Pharmacokinetics of Beclomethasone Dipropionate in an Hydrofluoroalkane-134a Propellant System in Japanese Children with Bronchial Asthma

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Background: Hydrofluoroalkane-134a (HFA) has been shown to be a safe replacement for chlorofluorocarbons (CFCs) as a pharmaceutical propellant, with the advantage that it has no ozone-depleting potential. This is the first report of the pharmacokinetics of beclomethasone dipropionate (BDP) delivered from a pressurized solution formulation using an HFA propellant system (HFA-BDP) in Japanese children with bronchial asthma.

Methods: Plasma concentrations of beclomethasone 17-monopropionate (17-BMP),a major metabolite of BDP, following an inhaled dose of HFA-BDP (200µg as four inhalations from 50µg/actuation) in five Japanese children with bronchial asthma were quantified and analyzed by a non-compartmental analysis to obtain pharmacokinetic parameters.

Results: The area under the concentration-time curve from time zero to the last quantifiable time (AUC0-t) was 1659 ± 850pg·h/mL (arithmetic mean ± standard deviation (SD)), the maximum concentration observed (Cmax) was 825 ± 453pg/mL and the apparent elimination half-life (t1/2) was 2.1 ± 0.7 hours. The time to reach Cmax (Tmax) was 0.5 hours in all patients. No special relationship was observed between these parameters and age or body weight. These parameters were compared with the previously reported parameters of American children with bronchial asthma. The Japanese/American ratio of the geometric means of each parameter was 1.36 for AUC0-t, 1.04 for Cmax and 1.4 for t1/2. The median of Tmax was 0.5 hours in American patients as well as Japanese patients.

Conclusions: The pharmacokinetics of HFA-BDP in Japanese children with bronchial asthma are reported for the first time and a similarity to those in American children is suggested.

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