



# Join Us in Advancing Asthma Treatment

A Phase 3, randomized, double-blind, placebo-controlled study with an optional open-label extension (OLE) investigates the safety, tolerability, and efficacy of GB-0895 in adults and adolescents with severe uncontrolled asthma. **(GB-0895-301)**

## Study Objective

To evaluate the efficacy of GB-0895 (every 6 months) versus placebo in reducing asthma exacerbations over 52 weeks, and to assess lung function, asthma control, and quality of life. An optional open-label extension (OLE) is available for patients completing the primary study.

## About the IP

- **TSLP Role:** Produced by airway epithelial cells, TSLP activates IL-5 and IL-13, key inflammation mediators in asthma.
- **High Affinity Antibody:** GB-0895 is a high affinity human monoclonal antibody (IgG1 type) antagonist of TSLP.
- **Extended Half-Life:** Designed for less frequent dosing.
- **Mechanism:** Blocks TSLP from binding to its receptor, preventing proinflammatory pathway activation.
- **Severity Correlation:** High TSLP levels correlate with severe asthma and airflow obstruction (FEV1).
- **Broad Impact:** Targeting TSLP downregulates airway responses across inflammatory phenotypes.

## Key Inclusion Criteria

- Adults and adolescents 12 to 80 years of age
- A documented diagnosis of asthma for  $\geq 2$  years that meets the National Heart, Lung, and Blood Institute guidelines or Global Initiative for Asthma (GINA) guidelines
- Must be on medium- to high-dose ICS plus at least one additional controller (e.g., LABA, LAMA) at stable doses for  $\geq 3$  months before Screening
- History of recent asthma exacerbations requiring systemic corticosteroids [or: History of at least two asthma exacerbations requiring systemic corticosteroids in the last 12 months]

## Key Exclusion Criteria

- Recent severe asthma exacerbation requiring therapy change (past 12 weeks)
- Significant lung or respiratory disease other than asthma (e.g., COPD, pulmonary fibrosis, active TB)
- Current/recent use of biologics for asthma (e.g., anti-IL-5, anti-TSLP) or systemic immunosuppressive therapy
- Current or former heavy smokers ( $\geq 10$  pack-years) or vaping/ecigarette use
- Pregnant, lactating, or planning pregnancy

## Your Benefits

- **Improve Patient Outcomes:** Help patients with severe uncontrolled asthma access an investigational drug.
- **Stay Informed:** Keep up to date with the latest advancements in asthma treatment.
- **Strengthen Patient Trust:** Show patients your commitment to exploring all available treatment options.

**Generate** : Biomedicines

## Condition or Disease

- Severe Uncontrolled Asthma

## Estimated Enrollment

- Approximately 786 patients in 24 countries globally

## Key Information

- **Randomization:** Eligible patients will be randomized in a 2:1 ratio to receive GB-0895 or placebo.
- **Primary Objective:** Evaluate the efficacy of GB-0895 (300 mg SC every 26 weeks) in reducing clinically significant asthma exacerbations over 52 weeks.
- **Primary Endpoint:** Annualized asthma exacerbation rate (AAER) over 52 weeks requiring systemic corticosteroids and/or hospitalization or emergency department visits.

## ICD Codes

- **ICD-10:** Asthma: J45; Severe Uncontrolled Asthma: J45.50, J45.51, J45.52; Exacerbation: J45.901
- **ICD-11:** Asthma: CA23, Severe Uncontrolled Asthma: CA23 (with postcoordination for severity XS25 and control XM0G); Exacerbation: CA23 (with postcoordination for exacerbation XT5R)

## Study Duration

- Screening Period: 6 weeks
- Treatment Period: 52 weeks
- Follow-Up Period: 38 weeks OR
- Optional Open-Label Extension (OLE)

## Trial Identifiers

- ClinicalTrials.gov: NCT07276724
- CTIS: 2025-521950-41-00

## Published Data

- [European Respiratory Society \(ERS\) 2025: GB-0895 Phase 1 Data](#)



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