Positive Clinical Translation of a Juvenile NHP Study for Evaluating SAB-142, a Multi-Specific T-Cell Targeting T1D Therapy, in Humans

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JUNE 9-12 FOCIS 2026 ANNUAL MEETING SAN FRANCISCO, CA

Introduction

Clinical Need

There is no licensed therapy to halt or reverse new-onset Type 1 Diabetes.

- Rabbit anti-thymocyte globulin (rATG) slows the progression of T1D by preserving C-peptide and improving glycemic control.
- rATG is limited by serum sickness, lymphodepletion, and the formation of neutralizing antibodies.

Multi-Specific Antibody

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

- SAB-142 is generated from a unique multi-specific antibody platform.
- No serum sickness.
- No lymphodepletion.
- No Adverse Events (AEs) associated with anti-drug antibodies (ADA).
- Well tolerated up to 4.5 mg/kg IV and redosing after about 6 months.

Aim of Study

This study compared the pharmacological outcomes of a 9-month two dose chronic GLP toxicology study in cynomolgus monkeys with the outcomes from a first-in-human Phase 1 clinical study of SAB-142 to assess clinical translatability.

Results

9 Month, Two Dose Chronic GLP Toxicology Study in Cynomolgus Monkeys

Safety Findings

- No SAB-142 or rATG-related mortality, organ toxicity, or weight changes.
- No effects on neurobehavior, ECG, urinalysis, or food consumption.
- No increases in pro-inflammatory cytokines (TNF-α, IL-8, etc.).
- Lymphocytes: transient peripheral lymphopenia only without lymphodepletion (see figure 3).
- Hematology and chemistry: no unexpected findings.
- Controls and treated animals had the same incidental microscopic findings.

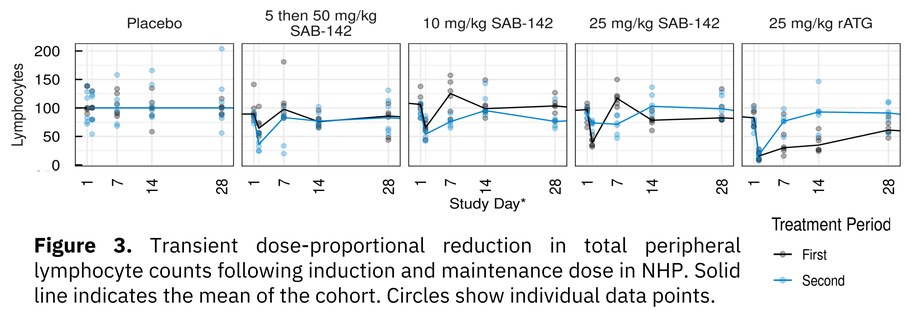

Figure 3. Transient dose-proportional reduction in total peripheral lymphocyte counts following induction and maintenance dose in NHP. Solid line indicates the mean of the cohort. Circles show individual data points.

SAB-142-101 First in Human Study

Safety Findings

- No deaths, drug-related SAEs, or study withdrawals.
- No serum sickness.
- Most treatment-related TEAEs were mild. The most frequent TEAEs included transient lymphopenia, headache, infusion site phlebitis, cytokine release syndrome (Grade 1 only), nausea, and glycosuria.
- The majority of treatment-related TEAEs were reported between Day 1 and Day 7 post-dose. The TEAEs from Day 8 onwards were comparable in the pooled SAB-142 vs the pooled placebo groups (54.0% and 61.1% of participants, respectively).
- No abnormal findings in neutrophils, erythrocytes, platelets or B cells.
- Lymphocytes: transient peripheral lymphopenia only (margination, not lymphodepletion). All lymphocytes recovered to the baseline by Day 4 (see figure 4).
- No clinically significant abnormalities in coagulation parameters.

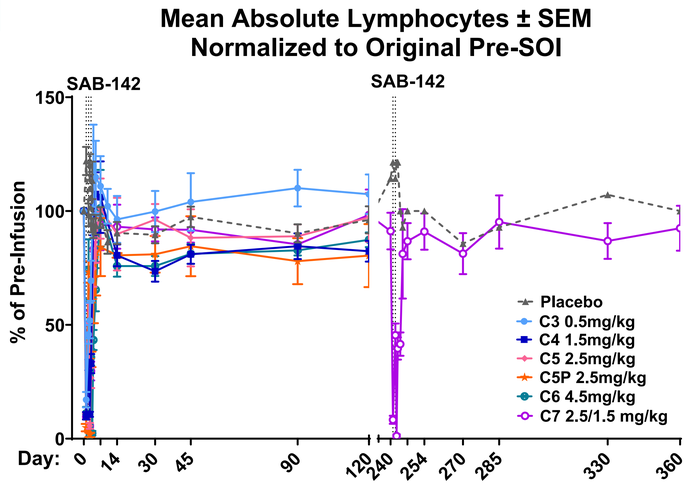

Figure 4. Transient lymphopenia occurs following SAB-142 induction and maintenance infusions, although, by day 7 lymphocyte populations recover back to baseline levels. Mean lymphocytes were quantified by flow cytometry and are shown as the % of pre-infusion ± SEM.

Methods

SAB-142 Non-Human Primate Study Design

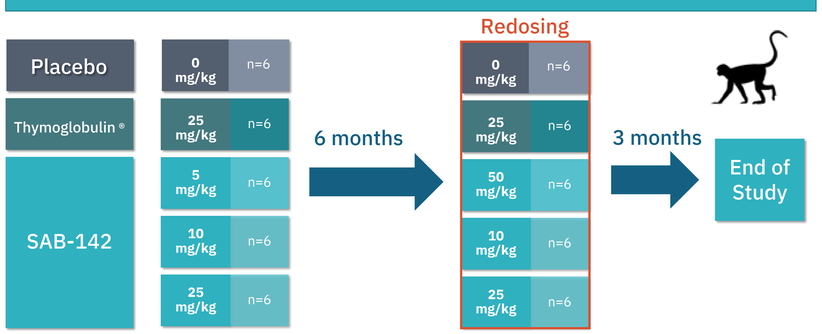

Figure 1. Schematic representation of a 9-month, two-dose GLP toxicology study of SAB-142 in 30 juvenile cynomolgus monkeys. Re-dosing was administered 6 months post induction followed by a 3-month observation period.

SAB-142-101 First in Human Study Design

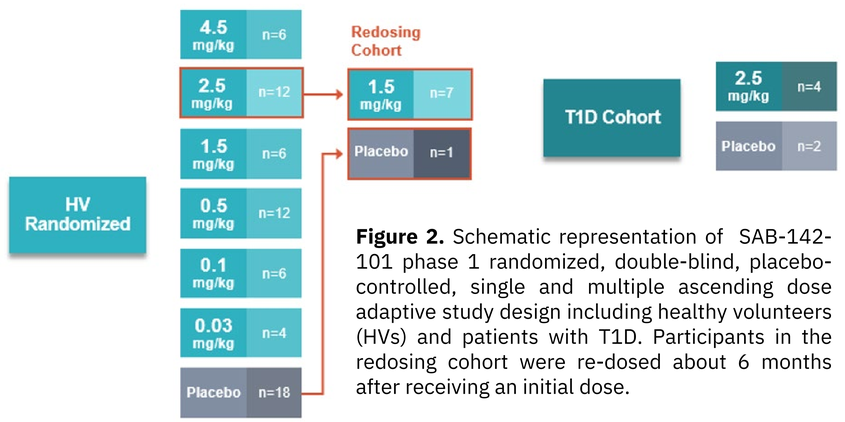

Figure 2. Schematic representation of SAB-142-101 phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose adaptive study design including healthy volunteers (HVs) and patients with T1D. Participants in the redosing cohort were re-dosed about 6 months after receiving an initial dose.

Conclusions

The safety findings of this juvenile NHP study are highly correlative with the outcomes of a phase 1 clinical study in HV and participants with T1D.

- SAB-142 treatment leads to transient lymphocyte margination not lymphodepletion.
- No AEs associated with ADAs and no ADA positivity following the redose administration of SAB-142.
- Redosing of SAB-142 is safe and predictable in both NHPs and humans.
- Consistent PD after redosing offers the potential for life-long disease modification with SAB-142.