This post-hoc analysis aimed to assess the effect of GB001 on time to asthma worsening in patients with mild-moderate asthma.

METHODS

Phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel-group study conducted in Japan from May 2015 through April 2016.

During a 4-week run-in period, patients received medium-dose inhaled corticosteroids (ICS) and oral placebo and were then randomized 1:1:1 to once-daily GB001 5 mg, 20 mg, or placebo for 16 weeks or until asthma worsening. ICS were tapered to and then discontinued from low-dose levels at randomization and 4 weeks post-randomization. (Figure 1)

A composite endpoint was used to define asthma worsening; if any of the criteria were met, the study drug was discontinued and patients were randomized on standard of care therapy. (1) = 25% decrease from baseline in morning peak expiratory flow (AM PEF) for 2 days; (2) ≥ 20% decrease from baseline in FEV1; (3) use of inhaled short-acting β-agonists at doses ≥ 5 puffs/day for 2 days, (4) a ≥ 0.5 point increase from baseline in the ACQ-5 score, or (5) asthma exacerbation requiring administration of oral corticosteroids or an unscheduled visit to the clinic

Results are presented for placebo- and GB001 20 mg-treated patients; results for the GB001 5 mg group were generally consistent with the 20 mg dose group (data not shown).

Conclusions

GB001 was associated with a longer time to asthma worsening.

Great treatment effect was observed in patients with high baseline FeNO and/or high baseline Eos.

In addition to being markers of airway inflammation, these biomarkers may be useful predictors for treatment response to GB001.

REFERENCES


