PROSPECTIVE, MULTICENTRE, PHASE IV TRIAL EVALUATING SAFETY AND EFFICACY OF GLYCOPYRRONIUM/FORMOTEROL/BUDESONIDE FIXED-DOSE COMBINATION (FDC) IN COPD PATIENTS

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Background: Triple inhaled therapy of ICS/LABA/LAMA is used frequently for COPD management. An FDC dry powder inhaler (DPI) containing Glycopyrronium/Formoterol/Budesonide was launched in India to address challenges arising with multiple inhaler usage.

Objectives: To evaluate safety and efficacy of Glycopyrronium/Formoterol/Budesonide DPI (25mcg/12mcg/400mcg) FDC, twice daily, in patients with moderate-severe COPD.

Methods: Spirometrically confirmed moderate-severe COPD subjects received Glycopyrronium/Formoterol/Budesonide (Glycohale FB™) after a 2-week run-in period.

Adverse events were monitored at follow-up visits over a 24-week period. CAT, SGRQ and mMRC scores and spirometry were assessed at baseline and at pre-defined visits.

Results: 202 patients with a mean age of 61.4 (±8.17) years were enrolled. 83.17% were males; 92.57% and 7.43% belonged to GOLD B and D category, respectively. At the baseline, mean FEV1 was 1.1L and %predicted FEV1 was 44%. 25 patients had 44 non serious adverse events. CAT score significantly reduced from 20.3 at baseline to 13.1 at week 24 (mean change 7.1 units, $p<0.001$). Average pre-dose trough FEV_1 significantly improved by 69 ml and pre-dose FVC improved significantly by 83ml at 24 weeks. Significant improvement (19 units) well above MCID was seen in the average SGRQ score at week 24. A significant improvement (-0.281 ± 0.61) was also observed in the mMRC score at week 24.

Conclusion: Glycopyrronium/Formoterol/Budesonide FDC is safe and effective in improving lung function, symptoms, and quality of life in patients with moderate-severe COPD.

Key words: Budesonide/Glycopyrronium/Formoterol; COPD; India

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