EFFICACY AND SAFETY OF ALBUTEROL MULTIDOSE DRY POWDER INHALER (MDPI) VERSUS PLACEBO IN CHILDREN WITH ASTHMA

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Background: To evaluate the chronic-dose efficacy and safety of albuterol delivered via a novel, inhalation-driven, multidose dry powder inhaler (MDPI) that does not require patient coordination of device actuation with inhalation relative to placebo in pediatric patients with asthma. **Methods:** This phase 3, double-blind, parallel-group, multicenter, 3-week study (ABS-AS-303; NCT02126839) included children (aged 4–11 years) with asthma and prestudy FEV_1 of 50%–95% of predicted. After a 14-day run-in period during which patients continued their current asthma therapy and received single-blind placebo MDPI, patients were randomized to albuterol MDPI 90 mcg/inhalation, 2 inhalations 4 times daily (total daily dose, 720 mcg), or placebo for 3 weeks. Serial FEV_1 measurements were obtained at designated time points over 6 hours after baseline FEV_1 assessment and completion of study drug administration on treatment day 1 (TD1) and 22 (TD22). Safety was evaluated by adverse events. **Results:** The full analysis set included 184 patients. Albuterol MDPI–treated patients experienced significantly (P<0.0001) greater improvements in area under the baseline-adjusted percent-predicted FEV_1-time curve over 6 hours postdose ($PPFEV_1$ AUC_{0-6}) over the 3-week study versus placebo patients (least squares mean difference of 25%•h in favor of albuterol). On TD1 and TD22, baseline-adjusted $PPFEV_1$ AUC_{0-6} for albuterol MDPI–treated patients was similar and greater than patients receiving placebo MDPI (P<0.0001). The benefit of albuterol (mean change in $PPFEV_1$) was evident 5 minutes after dosing and lasted several hours; maximal effect was noted 1–2 hours postdose. Albuterol MDPI was well tolerated. **Conclusions:** Albuterol MDPI, administered chronically for 3 weeks, improved pulmonary function in pediatric patients significantly better than placebo with similar improvements noted on TD1 and TD22. Clinical effects were evident within 5 minutes and maintained for >2 hours. Four-times-daily administration was generally well tolerated in pediatric patients.

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