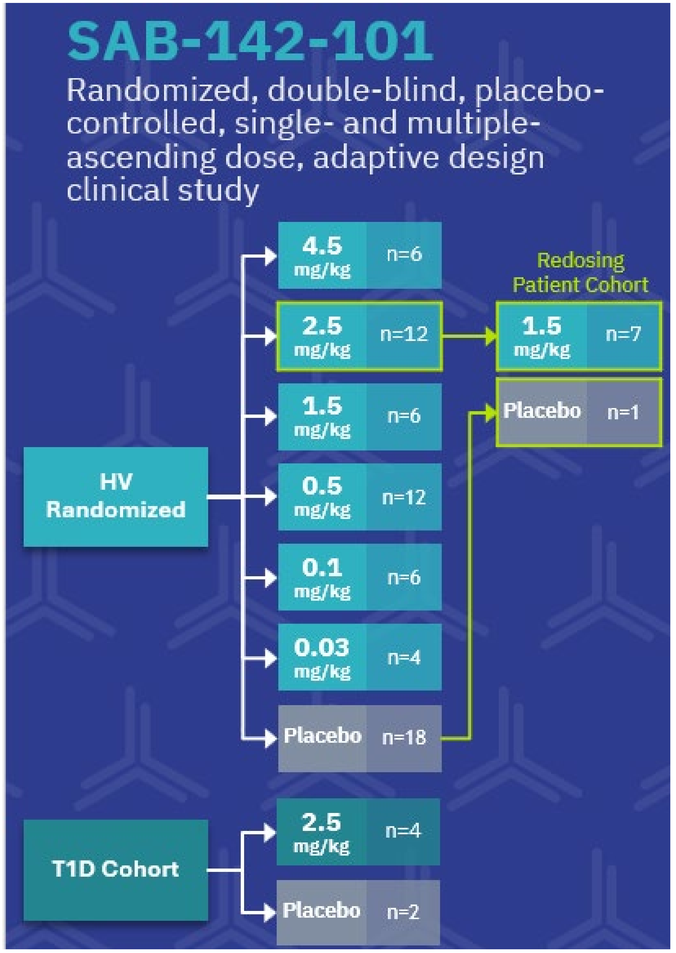
CHARTING THE SAFETY LANDSCAPE OF MULTI-SPECIFIC MODALITIES: SAFETY PROFILE OF MULTI-SPECIFIC ANTI-THYMOCYTE GLOBULIN SAB-142

ATTD Advanced Technologies & Treatments for Diabetes 11-14 MARCH 2026 BARCELONA & ONLINE

Introduction

- **There is no licensed therapy to halt or reverse new-onset Type 1 Diabetes (NOT1D).**
- Rabbit anti-thymocyte globulin (rATG) has been evaluated, but is limited by:
  - Neutralizing antibody formation
  - Hypersensitivity reactions
- **SAB-142**: a fully human, multi-specific anti-thymocyte globulin derived from the SAB Tc Bovine platform.
- **Aim:** To evaluate safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of SAB-142 in humans and juvenile non-human primates (NHPs).

Methods



Human Study (SAB-142-101)

- Design: Randomized, double-blind, placebo-controlled, Phase I.
- Population: Healthy volunteers + T1D cohort.
- Dosing: Single IV infusion, 0.03–4.5 mg/kg, and a redosing Cohort 1.5 mg/kg after 6 months.
- Endpoints: Safety, tolerability, PK, PD.

NHP Study Design

Duration of Observation		9 Months	
		~6 Months	~3 Months
Group	Test Material	Initial Dose (mg/kg)	Redose at ~6 months (mg/kg)
1	Placebo Control	0	0
2	Thymoglobulin®	25 (Split over 2 days: 10/15)	25 (Split over 2 days: 10/15)
3	SAB-142	5	50 (Split over 3 days: 20/20/10)
4	SAB-142	10	10
5	SAB-142	25 (Split over 2 days: 10/15)	25 (Split over 2 days: 10/15)

Number of Animals: 3 monkeys/sex per treatment arm: 30 monkeys Total
Test article, active comparator or placebo were administered in a volume of 10 mL/kg and infused over 2 hours via intravenous infusion.

NHP Study

Design: GLP study in juvenile cynomolgus monkeys.
Dosing: Initial and Redose with SAB-142, rATG or Placebo.
Endpoints: Safety, toxicokinetics, immunologic effects.

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Results

SAB-142-101 First-in-Human (FIH) Clinical 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, 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 (see figure 1).
- Lymphocytes: transient peripheral lymphopenia only (margination, not lymphodepletion). All lymphocytes recovered to the baseline by Day 4 (see figure 2).
- No clinically significant abnormalities in coagulation parameters.

Juvenile Non-Human Primate (NHP) Toxicology Study: 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.).
- Hematology and chemistry: no unexpected findings.
- Only incidental microscopic findings were also seen in controls.

SAB-142-101: SAB-142 does not cause sustained cellular depletion

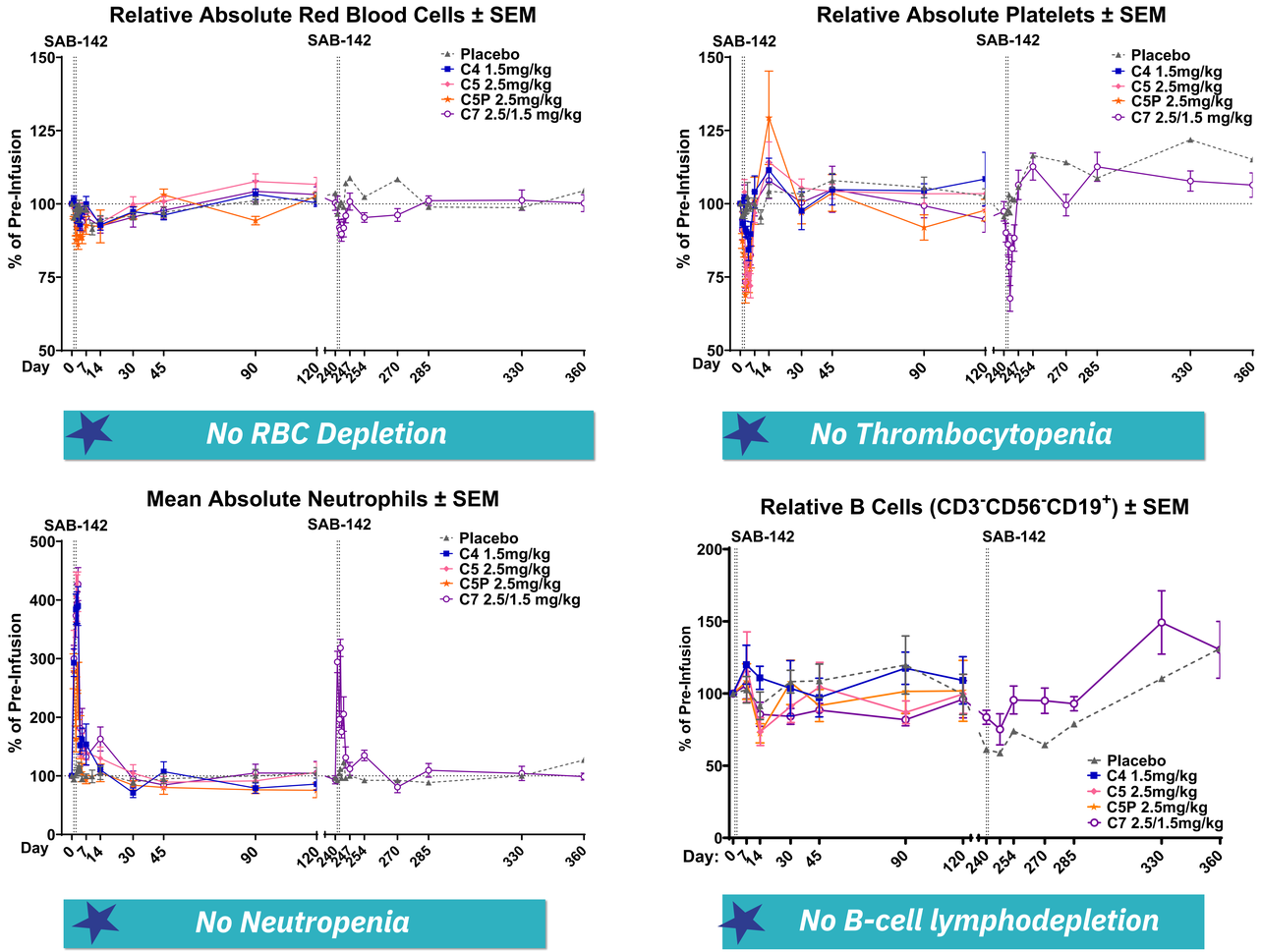

Figure 1. SAB-142 does not cause sustained depletion of red blood cells (RBC), platelets, neutrophils, or B cells.
Results normalized to pre-infusion sample. C4,C5 and C7: Healthy Volunteers; C5P: T1D patients. N indicates the number of participants.

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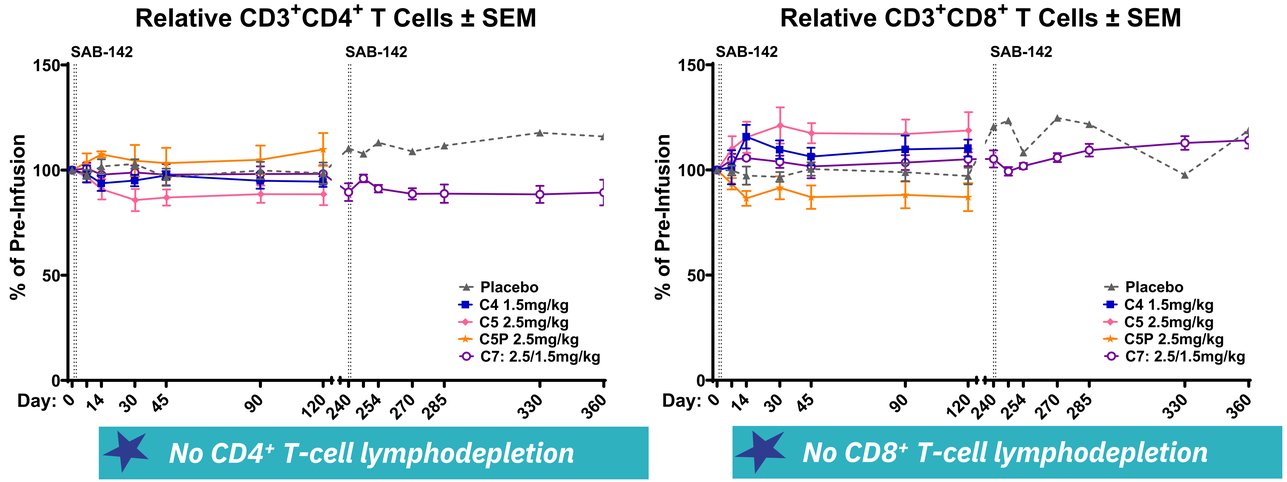
Results

SAB-142-101: SAB-142 does not cause sustained lymphodepletion



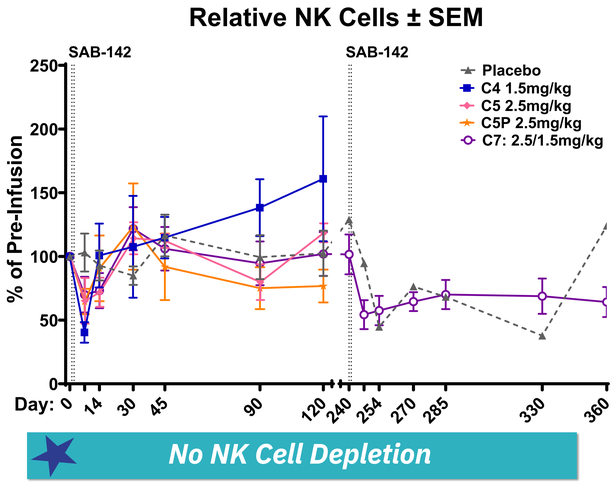


Figure 2. SAB-142 does not cause sustained lymphodepletion. Results normalized to pre-infusion sample. C4,C5 and C7: Healthy Volunteers; C5P: T1D patients. N indicates number of participants.

Conclusion

FIH — SAB-142 demonstrated a favorable safety profile in humans

- Well tolerated up to 4.5 mg/kg IV and re-dosing after 6 months.
- No drug-related SAEs, withdrawals, serum sickness, or anti-drug antibodies.

NHPs — SAB-142 demonstrated a favorable safety profile in Juvenile NHPs

- Tolerated up to 50 mg/kg with redosing after 6 months.
- NOAEL = 50 mg/kg, corresponding to ~20X human exposure safety margin.

Safety & Tolerability — Phase 1 results support the safe use and redosing of SAB-142 in the Phase 2B SAFEGUARD study in patients 5-40yo with new-onset T1D.