GB-0895, a next-generation anti-TSLP mAb, demonstrates durable pharmacologic activity supporting a single subcutaneous injection every 6 months for asthma patients.

Generate:Biomedicines℠

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Background & Aims of Study

- Thymic Stromal Lymphopoietin (TSLP), an alarmin, drives inflammatory responses in the airways and is a validated therapeutic target in severe asthma.
- **Generate:Biomedicines developed GB-0895**, a next-generation human monoclonal antibody (mAb) against TSLP, with the following properties to achieve a dosing regimen of a single subcutaneous (SC) injection every 6 months:
  - ~20-fold higher affinity for TSLP compared with tezepelumab
  - YTE Fc modifications for an extended half-life
- GB-0895-101 is an ongoing Phase 1, randomized, placebo-controlled study investigating single ascending doses (SAD-Part A) or multiple ascending doses (MAD-Part B) of GB-0895 or placebo administered SC in participants with mild-to-moderate asthma or a single dose in participants with chronic obstructive pulmonary disease (COPD). Unblinded data from Parts A and B of the study in asthma participants are presented here.

Study Design

Population

- Physician diagnosed mild-to-moderate asthma for ≥12 months controlled on as needed SABA and stable low-to-moderate dose of ICS or stable low-to-moderate dose of ICS/LABA
- Pre-BD FEV1 ≥ 60% of predicted normal value
- BEC ≥ 150 cells/μL at Screening
- ACT ≥ 20

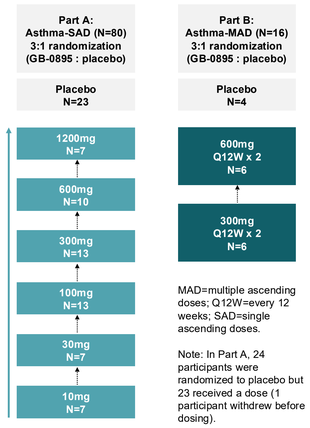
Participant Disposition

Part A
- 40 (50%) remain on study
- 37 (45.7%) completed study
- 4 (5%) discontinued

Part B
- 16 (100%) remain on study

All participants have completed 12-month follow-up post-dose

Participant Dosing



MAD=multiple ascending doses; Q12W=every 12 weeks; SAD=single ascending doses.

Note: In Part A, 24 participants were randomized to placebo but 23 received a dose (1 participant withdrew before dosing).

Results

Baseline disease characteristics.

Characteristic	Part A Pooled GB-0895 (N=57)	Part A Placebo (N=23)	Part B Pooled GB-0895 (N=12)	Part B Placebo (N=4)
Age, mean yrs	39.4	42.0	38.5	35.8
Male, n (%)	35 (61)	14 (61)	6 (50)	1 (25)
White, n (%)	50 (88)	21 (91)	9 (75)	3 (75)
BEC, cells/μL*	270.2 (127.86)	279.6 (125.10)	350.8 (310.47)	230.0 (70.71)
FeNO, PPB*	33.0 (24.02)	31.6 (23.64)	54.0 (35.14)	35.9 (23.96)
ACT Total Score*	23.1 (1.55)	22.1 (1.74)	23.3 (1.36)	22.5 (0.58)
FEV_1, L*	3.3 (0.86)	3.2 (0.62)	3.4 (0.93)	3.6 (1.01)
FEV_1 %predicted*	88.7 (12.94)	86.9 (9.31)	95.3 (11.27)	101.3 (6.75)

Abbreviations: ACT = asthma control test; BEC = blood eosinophil count; FeNO = fractional exhaled nitric oxide; FEV1 = forced expiratory volume in 1 second; PPB = parts per billion.
Notes: *mean(SD). Data cutoff: 26Jan2026

GB-0895 is well-tolerated with no treatment-related SAEs.

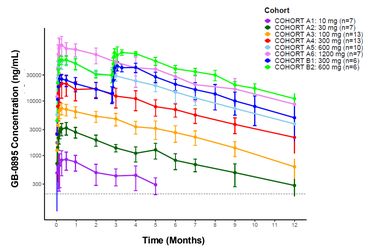
Subjects with, n (%)	Pooled (Part A & Part B) GB-0895 (N=69)	Placebo (N=27)
Any TEAE	66 (95.7)	26 (96.3)
Any serious TEAE	1 (1.4)	2 (7.4)
Any ISR*	10 (14.5)	4 (14.8)

Abbreviations: TEAE = Treatment emergent adverse event; ISR = Injection Site Reaction; SAE = Serious adverse event.
Notes:*ISRs include AEs reported under the MedDRA High Level Term 'Injection Site Reactions'. Data cutoff: 26Jan2026

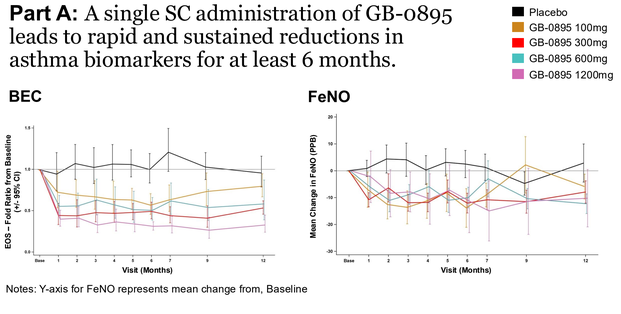
- Most common TEAEs (>5%, pooled GB-0895) were: nasopharyngitis (39.1%), headache (18.8%), rhinitis (15.9%), ISRs (14.5%), oropharyngeal pain (13.0%), URTI (10.1%), gastroenteritis (10.1%), COVID-19 (10.1%), back pain (5.8%), influenza (5.8%).
- 3 SAEs were reported (1 in GB-0895, 2 in placebo), all Grade 3, none related to GB-0895.
- Majority of TEAEs were mild–moderate (Grade 1–2); ISRs were all Grade 1.
- No trend was observed in TEAE incidence or severity across dose levels.

GB-0895 shows sustained dose-proportional PK with a ~ 98 days half-life at 300 mg.

- No evidence of target-mediated drug disposition.
- No evidence of anti-drug antibodies (ADA) impacting GB-0895 half-life.



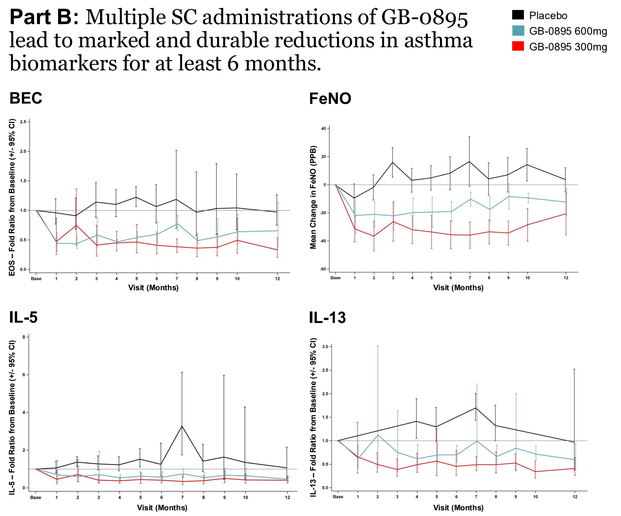
Part A: A single SC administration of GB-0895 leads to rapid and sustained reductions in asthma biomarkers for at least 6 months.



Notes: Y-axis for FeNO represents mean change from, Baseline

Notes: Fold ratio of geometric means from baseline by dose ±95% CI are presented; for FeNO: mean change from baseline is presented. GB-0895 10 mg and 30 mg dose groups induced suppression of PD biomarkers, albeit at lower levels compared with the other dose groups. Data cutoff: 26Jan2026

Part B: Multiple SC administrations of GB-0895 lead to marked and durable reductions in asthma biomarkers for at least 6 months.

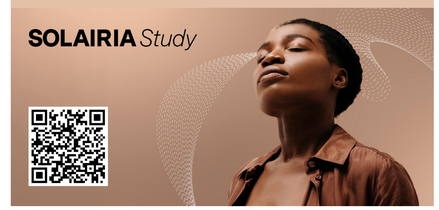


Notes: Fold ratio of geometric means from baseline by dose ±95% CI are presented; for FeNO: mean change from baseline is presented. Data cutoff: 26Jan2026

Conclusions

- GB-0895 is well-tolerated with the majority of TEAEs mild-moderate in severity.
- GB-0895 demonstrates a sustained dose-proportional PK with a half life of~ 98 days.
- GB-0895 induced marked and durable reductions in BEC, FeNO, IL-5, and IL-13 in participants with mild-to-moderate asthma in SAD and MAD cohorts.
- GB-0895 300 mg achieves maximal PD biomarker suppression for at least 6 months. Higher than 300 mg doses do not show a meaningful improvement in PD biomarker suppression.
- A single subcutaneous injection of 300 mg GB-0895 exhibits broad anti-inflammatory activity for at least 6 months.

GB-0895 is being evaluated in two ongoing Phase 3, global, randomized, double-blind, placebo-controlled studies in adults and adolescents with severe uncontrolled asthma (SOLAIRIA-1 & SOLAIRIA-2).



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