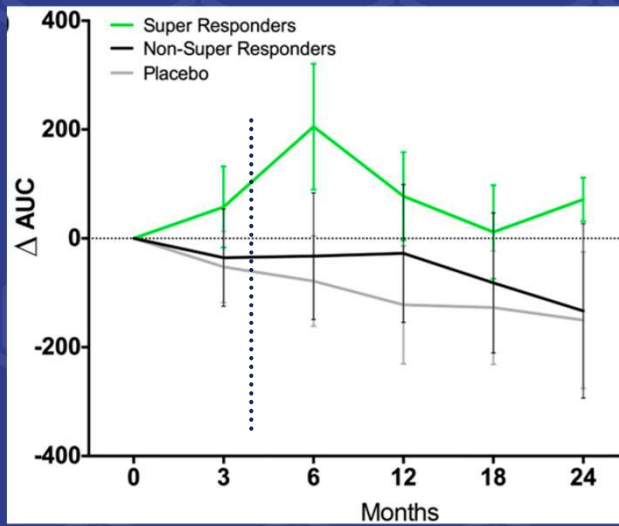


Predicted Decline was estimated by first calculating the AUC of TN19 PBO subject C-peptide MMTT data (n=26) for Weeks 48-96 with post-2hr values masked. The linear slope was used to calculate the predicted rate of decline in days:  $AUC_{BL} - (-0.6108 * (Study Day / 7))$

# SAB-142-101

T1D Cohort at 2.5mg/kg

“Antithymocyte Globulin Plus G-CSF Combination Therapy Leads to Sustained Immunomodulatory and Metabolic Effects in a Subset of Responders With Established Type 1 Diabetes.”

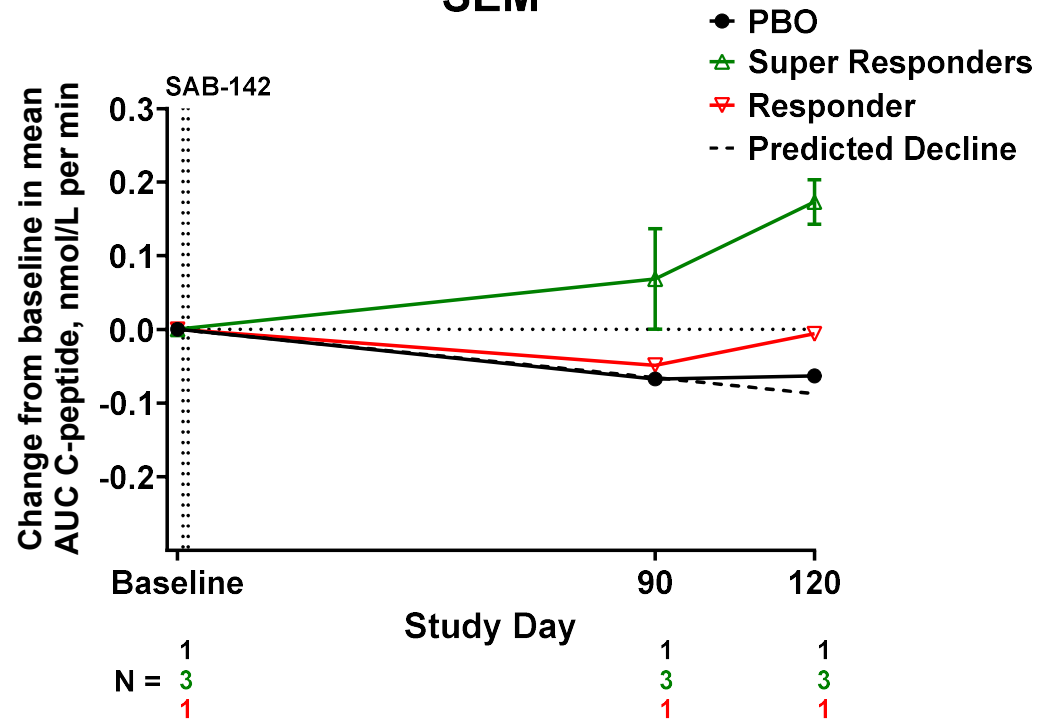


Haller MJ, Gitelman SE, Gottlieb PA, Michels AW, Perry DJ, Schultz AR, Hulme MA, Shuster JJ, Zou B, Wasserfall CH, Posgai AL, Mathews CE, Brusko TM, Atkinson MA, Schatz DA. Antithymocyte Globulin Plus G-CSF Combination Therapy Leads to Sustained Immunomodulatory and Metabolic Effects in a Subset of Responders With Established Type 1 Diabetes. Diabetes. 2016 Dec;65(12):3765-3775. doi: 10.2337/db16-0823. Epub 2016 Sep 26. PMID: 27669730; PMCID: PMC5127248.



SAB-142 exhibits super responder vs responder C-Peptide profile, similar to rATG

## Baseline-Corrected MMTT C-Peptide Mean AUC ± SEM



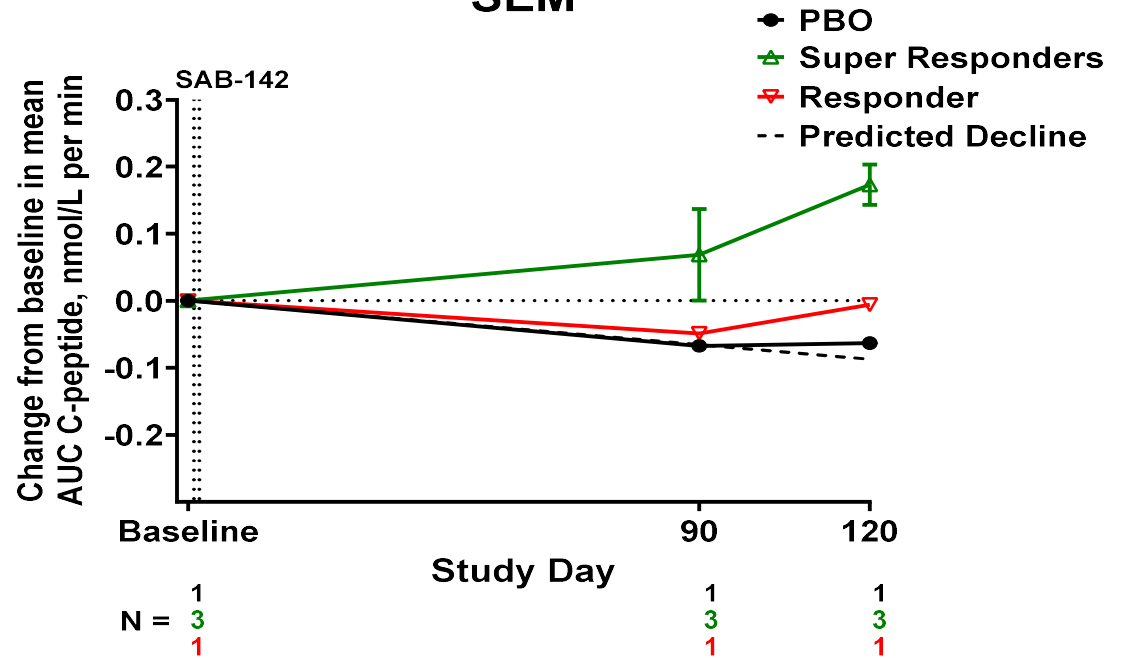
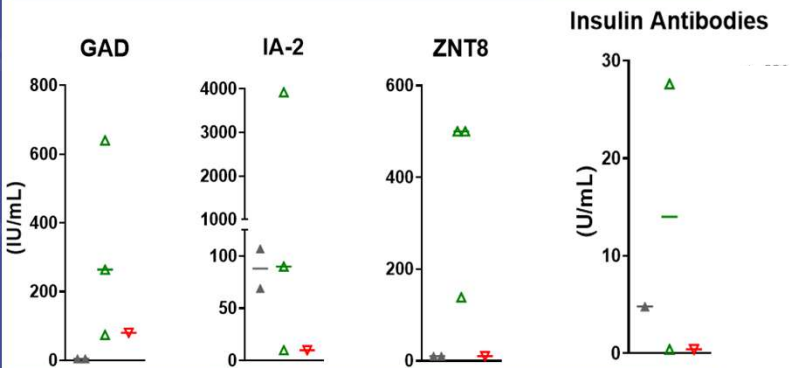
Predicted Decline was estimated by first calculating the incremental AUC of TN19 PBO subject C-peptide MMTT data (n=26) for Weeks 48-96 with post-2hr values masked. The linear slope was used to calculate the predicted rate of decline in days:  $AUC_{BL} - (-0.6108 * (Study Day / 7))$

# SAB-142-101

T1D Cohort at 2.5mg/kg

## SAB-142 exhibits super responder vs responder C-Peptide profile, similar to rATG

### Baseline-Corrected MMTT C-Peptide Mean AUC ± SEM



Predicted Decline was estimated by first calculating the incremental AUC of TN19 PBO 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:  $AUC_{BL} - (-0.6108 * (Study\ Day/7))$

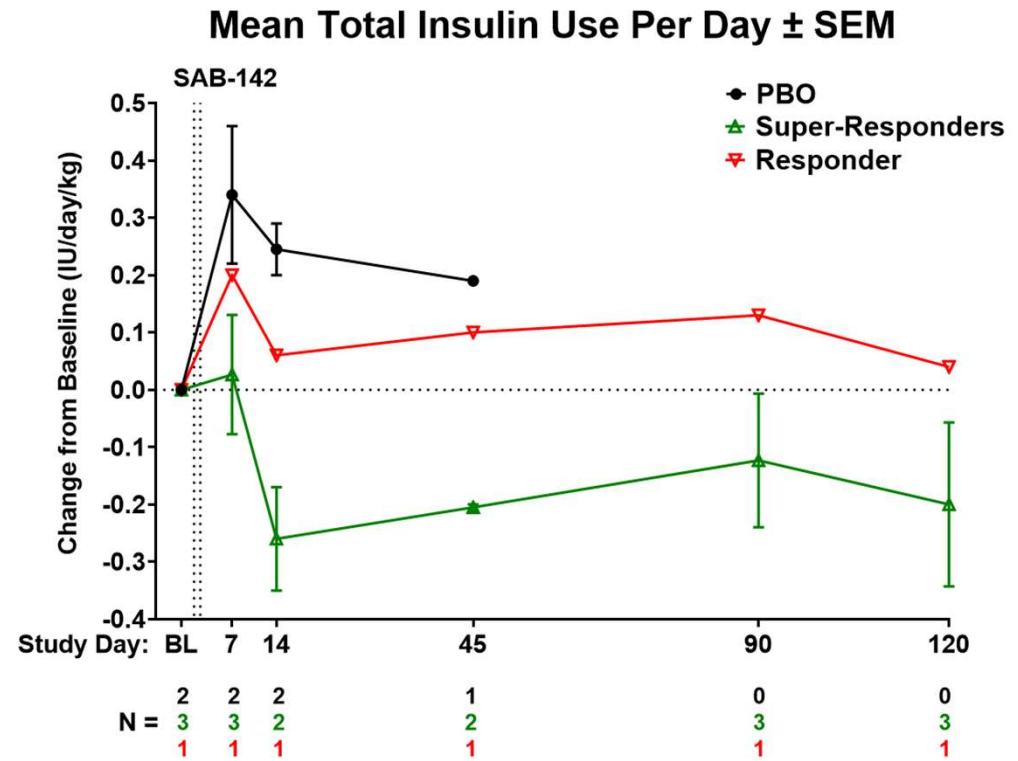
# SAB-142-101

T1D Cohort at 2.5mg/kg

SAB-142 improvements in glycemic control were not driven by increase in insulin doses

Insulin doses decreased over time in SAB-142 group

Total Insulin per day and participant weight (IU/day/kg):  
Insulin use decreased in SAB-142 group



# SAB-142-101

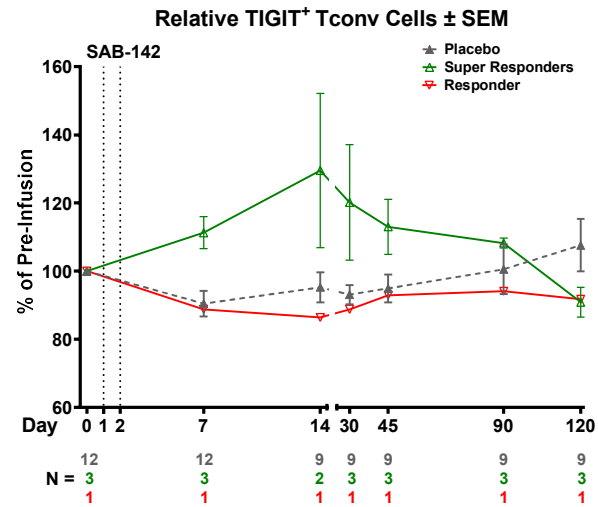
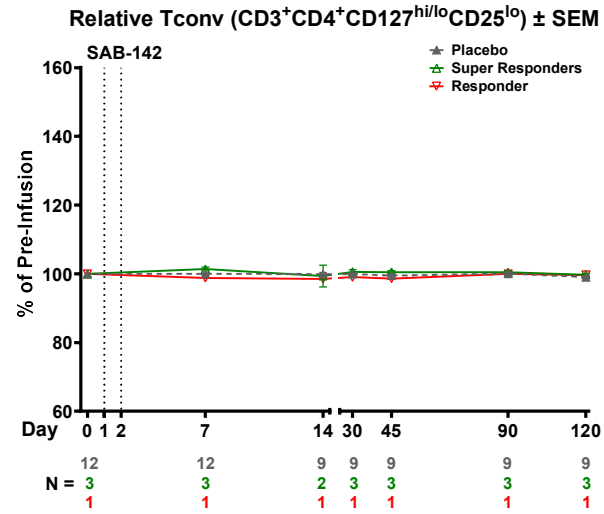
PD profile of T1D Cohort responders at 2.5mg/kg

SAB-142 preserves CD4<sup>+</sup> Tconv cells

SAB-142 induced Tconv cell exhaustion  
correlative to anticipated C-Peptide  
response, similar to rATG



## T1D Cohort: Effect on CD4<sup>+</sup> Tconv Cells





# SAFEGUARD study



# SAFEGUARD: Multicenter, Global Phase 2b Safety and Efficacy Trial of SAB-142 in Stage 3 Type 1 Diabetes Patients



**SAFety and Efficacy of human anti-thymocyte immunoGloUlin 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 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 2.5mg/kg; Maintenance dose: 1.5mg/kg q6 month

Global study initiated, first patient dosed in **December 2025** **Topline results expected 2H 2027**



**United States**  
(FDA) NCT07187531



**Europe**  
(EMA)



**United Kingdom**  
(MHRA)

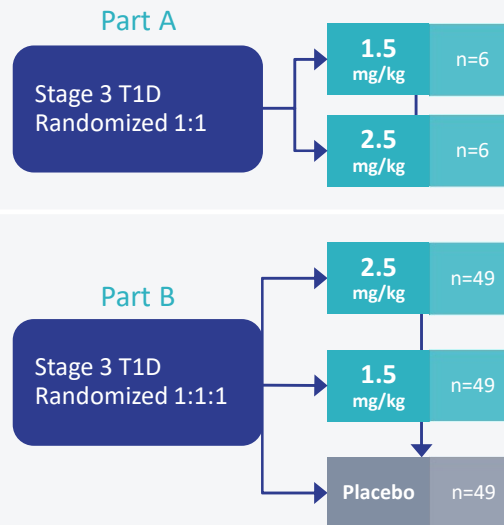


**Australia**  
(TGA)



**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:

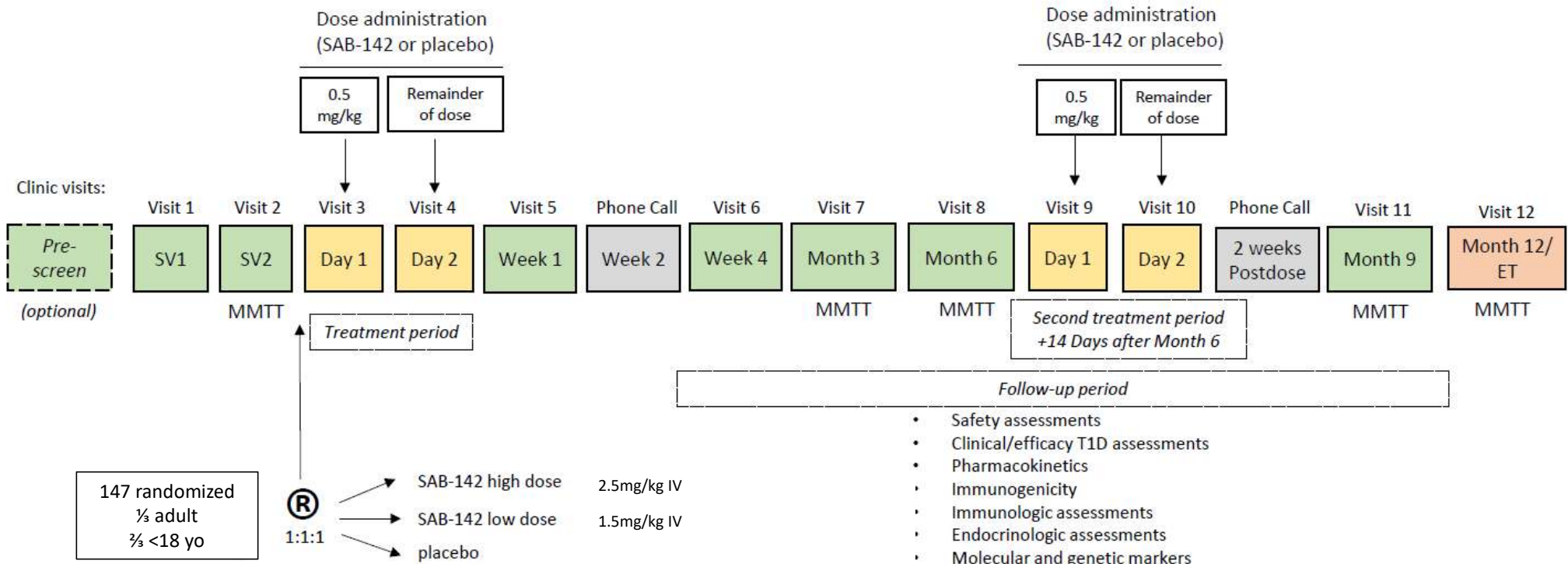
- > Time in Tight Range, Time in Range, Time Above and Below Range
- > Hypoglycemic episodes
- > Safety



# SAFEGUARD Study Design: Part A and B



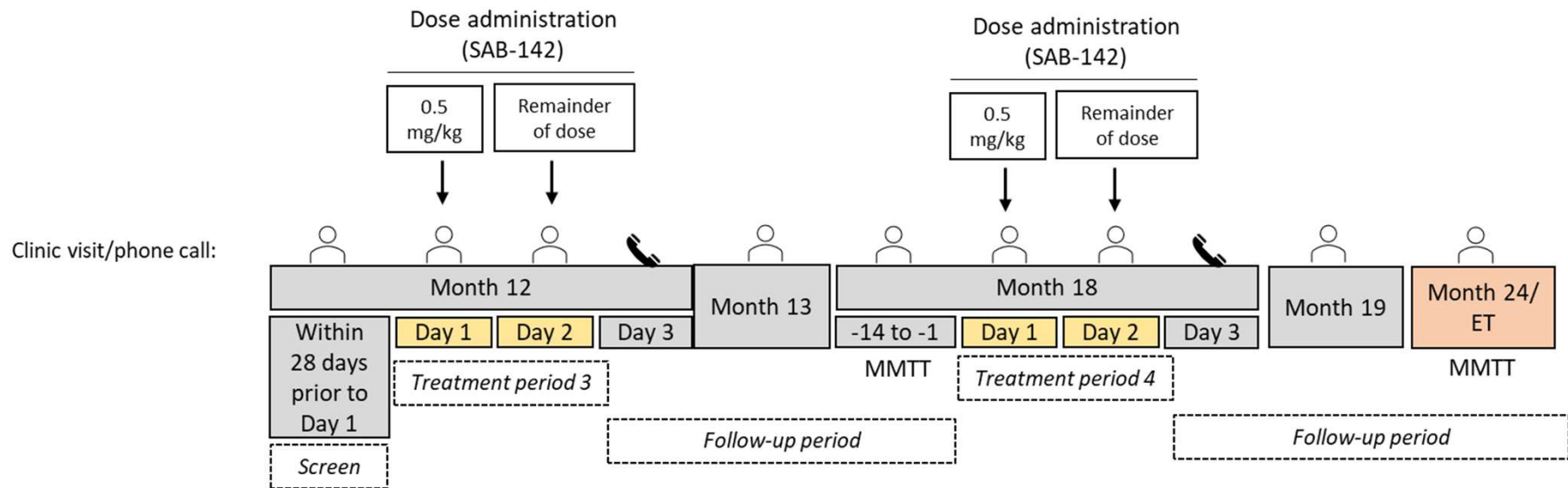
A Phase 2B, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study Evaluating the Efficacy and Safety of SAB-142 for the delay of progression of Type 1 Diabetes in new/recent onset Stage 3 T1D patients





# SAFEGUARD Study Design: Part C

Randomized Study to Establish Maintenance Safety and Efficacy of SAB-142 over 24 months



= in person clinic visit  
 = telephone call

• Safety assessments



Abbreviations: ET = Early Termination; MMTT = mixed meal tolerance test; \* = randomisation; SV = Screening Visit; T1D = type 1 diabetes.  
 \*Optional clinic visit or mandatory phone call for participants who choose not to attend the optional clinic visit