

# Effect of Gender on Lung Function and Patient-Reported Outcomes in Patients with COPD Receiving Nebulized Glycopyrrolate

Ohar JA, et al. *Int J Chron Obstruct Pulmon Dis.* 2020;15:995–1004



## KEY FINDINGS

Treatment with GLY 25 µg BID resulted in improvements in FEV<sub>1</sub>, SGRQ total score and EXACT-RS total score vs. placebo at 12 weeks in both male and female patients. However, changes in EXACT-RS total score at 12 weeks were significantly greater in female patients compared with male patients. The safety profile of GLY was similar between genders.



## OBJECTIVE

To investigate the impact of gender on response to nebulized GLY 25 µg BID (FDA-approved dose) using the pooled GOLDEN-3 and -4 study data



## 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 gender

Screening  
1–3 weeks

### Randomized 1:1:1 to placebo, GLY 25 µg BID, or GLY 50 µg BID

Double-blind treatment period  
12 weeks

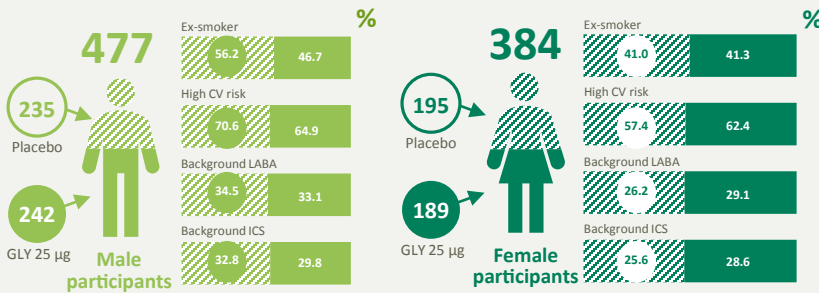
Follow-up  
5–7 days

Continuation of background LABA ± ICS permitted

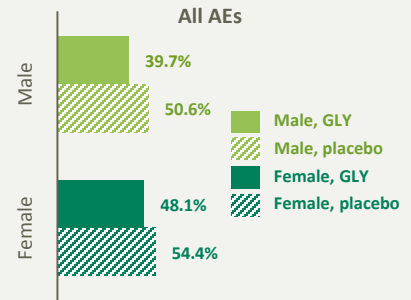


## RESULTS

### BASELINE DEMOGRAPHICS

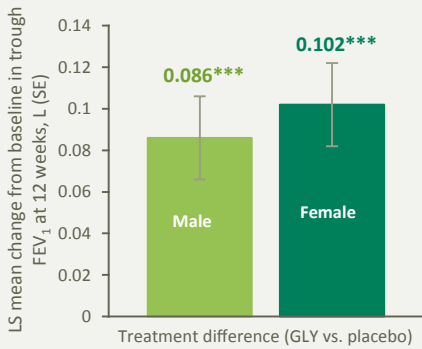


### SAFETY



### LUNG FUNCTION

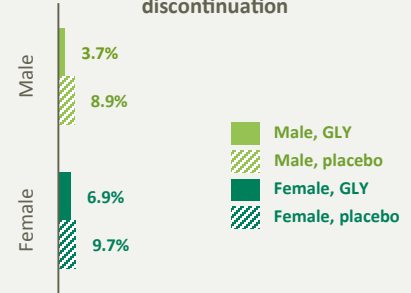
#### Trough FEV<sub>1</sub> improved with GLY 25 µg vs. placebo regardless of gender



GLY 25 µg produced significant and clinically important improvements in change from baseline in trough FEV<sub>1</sub> vs. placebo in both male and female patients

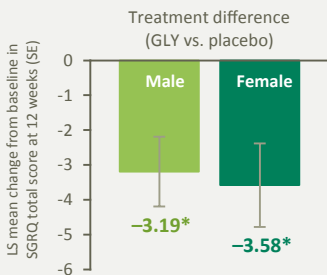
The difference in improvement in FEV<sub>1</sub> was numerically but not significantly greater in women (p=0.221)

#### AEs leading to study discontinuation

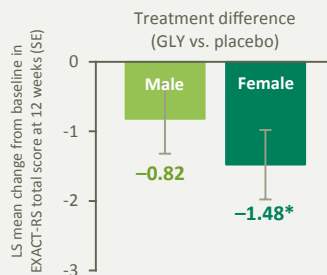


### PATIENT-REPORTED OUTCOMES

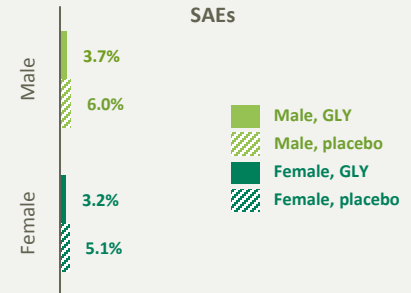
#### SGRQ total score improved with GLY 25 µg vs. placebo regardless of gender



#### Improvements in EXACT-RS with GLY 25 µg vs. placebo was greater in female patients



#### SAEs



The safety profile of GLY 25 µg was similar between genders. Incidences of AEs and SAEs were lower in GLY 25 µg vs. placebo treatment groups in both genders.