CAPTAIN Study: Treatment Outcomes From Fluticasone Furoate/Umeclidinium/Vilanterol According to History of Severe Asthma Exacerbations

Objective

To evaluate the efficacy and safety of fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) compared with fluticasone propionate/salmeterol (FP/SAL) and fluticasone/vilanterol (FF/VI) in patients with uncontrolled asthma despite inhaled corticosteroid (ICS)/long-acting β2-agonist (LABA) therapy.

Methods

CAPTAIN was a Phase III, randomized, double-blind, 24–52-week, parallel-group study (GSK study 205715, NCT02924688). All patients in the study had a safety follow-up contact approximately 7 days after the End of Study Visit (Week 24, 36, or 52) or Early Withdrawal Visit.

FP/SAL provided BID as a fixed dose via the Diskus DPI; FF/VI and FF/UMEC/VI provided QD as a fixed dose via the Ellipta DPI. Patients had up to 5 on-treatment clinic visits. Objective

On- and post-treatment exacerbations (over Weeks 1–52) were defined as follows:

- Pre-dose FEV1/FVC ratio, mean (SD)
- Difference in change from baseline (mL)
- Difference in change from baseline (mL) (95% CI)
- LS mean CFB, mL (95% CI)
- Mean rate (95% CI)
- Difference, mL (95% CI)
- n=number of patients with analyzable data at Week 24 for each treatment. CI, confidence interval

Results

In the overall population, adding a LAMA, increasing FF dose, or both, in patients with uncontrolled GINA-defined moderate/severe asthma despite ICS/LABA therapy, when adding a LAMA or doubling ICS dose, rate ratios for subjects with severe exacerbations vs those with no prior severe exacerbations and to the overall population.

Conclusions

For patients controlled on ICS/LABA, the addition of UMEC was associated with improved lung function, with a significant difference in lung function between patients with and without a history of ≥1 severe exacerbation. This difference in lung function was observed in patients with a history of ≥1 severe exacerbation vs those with no prior severe exacerbations and to the overall population.