Objectives: In the model-building, the data from three randomized, multi-center, placebo- and active-controlled, double-blind, parallel-design Phase 3 clinical trials in adult and pediatric asthma patients were pooled. Data were pooled from 81 pediatric and 551 adult subjects (aged 4-81 years) enrolled in three Phase 3 clinical trials. Plasma drug concentrations were analyzed following the first dose and after 8 weeks of oral dosing (90 μg LEV or 180 μg RA via HFA MDI) were modeled using NONMEM®. The current analysis focuses on creating a PPK model for (R)-albuterol following administration via a hydrofluoroalkane (HFA) MDI formulation of LEV or via the pre-existing LEV MDI formulation of RA.

Methods: Data from three randomized, multi-center, placebo- and active-controlled, double-blind, parallel-design Phase 3 clinical trials in adult and pediatric asthma patients were pooled. Data were pooled from 81 pediatric and 551 adult subjects (aged 4-81 years) enrolled in three Phase 3 clinical trials. Plasma drug concentrations were analyzed following the first dose and after 8 weeks of oral dosing (90 μg LEV or 180 μg RA via HFA MDI) were modeled using NONMEM®. The current analysis focuses on creating a PPK model for (R)-albuterol following administration via a hydrofluoroalkane (HFA) MDI formulation of LEV or via the pre-existing LEV MDI formulation of RA.

RESULTS: The pharmacokinetics of (R)-albuterol were lower in patients receiving levalbuterol HFA MDI as compared to racemic albuterol HFA MDI.

Figure 1: Scatterplots of (R)-Albuterol Concentration-Time Data for 50 μg Levalbuterol HFA MDI and 180 μg Racemic Albuterol HFA MDI.