THE EFFICACY AND SAFETY OF BECLOMETHASONE DIPROPIONATE DELIVERED VIA A BREATH-ACTUATED INHALER IN ADULT AND ADOLESCENT PATIENTS WITH PERSISTENT ASTHMA

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Background: To evaluate the efficacy and safety of beclomethasone dipropionate (BDP) delivered via a breath-actuated inhaler (BAI) versus placebo in asthmatic patients. Methods: This phase 3, 6-week, double-blind study (NCT02513160) included patients with persistent asthma (aged ≥12 years). During a 14-to 30-day single-blind run-in, patients discontinued asthma medications and received albuterol metered-dose inhaler (MDI) for rescue and twice-daily placebo BAI or MDI for training. At randomization, BAI patients received BDP BAI 320 mcg/day, BDP BAI 640 mcg/day, or placebo BAI. MDI patients were randomized to receive BDP MDI 320 mcg/day or placebo MDI. Standardized baseline-adjusted trough morning forced expiratory volume in 1 second area under the effect curve from 0 to 6 weeks (FEV₁AUEC₀–₆wk; primary), morning peak expiratory flow (PEF), rescue medication use, asthma symptoms, withdrawals, and tolerability were assessed. Results: The modified intent-to-treat and safety populations each included 425 patients. BDP BAI 320 and 640 mcg/day significantly improved FEV₁AUEC₀–₆wk versus placebo (P<0.0001). Active BAI treatment groups exhibited significantly improved morning PEF, rescue medication use, and asthma symptoms versus placebo (P≤0.0003). Similar treatment effects were demonstrated for BDP MDI (P≤0.0006). Fewer patients withdrew due to worsening asthma while taking BDP BAI 320 mcg/day (n=1), BDP BAI 640 mcg/day (n=0), and BDP MDI 320 mcg/day (n=1) versus placebo (n=10). BDP BAI was safe and well tolerated. Conclusions: BDP BAI demonstrated significant improvements in lung function and symptom control versus placebo with similar results for BDP MDI. BDP BAI’s safety profile was comparable to BDP MDI, with no new safety signals.

Funding: Teva Pharmaceuticals