

Efficacy of Budesonide/Glycopyrronium/Formoterol FDC Across Blood Eosinophil Ranges in Indian COPD Patients: Post Hoc Analysis of Phase-4 Clinical Trial

Dr Sanjana Shastri¹, Dr Meena Lopez¹, Dr Priti Meshram², Dr Anand Kumar³, Dr Ajeet Singh⁴, Dr K Srikanth⁵, Dr Raja Dhar⁶, Dr Sandesh Sawant¹, Sushmeeta Chowala¹, Dr Senthilnathan M¹, Dr Jaideep Gogtay¹

¹Medical Dept, Cipla Ltd, Mumbai, Maharashtra, India

²Grant Government Medical College & Sir JJ Group of Hospital

³GSVM Medical College, Kanpur, Uttar Pradesh, India

⁴SMS Medical College & Hospital Jaipur, Rajasthan, India

⁵Hindusthan Hospital, Coimbatore, Tamil Nadu, India

⁶C K Birla Hospital, Kolkata, West Bengal, India

Background: GOLD-2024 recommends triple therapy for COPD patients with high blood eosinophil count(BEC). Evidence is emerging on its use in patients irrespective of BEC; however, this data is lacking in Indian patients. In a Phase-4-clinical-trial, FDC of Budesonide/Glycopyrronium/Formoterol(BGF) (400/25/12mcg) Dry-Powder-Inhaler(DPI) was well-tolerated and improved lung-function, CAT, SGRQ and mMRC in Indian COPD patients. A post-hoc analysis was conducted to evaluate treatment benefits based on BEC.

Aims: To assess impact of triple therapy on symptoms, QoL and FEV1 as per eosinophil counts at baseline.

Methods: The 24-week open-label, prospective, non-comparative, multicenter phase-4-trial was conducted in moderate-severe COPD patients, between 40-75 years, who were current/ex-smokers, had spirometrically-diagnosed-COPD(GOLD-2020), CAT>10 and able to use DPI. Efficacy outcomes in this post-hoc analysis were change from baseline till 24-weeks in CAT, trough-FEV1, SGRQ and mMRC in high(≥ 300), intermediate (100-299) & low(<100) BEC.

Results: Of 179-analyzed per-protocol-population, 35.75%, 51.4% and 12.8% had BEC ≥ 300 , 100-299 and <100 respectively. Improvement($p<0.001$) of 7.14 ± 4.14 , 6.52 ± 4.13 and 7.23 ± 5.35 units was observed in CAT in high, low and intermediate BEC groups respectively. Improvement in trough-FEV1 at 24-weeks from baseline was 0.082 ± 0.25 L($p=0.005$), 0.029 ± 0.147 ($p=0.372$) and 0.069 ± 0.240 L($p=0.002$) in high, low and intermediate BEC groups, respectively. SGRQ improved($p<0.001$) for all groups(19.43, 22.35 & 18.03 in high, low & intermediate, respectively). mMRC improved($p<0.001$) by 0.313 ± 0.61 and 0.272 ± 0.631 in high and intermediate BEC groups, respectively and 0.217 ± 0.518 ($p=0.059$) in low BEC group.

Conclusion: The findings of this post-hoc analysis indicate that the benefits of BGF FDC in moderate-severe Indian COPD patients are not restricted to high eosinophil counts.