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Title: Effect of roflumilast on hospitalizations in COPD patients

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Body: Background: Severe exacerbations of COPD require hospitalization and have serious long-term consequences for patients. Roflumilast (ROF) is a PDE4 inhibitor that significantly reduced moderate-to-severe exacerbations in clinical studies. Its effects on severe exacerbations and any adverse events leading to hospitalization have not been described previously. Aim: To investigate the effects of ROF on the rate of hospitalizations resulting from severe exacerbations or any other adverse events in two 1-year studies (M2-124 and M2 125). Methods: In a post-hoc pooled analysis of the pivotal studies of ROF 500µg (n=1537) vs placebo (n=1554), statistical analyses were performed on the overall population and in patient subgroups with: A) severe/very severe COPD; B) frequent COPD exacerbations; and C) severe/very severe COPD and frequent COPD exacerbations. Negative binomial regression analyses were used to investigate the rate reduction for hospitalizations. Results: In the overall population, ROF decreased the rate of hospitalizations resulting from severe exacerbations vs placebo by 21.6% (rate ratio 0.784, [95% CI 0.619, 0.993, p=0.0439), and overall there were trends towards extended times-to-onset of severe exacerbations leading to hospitalization. Although not statistically significant, ROF reduced hospitalizations resulting from any adverse event compared with placebo. In all subgroups analyzed, ROF had a positive numerical but not statistically significant effect on rate reduction of all-cause hospitalizations, time to hospitalization and risk of hospitalizations. Conclusions: Roflumilast significantly reduces the rate of severe exacerbations leading to hospitalization vs placebo.