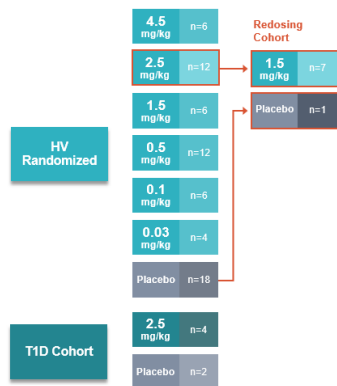


Introduction

- 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

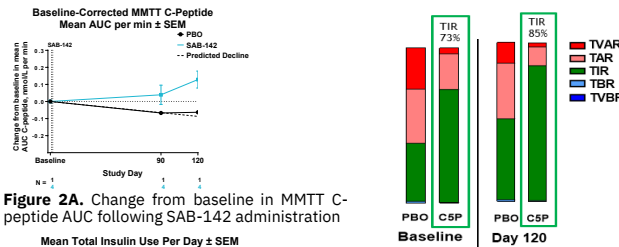


Figure 2A. Change from baseline in MMTT C-peptide AUC following SAB-142 administration

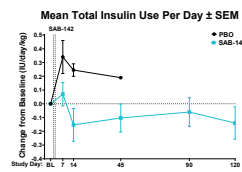


Figure 2B. Change from baseline in mean total daily insulin use following SAB-142 administration

Pharmacokinetics (Pk)

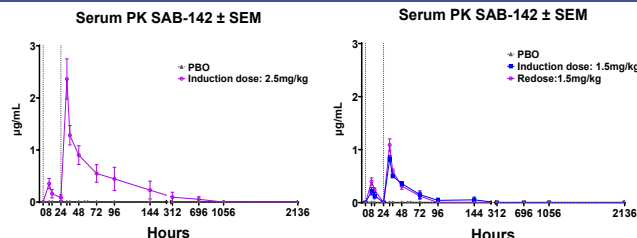


Figure 3. Serum SAB-142 concentration over time following initial and redosing administration at 1.5 and 2.5 mg/kg

Results

Pharmacodynamics (PD)

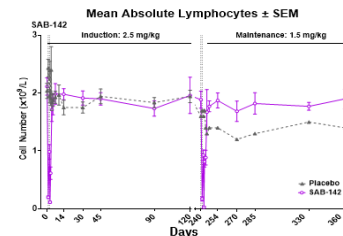


Figure 4A. Circulating lymphocyte dynamics following induction and maintenance doses of SAB-142

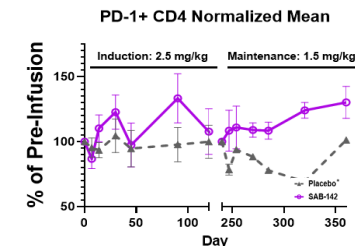


Figure 4B. PD-1 expression on CD4⁺ conventional T cells following initial and maintenance dosing of SAB-142

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