Background

- Achieving and maintaining symptom control over the long term is a key goal for asthma treatment according to the Global Initiative for Asthma 2019 guidelines.
- Approximately 30%-50% of patients with moderate/severe asthma remain symptomatic with poorly controlled disease despite adherence to inhaled corticosteroids (ICS)/long-acting β2-agonist (LABA) therapy.
- The addition of a long-acting muscarinic antagonist (LAMA) to ICS/LABA therapy improves lung function and reduces exacerbation rates in patients with asthma; improvements in symptoms are less consistent.
- Fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) is widely approved as a once-daily treatment for chronic obstructive pulmonary disease (COPD).

Aims

- To report Asthma Control Questionnaire (ACQ) data from the CAPTAIN study, and explore the relationship between changes in ACQ-7 score and trough forced expiratory volume in 1 second (FEV1).

Methods

- CAPTAIN was a Phase IIIA randomized, 24-week, parallel-group study (study NCT02930048), enrolling adults with asthma on maintenance ICS/LABA therapy with a pre-bronchodilator FEV1 of ≥10% and <80% of predicted, with an increase in FEV1 of ≥12% and ≥250 mL, following 14 days of double-blind ACQ-5 or ACQ-7 (Figure 1).
- Patients with COPD or other respiratory disorders and pneumonia/pneumonia risk factors were excluded.
- For all analyses reported, P-values are not adjusted for multiplicity. All doses are mcg.

Results

- 2436 patients were included in the ITT (intent-to-treat) population.
- Greater improvements in least squares (LS) mean change from baseline in trough FEV1 were observed in the pooled analysis of FF/UMEC 62.5 mcg/VI versus FF/VI (101 mL vs. 95% confidence interval [CI] 70–123 at Week 24 (Figure 2A)).
- Improvements were seen as early as Week 4 (40 mcg CI: 23–57).

Conclusions

- A higher proportion of ACQ responders was observed with FF/UMEC 62.5 mcg/VI versus FF/VI at Week 24 (ITT population). Greater proportions of ACQ responders were seen with FF/UMEC 62.5 mcg/VI versus FF/VI as early as Week 4 (50% vs. 40%; odds ratio: 1.45 [95% CI: 1.18, 1.79]).
- The limited correlation between changes in lung function (FEV1) and disease control (ACQ-7 score) was observed for symptom improvement as well as changes in lung function.

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