Abstract Group: 5.1. Airway Pharmacology and Treatment  
Keyword 1: COPD - exacerbations  Keyword 2: COPD - management  Keyword 3: Comorbidities

Title: Efficacy of roflumilast with concomitant cardiovascular medication in patients with COPD

Prof. Peter 29651 Calverley pmacal@liverpool.ac.uk MD 1, Prof. Leonardo 29652 Fabbri leonardo.fabbri@unimore.it MD 2, Prof. Fernando 29653 Martinez fmartine@med.umich.edu MD 3, Dr. Udo-Michael 29700 Goehring Udo-Michael.Goehring@takeda.com 4, Dr. Manja 29701 Brose Manja.Brose@takeda.com 5 and Prof. Klaus 29730 Rabe k.f.rabe@lungenclinic.de MD 6. 1 Clinical Science Centre, University Hospital Aintree, Liverpool, United Kingdom; 2 Respiratory Medicine, University of Modena and Reggio Emilia, Modena, Italy; 3 Department of Internal Medicine, University of Michigan, Ann Arbor, MI, United States; 4 Clinical Science, Takeda Pharmaceuticals International GmbH, Zurich, Switzerland; 5 Analytical Science, Takeda Pharmaceuticals International GmbH, Zurich, Switzerland and 6 Department of Internal Medicine, University of Kiel, Kiel, Germany.

Body: Background Cardiovascular disease is common in patients with COPD and systemic inflammation has been proposed as a link between the two. Roflumilast, a phosphodiesterase 4 inhibitor, has shown efficacy in reducing exacerbation frequency in patients with severe COPD. Here we investigate whether the efficacy of roflumilast is influenced by concomitant treatment with cardiovascular medication. Methods Data were pooled from two identically designed randomized studies. Patients with severe COPD, chronic bronchitis and a history of exacerbations received either roflumilast 500µg o.d. (n=1537) or placebo (n=1554) for 52 weeks and were classified by concomitant treatment with statins or ACE inhibitors. Results In the roflumilast group, statins or ACE inhibitors were used by 225 (15%) and 301 (20%) patients, respectively; in the placebo group they were used by 241 (16%) and 323 (21%), respectively. In the overall population the exacerbation rate was significantly lower in the roflumilast group compared with placebo (–16.9% [95% CI –25, –8], p=0.0003). This difference remained significant independent of treatment with statins (–37.4% [95% CI –52, –18], p=0.0008) or not (–14.1% [95% CI –23, –4], p=0.0064) or treatment with ACE inhibitors (–23.0% [95% CI –39, –3], p=0.0278) or not (–16.8% [95% CI –26, –7], p=0.0013). There was a trend for greater reduction of exacerbations induced by roflumilast in subjects treated with statins. Roflumilast significantly improved FEV1 in the overall population and in each subgroup. Conclusions Roflumilast reduces the rate of moderate or severe exacerbations and improves lung function in patients with severe COPD, independent of concomitant treatment with statins or ACE inhibitors.