



27 September – 1 October | Amsterdam, Netherlands

GB-0895, a high-affinity anti-TSLP mAb, demonstrates prolonged half-life and sustained pharmacological activity supporting every 6-month dosing in asthma

Generate: BiomedicinesSM

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I have the following real or perceived conflicts of interest that relate to this presentation:

Received sponsorship to attend and speak at international meetings, honoraria for lecturing or attending advisory boards from the following companies:

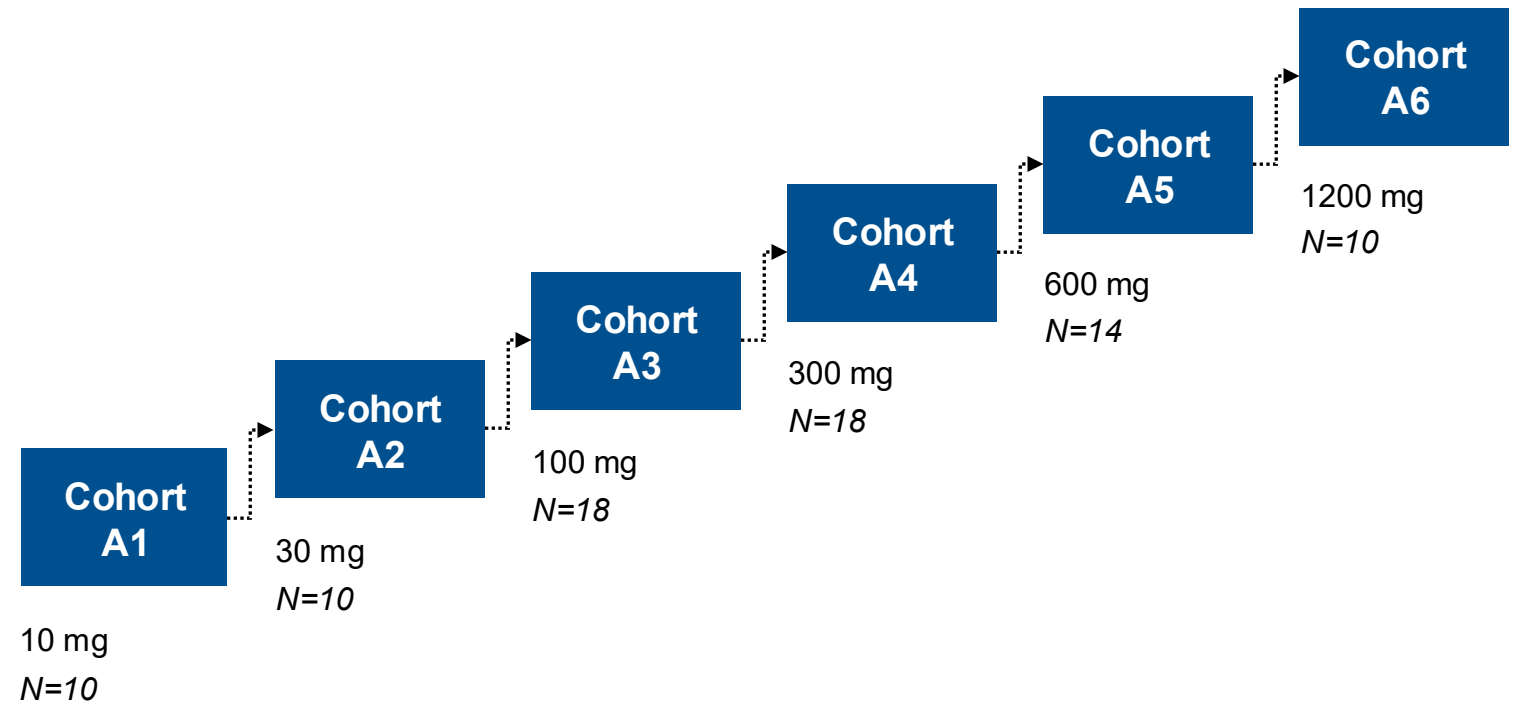
Adovate, Almirall, Anaveon, Apogee, Arcutis Biotherapeutics, Arrowhead, AstraZeneca, Belenos Biosciences, Bial, Celldex, Chiesi, Cipla, CONNECT Biopharm, Covis, DevPro Biopharma LCC, Elpen, Empirico, EpiEndo, Generate Biomedicines, GlaxoSmithKline, Glenmark, Jasper, Kinaset Therapeutics, KOLON, Kymera, Lupin, Melodia, Menarini, MicroA, OM Pharma, OrientEuroPharma, Recipharm, Revolo, RIGImmune Inc, Roche, Roivant Sciences, Sanofi, Sitryx, Synairgen, Tetherex, UCB, Upstream, Verona Pharma, Winward, Zura Bio, Zymeworks

- Thymic stromal lymphopoietin (TSLP) is a validated target in asthma that drives lung inflammation
- Generate:Biomedicines developed GB-0895, a next generation, anti-TSLP mAb with
 - ~20-fold higher affinity for TSLP compared to tezepelumab
 - YTE Fc modifications for extended half-life
- Here we present interim data from an ongoing phase 1 randomized, placebo-controlled trial in participants with mild to moderate asthma
 - The study aimed to characterize safety, pharmacokinetics, and pharmacodynamics of GB-0895
 - All safety data are summarized by blinded cohorts
 - PK/PD data are presented in aggregate across active doses versus placebo to maintain trial integrity
 - Only data from the Part A (single ascending dose) are presented

GB-o895 Phase 1, Double Blind, Placebo-Controlled Clinical Trial in Mild-to-Moderate Asthma Patients

- Mild-to-moderate asthma patients
- Subcutaneous administration
- Sentinels 1:1 randomization; Remainder 3:1 randomization
- Blood eosinophils ≥ 150 cells/ μ L
- Asthma controlled on as-needed SABA and stable low-to-moderate dose of ICS or stable low-to-moderate dose of ICS/LABA combination
- FEV1 $\geq 60\%$ of predicted normal value
- ACT > 19

Part A: Single-ascending dose (SAD) | N=80



Conducted in the United Kingdom, Germany, and USA at 8 sites

MAD portion of study enrolled an additional 16 participants

Baseline characteristics are consistent across cohorts of our Ph 1 study

	Cohort A1 10mg (N=10)	Cohort A2 30mg (N=10)	Cohort A3 100mg (N=18)	Cohort A4 300mg (N=18)	Cohort A5 600mg (N=14)	Cohort A6 1200mg (N=10)	Total (N=80)
Age, years Mean (SD)	40 (12)	42 (12)	40 (13)	41 (13)	36 (13)	41 (11)	40 (13)
Sex, M/F %	70/30	50/50	72/28	56/44	50/50	70/30	61/39
Baseline Eos, cells/uL Mean (SD)	255 (123)	231 (59)	276 (166)	269 (110)	338 (136)	244 (100)	273 (126)
FEV1, Predicted % Mean (SD)	87.5 (9.9)	88.0 (19.8)	85.8 (9.2)	90.3 (11.9)	85.9 (11.1)	92.6 (10.7)	88.2 (12.0)
FeNO, PPB Mean (SD)	37.7 (12.4)	25.8 (19.8)	34.8 (33.1)	32.7 (24.6)	33.6 (13.6)	28.8 (27.8)	32.6 (23.8)
ACT Score Mean (SD)	21.7 (1.7)	23.7 (1.3)	23.2 (1.7)	22.6 (1.7)	23.0 (1.6)	22.5 (1.5)	22.8 (1.7)

Each cohort includes randomized active and placebo participants; presented blinded to preserve trial integrity

Safety data are summarized by blinded cohorts including active and placebo subjects

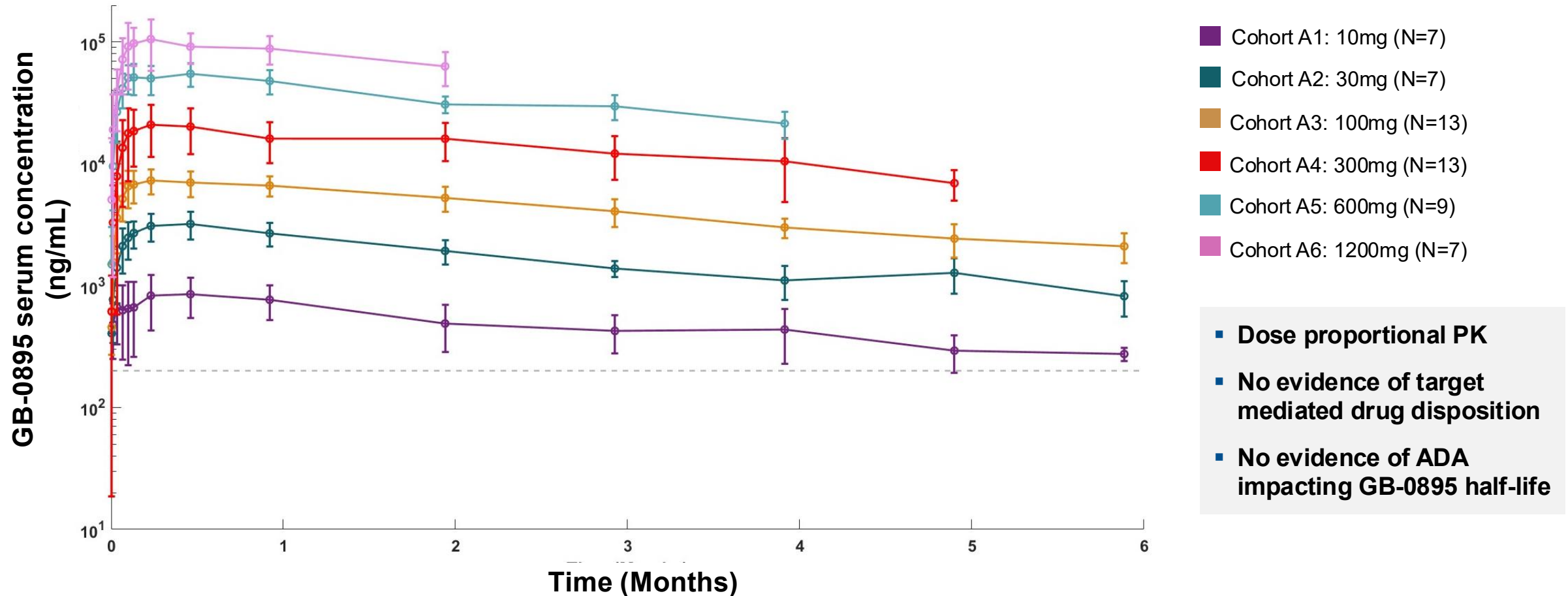
- 80 subjects received a single dose of GB-0895 or placebo; followed ≥ 26 weeks
- Most common TEAEs by PT (≥10% incidence in all treatment groups): nasopharyngitis, rhinitis, headache
- 3 SAEs reported: Occurred in cohort A3: 100mg (n=2) and cohort A4: 300mg (n=1)
 - All Grade 3, Not Related to study drug
- All other TEAEs mild-moderate in severity (Grade 1-2); ISR all Grade 1
- No trend in increasing incidence or severity of TEAEs vs dose

Subject Incidence of:	Cohort A1 (10mg) N=10	Cohort A2 (30mg) N=10	Cohort A3 (100mg) N=18	Cohort A4 (300mg) N=18	Cohort A5 (600mg) N=14	Cohort A6 (1200mg) N=10	Total N=80
Any TEAE	9 (90.0%)	8 (80.0%)	18 (100%)	17 (94.4%)	12 (85.7%)	9 (90.0%)	73 (91.3%)
Any ISR*	1 (10.0%)	0 (0.0%)	1 (5.6%)	3 (16.7%)	4 (28.6%)	1 (10.0%)	10 (12.5%)

Date of Data Extract: 04Aug2025.

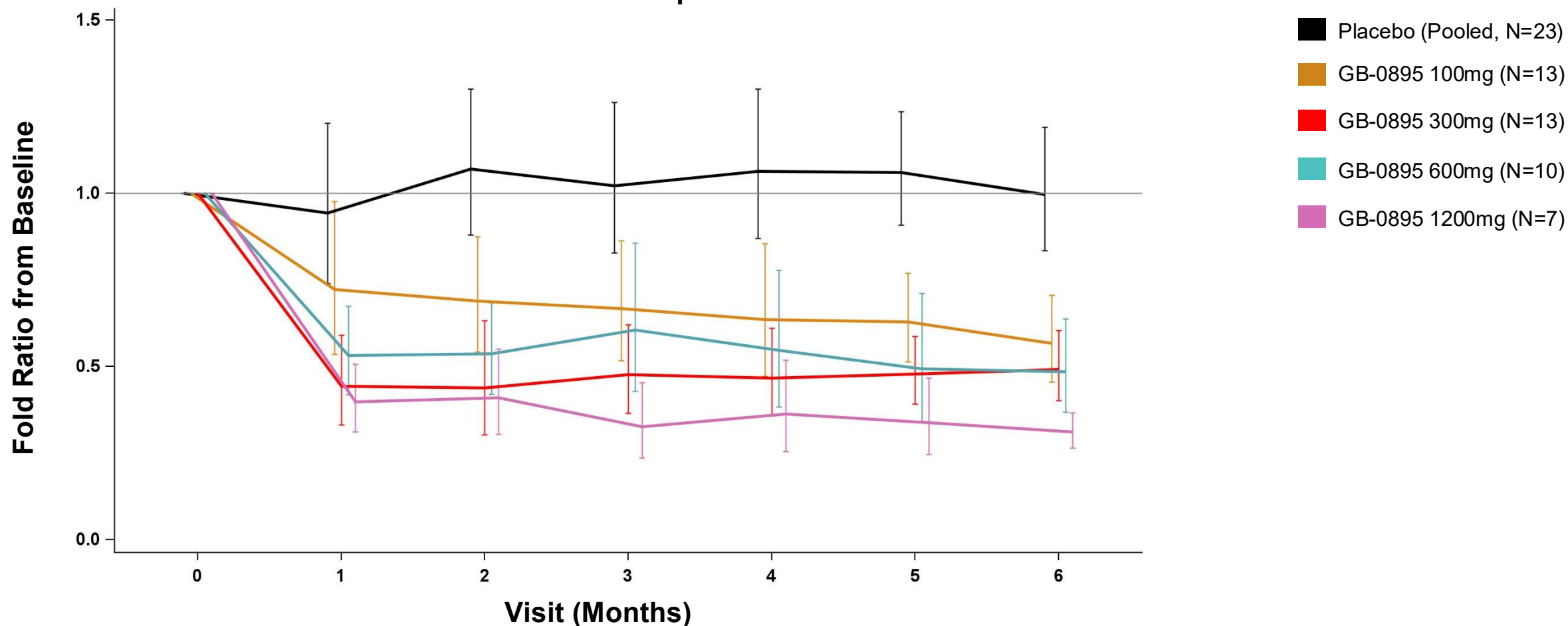
*ISRs include AEs reported under the MedDRA High Level Term ‘Injection Site Reactions’
TEAE = Treatment emergent adverse event; ISR = Injection Site Reaction; SAE = Serious adverse event, PT = Preferred Term

Clinical PK data for GB-0895 show half-life of ~89 days

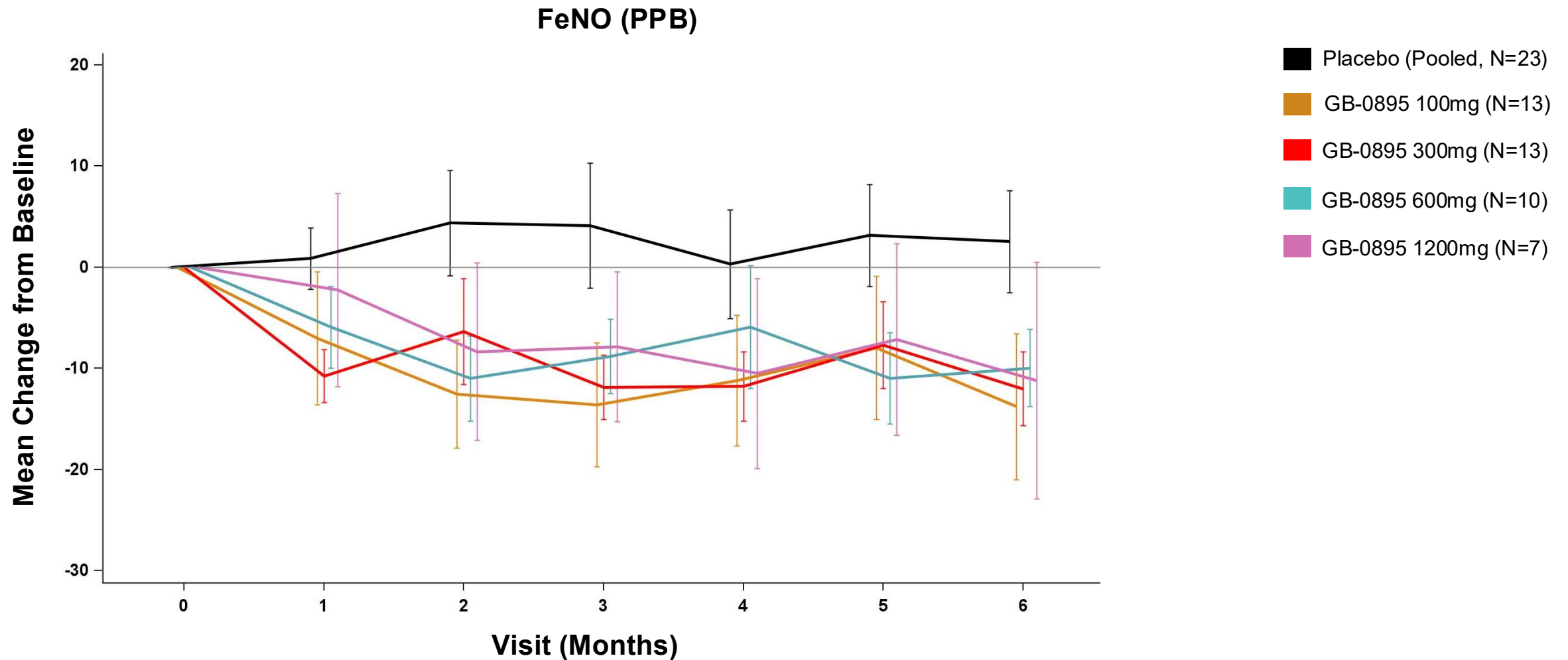


A single subcutaneous administration of GB-0895 leads to sustained reductions in blood eosinophils for 6 months at 100-1200 mg doses

Blood Eosinophils

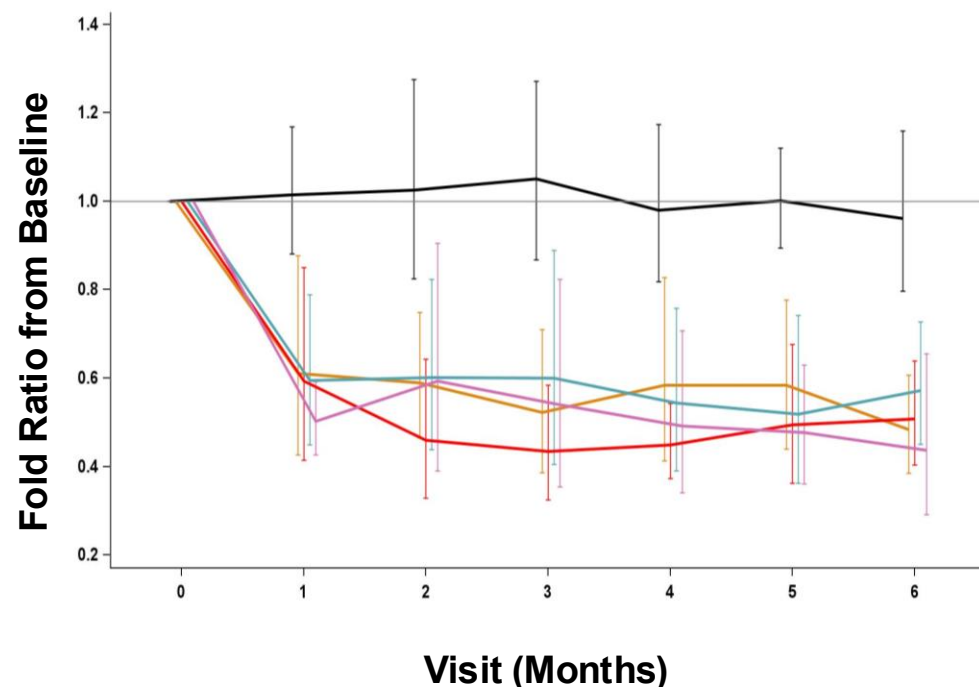


A single subcutaneous administration of GB-0895 leads to sustained reductions in FeNO for 6 months at 100-1200 mg doses

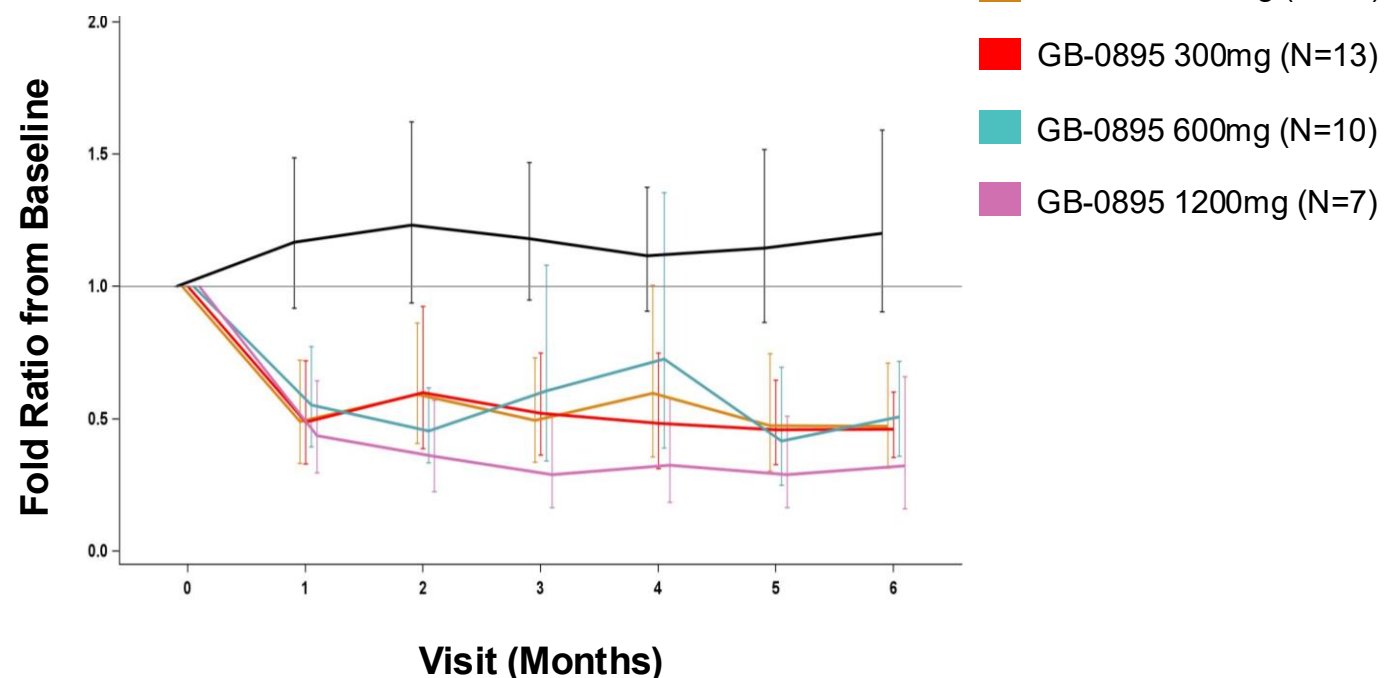


A single subcutaneous administration of GB-0895 leads to sustained reductions in IL-13 and IL-5 for 6 months at 100-1200 mg doses

IL-13



IL-5



- GB-0895 has been well tolerated
- GB-0895 demonstrates dose-proportional pharmacokinetics with a half-life of ~89 days
- A single subcutaneous dose provides 6 months of pharmacologic activity, as evidenced by reductions in EOS, FeNO, IL-5, and IL-13
- Broad anti-inflammatory activity of GB-0895 is consistent with the mechanism of action as previously reported with tezepelumab
- These data support dosing of GB-0895 subcutaneously every 6-months for severe asthma

PHASE 3 TRIALS OF GB-0895 EXPECTED TO INITIATE IN Q4 2025