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Title: Effects of roflumilast in highly symptomatic COPD patients

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Body: Background: GOLD currently recommends making treatment decisions based on a combined assessment of current symptoms and future risk. The modified MRC (mMRC) dyspnoea scale (grade 0–4) is recommended to assess the level of current symptoms, but data on the efficacy of different treatments in subgroups based on symptom-grading are lacking. Roflumilast (ROF) is a PDE4 inhibitor approved for maintenance treatment of severe COPD associated with chronic bronchitis, in adult patients with a history of frequent exacerbations. GOLD recommends ROF as an option for patients with mMRC grade ≥2, severe lung function impairment and/or frequent exacerbations (Group D). Aims: To determine the effects of ROF on exacerbations and lung function when added to tiotropium (TIO) in patients with baseline mMRC grade ≥2. Methods: Study M2-128 included symptomatic patients with moderate-to-severe lung function impairment. ROF 500µg or placebo (PBO) was added to TIO for 24 weeks. A post-hoc subgroup analysis of patients with mMRC grade ≥2 at baseline was performed. Results: This subgroup included 395 patients (ROF n=208, PBO n=187). ROF reduced the mean rate of moderate/severe exacerbations/patient/year by 45.5% (annualized exacerbation rate ROF 0.22, PBO 0.40; rate ratio 0.55, [95% CI 0.31, 0.96], p=0.034) vs PBO. The mean between-treatment difference in pre-bronchodilator FEV_1 was 79mL ([95% CI 38, 119], p=0.0002), and in post-bronchodilator FEV_1 78mL ([95% CI 38, 118], p=0.0002). Conclusions: ROF reduces moderate/severe exacerbations when added to TIO in COPD patients with moderate-to-severe lung function impairment and mMRC grade ≥2. These results support the GOLD recommendation for combined assessment of current symptoms and future risk.