CAPTAIN Study: Daily Digital Spirometry and Symptom Data for Once-Daily, Single-Inhaler Fluticasone Furoate/Umeclidinium/Vilanterol (FF/UMEC/VI) in Asthma

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*Vitalation at time of study

Background

- Achieving and maintaining long-term symptom control is a key goal in asthma treatment.
- The addition of a long-acting muscarinic antagonist (LAMA) to inhaled corticosteroid (ICS)/long-acting β2-agonist (LABA) therapy has been shown to improve lung function and reduce exacerbation rates in patients with asthma.1

The Phase 3 CAPTAIN study aimed to evaluate the efficacy and safety of once-daily Fluticasone Furoate/Umeclidinium/Vilanterol (FF/UMEC/VI) in comparison to FF/VI in patients with asthma inadequately controlled on ICS/LABA. Results showed improved lung function and numerical reductions in the annualized rate of exacerbation in the FF/UMEC/VI versus FF/VI arm, with no new or unexpected safety findings.2

Methods

- CAPTAIN was a Phase 3A, randomized, 24–52-week, parallel-group study (study 205715, NCT02924688). The study design is shown in Figure 1.

- Eligibility:
  - E-RS: Asthma total score ≥12 at screening and ≤100 at baseline
  - FEV1 ≥60% predicted
  - Over 18 years of age
  - Received ICS/LABA therapy
  - Eligible patients for treatment of acute asthma

- Randomization:
  - Fixed treatment period: 24 weeks
  - Variable treatment period: 24–52 weeks

- Efficacy and safety were assessed using the E-RS: Asthma (scoring range 0–40, with higher scores indicating more severe respiratory symptoms) and (D) containing therapies, respectively.

Results

- E-RS: Asthma total score improved from baseline in all treatment groups at all timepoints assessed and was higher in the FF/UMEC/VI group compared to FF/VI at 24 weeks and (B) evening FEV1 over 24 weeks (Figure 2C). The E-RS: Asthma responders were significantly greater in the FF/UMEC/VI group compared to FF/VI therapy (Figure 3).

- Changes from baseline in morning and evening trough FEV1 over 24 weeks are shown in Figures 3A and 3B.

- The primary analysis of non-symptom responders, including E-RS: Asthma, were pre-specified to be performed on pooled data for both FF doses, however, the safety and primary outcome data are presented in the analysis of the data from the fixed treatment arm.

Conclusions

- A greater proportion of patients on FF/UMEC/VI versus FF/VI therapy were E-RS: Asthma responders compared to FF/VI therapy.
- A greater proportion of patients on FF/UMEC/VI versus FF/VI therapy were E-RS: Asthma responders with ERS ≥2 points from baseline.
- Differences from baseline in mean home daily morning trough FEV1 were shown in Figure 1.
- The E-RS: Asthma total scores and FEV1 were improved in all treatment groups at all timepoints assessed (D) containing therapies, respectively.

Figure 1. Change from baseline to (A) home daily morning trough FEV1, and (B) evening FEV1 over 24 weeks

References

- Lee LA, Kerwin E, Fixler A, Tabberer M, Balles Z, Pearce S, Kanem S. GSK, Collegeville, PA, USA; 2Ameron University, Quebec, QC, Canada; 3GSK, Stockley Park West, Uxbridge, Middlesex, UK; 4Cirrus LLC Research, Clinical Research Institute of Southern Oregon, Medford, OR, USA

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