

Improvement in Lung Function and Patient-Reported Outcomes in Patients with COPD with Comorbid Anxiety and Depression Receiving Nebulized Glycopyrrolate in the GOLDEN 3 and 4 Studies

Hanania NA, et al. *Int J Chron Obstruct Pulmon Dis* 2021;16:865–875



KEY FINDINGS

Treatment with GLY resulted in improvements in FEV₁ and SGRQ total score vs. placebo at 12 weeks regardless of A/D status, although significant improvements were observed only in the A/D (-) group. GLY was generally well tolerated, independent of A/D status. This emphasizes the importance of considering comorbidities when evaluating COPD treatments.

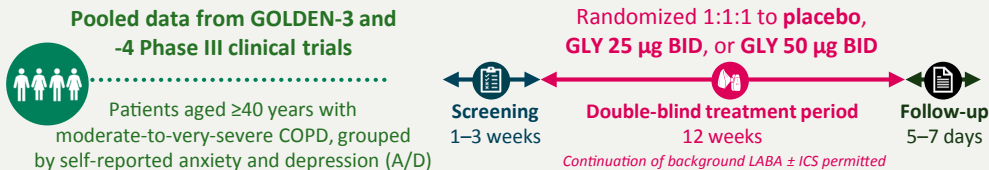


OBJECTIVE

To investigate the efficacy and safety of nebulized GLY 25 µg BID (FDA-approved dose) in patients with anxiety and depression in the GOLDEN-3 and -4 studies



STUDY DESIGN



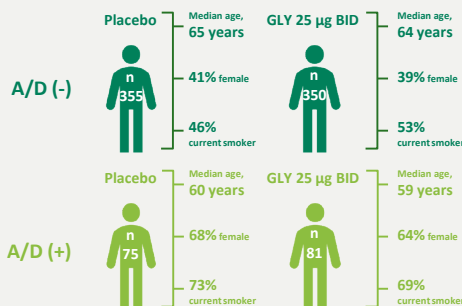
RESULTS

PATIENT DISTRIBUTION & BASELINE DEMOGRAPHICS

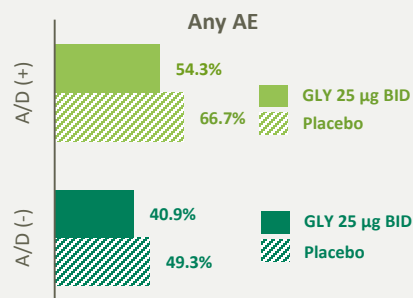
A/D (+) patients had a self-report history of A/D ≥6 months prior to and ongoing at the first study treatment.

A/D (-) patients had no history of either A/D, or anxiety alone, or depression alone but did not have both disorders concurrently.

In the pooled population, 18.1% (n=156) of patients were A/D (+)

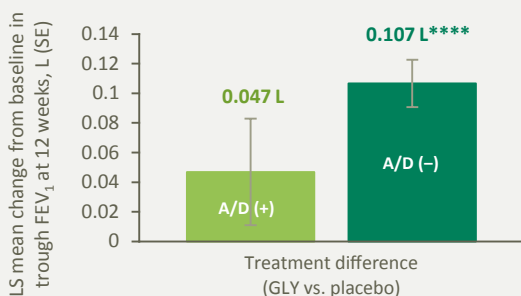


SAFETY



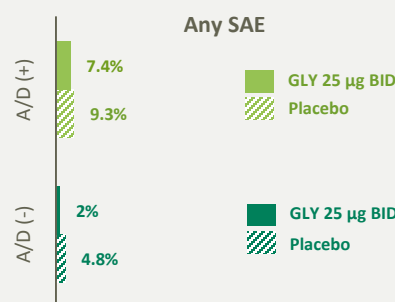
LUNG FUNCTION

Trough FEV₁ improved with GLY 25 µg BID vs. placebo regardless of A/D status



Treatment with GLY 25 µg BID resulted in numerical improvements in change from baseline in trough FEV₁ vs. placebo regardless of A/D status at baseline

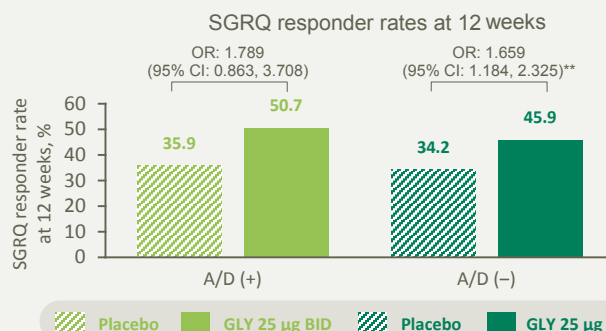
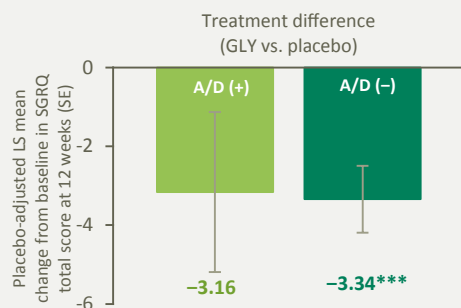
Significant improvements were noted only in the A/D (-) group (p < 0.0001)



GLY 25 µg BID was generally well tolerated, regardless of A/D status. Incidences of AEs and SAEs were lower in GLY 25 µg BID vs. placebo treatment groups

PATIENT-REPORTED OUTCOMES

SGRQ total score improved with GLY 25 µg BID vs. placebo regardless of A/D status



p<0.01 vs. placebo; *p<0.001 vs. placebo; *****p<0.0001 vs. placebo.

Abbreviations: A/D, anxiety and depression; AE, adverse event; BID, twice daily; COPD, chronic obstructive pulmonary disease; FEV₁, forced expiratory volume in one second; GLY, nebulized glycopyrrolate; ICS, inhaled corticosteroid; LABA, long-acting β₂-agonist; LS, least squares; SAE, serious adverse event; SE, standard error; SGRQ, St George's Respiratory Questionnaire.