

Efficacy and Safety of a Novel, Nebulized Glycopyrrolate for the Treatment of COPD: Effect of Baseline Disease Severity and Age; Pooled Analysis of GOLDEN 3 and GOLDEN 4

Ohar J, et al. *Int J Chron Obstruct Pulmon Dis.* 2019;14:27–37



KEY FINDINGS

GLY produced statistically significant and clinically important improvements in change from baseline in trough FEV₁ and total SGRQ score vs. placebo in all baseline severity and age subgroups studied. GLY was generally well tolerated across all patient subgroups.



OBJECTIVE

To assess the effect of age and disease severity at baseline on lung function, impact on health and well being, and safety parameters following treatment with nebulized GLY 25 µg BID (FDA-approved dose)



STUDY DESIGN

Pooled data from GOLDEN-3 and -4 Phase III clinical trials

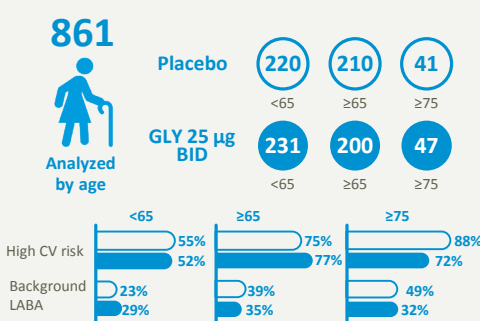
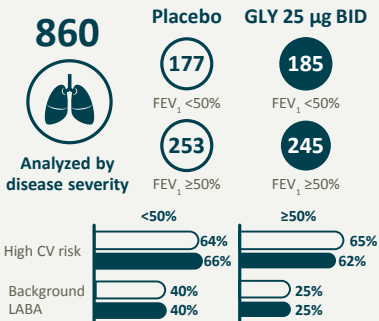


Patients aged ≥40 years with moderate-to-very-severe COPD, grouped by age and baseline post-bronchodilator FEV₁ % predicted

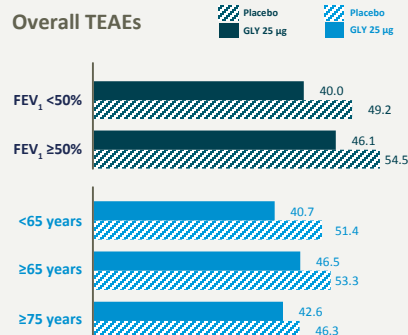


RESULTS

BASELINE DEMOGRAPHICS

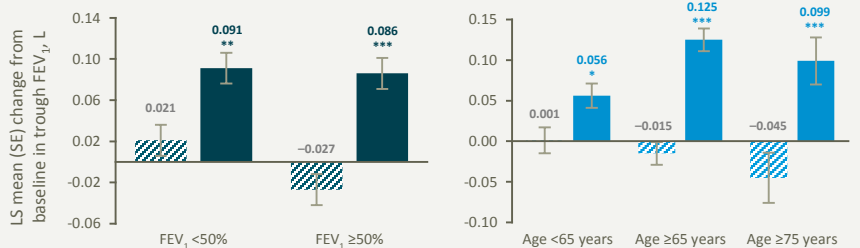


SAFETY



LUNG FUNCTION

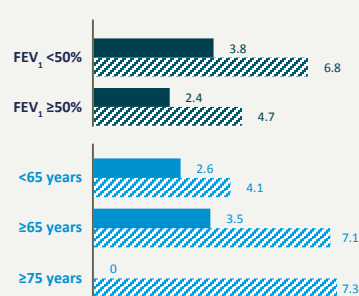
Trough FEV₁ improved with GLY 25 µg vs. placebo regardless of disease severity or age



↑ **≥50%** Placebo-adjusted change from baseline in trough FEV₁ was numerically, but not significantly, higher in the FEV₁ ≥50% subgroup

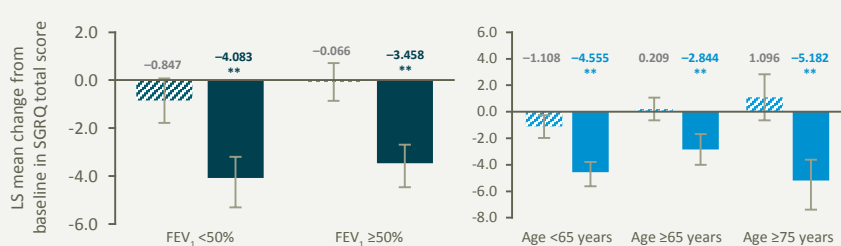
↑ **≥65** Placebo-adjusted change from baseline in trough FEV₁ was numerically, but not significantly, higher in the ≥65 years subgroup

Overall serious TEAEs



PATIENT-REPORTED OUTCOMES

SGRQ total score improved with GLY vs. placebo regardless of disease severity or age



↑ **<50%** GLY produced a significant improvement in SGRQ vs. placebo in both the FEV₁ <50% and FEV₁ ≥50% subgroups

↑ **<65** GLY produced a significant improvement in SGRQ vs. placebo in the <65 and ≥65 years subgroups

TEAEs leading to discontinuation



Efficacy and safety data are shown only for the FDA-approved dose of GLY (25 µg BID) and placebo. The ≥75 year age group is a subgroup of the ≥65 years age group; *p<0.05, **p<0.01, ***p<0.001. Abbrevia ions: BID, twice daily; CV, cardiovascular; FEV₁, forced expiratory volume in one second; GLY, nebulized glycopyrrolate; ICS, inhaled corticosteroid; LABA, long-acting β₂-agonist; LS, least squares; SE, standard error; SGRQ, St George's Respiratory Questionnaire; TEAE, treatment-emergent adverse event.