This analysis of the CAPTAIN study reports on the effects of doubling the FF dose in FF/VI dual therapy in patients with inadequately controlled asthma symptoms in the year prior to screening. Up to 50% of patients with asthma are inadequately controlled despite receiving dual therapy with an inhaled corticosteroid (ICS) and long-acting beta-agonist (LABA). Current guidance for these patients recommends increasing the ICS dose in a stepwise manner.

**Background**

Step-up to High Dose Fluticasone Furoate in Combination With Long-Acting Bronchodilator in Inadequately Controlled Asthma: The CAPTAIN Study

Poster No. 072

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![Figure 1](image.png)

**Methods**

CAPTAIN (study 205715, NCT02924688) was a Phase IIIa, randomized, double-blind, 24–52-week, parallel-group study investigating the efficacy and safety of once-daily, single-inhaler dual therapy with FF/VI and triple therapy with FF, umeclidinium (UMEC; a long-acting muscarinic antagonist), and vilanterol (VI; a long-acting beta-agonist) delivered via an electronic inhaler (the ELLIPTA dry powder inhaler) as shown in Figure 1.

**Results**

In total, 468 patients (28%) experienced moderate/severe exacerbations over 52 weeks. FF/VI 200/25 mcg (mean (SD) change from baseline: 36 mL (95% CI: -8, 81)) was non-inferior to the comparator arm (FF/VI 100/25 mcg; mean (SD) change from baseline: 26 mL (95% CI: -20, 73)). Clinically significant improvements from baseline in clinic trough FEV1 were reported in this poster.

**Conclusions**

Doubling the FF dose provided moderate long-term efficacy and a 33% reduction in the rate of moderate/severe exacerbations. Trends for improvements in asthma control over 52 weeks and asthma control over 12 months were consistent with the results of other trials and no increase in the risk of AEs was observed.

**References**


**Disclosures**

I am an employee of GlobalAlliance (GINA, 2018), NCT02924688, and SLIGHTS and SLIGHTS II are revealed in the US in 2019. This work was supported in part by AstraZeneca and Teva. Reimbursements from Amphastar, AstraZeneca, Boehringer Ingelheim, Forest, GSK, Mylan, Novartis, Pearl, Sunovion, Teva, and others reimburse my institution for the preparation of this manuscript. I am an employee of AstraZeneca. My institution administered the study and I administered the study in an investigator site.