European Respiratory Society
Annual Congress 2012

Abstract Number: 2278

Publication Number: P2103

Abstract Group: 5.1. Airway Pharmacology and Treatment

Keyword 1: COPD - management **Keyword 2:** COPD - exacerbations **Keyword 3:** Bronchodilators

Title: Safety and efficacy of NVA237 once daily in Japanese patients: The GLOW4 trial

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Body: Introduction: NVA237 (glycopyrronium bromide) is a once-daily (QD) inhaled long-acting muscarinic antagonist for the maintenance treatment of COPD. Methods: The primary objective of the 52-week, multi-center, randomized, open label, parallel group GLycopyrronium bromide in COPD airWays clinical study 4 (GLOW4) was to assess the safety and tolerability of NVA237 50µg QD for 52 wks in Japanese patients with moderate-to-severe COPD. A secondary objective was to compare the safety and efficacy of NVA237 to open-label tiotropium 18 µg QD (TIO). Results: 163 patients were randomized (NVA237=123, TIO=40); 84% completed. Mean age was 68.7 yrs, 97.5% male. Overall adverse events (AE) incidence was similar between NVA237 and TIO. The only AEs with >10% incidence in any group were COPD worsening (24.4 and 32.5%) and nasopharyngitis (30.9 and 32.5%) for NVA237 and TIO, respectively. Serious AEs occurred in 13 and 15% patients for NVA237 and TIO, respectively, with no deaths. There were no reports of notable pulse rate (>130 bpm, or ≥120 and +15 bpm from baseline) and QTc interval (Fridericia) >500ms over 52 wks. Dry mouth incidence was less frequent with NVA237 (1.6%) vs TIO (5%). A clinically significant increase from baseline in pre-dose FEV_1 was observed for NVA (101 mL) and TIO (173 mL) at Wk 12. The event-free rate for moderate or severe COPD exacerbation was 78.9% for NVA237 and 76.6% for TIO at Wk 52. Conclusion: NVA237 once daily had a safety and tolerability and efficacy profile similar to tiotropium in Japanese patients with moderate-to-severe COPD over 52 weeks.