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Title: FORWARD: A study of extrafine beclomethasone/formoterol compared with formoterol alone in patients with severe COPD and a history of exacerbations

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Body: FORWARD, a phase III, randomised, double-blind trial, compared the efficacy and safety of 48 weeks treatment with Foster® pMDI (extrafine beclomethasone dipropionate/formoterol fumarate, BDP/FF 100/6µg), 2 puffs bid versus Atimos® pMDI (extrafine FF 12µg), 1 puff bid, in patients with severe COPD. Co-primary endpoints were pre-dose morning FEV_1 after 12 weeks of treatment and health care resource use defined exacerbation rate over 48 weeks (detection enhanced with EXACT electronic diary cards). The ITT population included 1186 severe COPD patients (69% males, mean age 64 years, post-bronchodilator FEV_1 42% of predicted) with a smoking exposure of ≥10 pack-year and at least 1 exacerbation in the previous year. Salbutamol on an as-needed basis, theophylline and tiotropium (if stable regimen prior to screening) were allowed. Results showed that, compared to FF, BDP/FF: (1) reduced exacerbation rate by 28% (rate ratio 0.72 [95% CI: 0.62, 0.84], p<0.001); (2) improved mean change in morning trough FEV_1 from baseline to Week 12 (0.069 L [95% CI: 0.043, 0.095] p<0.001) and FEV_1 or FVC 2hr post dose; and, (3) reduced EXACT-reported symptoms scores over 48 weeks and SGRQ score at the end of treatment. The number of adverse effects was relatively small and similar in both groups. Most patients did not show changes of clinical concern in laboratory parameters, ECG or vital signs. Extrafine BDP/FF pMDI significantly reduced the annual exacerbation rate and improved lung function of severe COPD patients as compared to FF alone, thus supporting the positioning of this pMDI combination among the appropriate

therapeutic options for these patients.