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Title: Lung bioavailability of beclometasone dipropionate and formoterol fumarate fixed dose combination administered using a pMDI or a novel DPI: NEXThaler®

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Body: INTRODUCTION: NEXThaler® is a novel, easy to use, dry powder inhaler (DPI) containing the fixed combination of beclometasone dipropionate (BDP) 100 µg and formoterol fumarate (FF) 6 µg, formulated for extrafine delivery. This will provide physicians and patients with an alternative inhaler device for treatment of asthma able to ensure delivery of the drugs to the lungs especially in patients with poor hand-breath coordination. OBJECTIVE: To compare the lung bioavailability of beclometasone monopropionate B17MP (active metabolite of BDP) and FF after administration of the fixed combinations using NEXThaler® or the pMDI Foster®. METHODS: An open-label, two-way crossover, single-dose design was used. Activated charcoal was administered to block gastrointestinal absorption and pMDI use was optimized via spacer device. Adult asthmatic patients (n=24) were randomized to undergo two single dose treatment clinic visits, separated by a 7-day wash-out period. At each treatment visit, blood samples were collected over 24h for pharmacokinetic evaluation. RESULTS: The ratios (and 90% CI) for AUC_{0-t} of B17MP and FF when comparing NEXThaler® to pMDI fell entirely within the bioequivalence region of 80-125 %, showing that the lung bioavailability of both components was equivalent. No clinically significant trend to change in blood pressure or heart rate after dosing with either NEXThaler® or pMDI was observed. CONCLUSIONS: BDP and FF lung bioavailability using the fixed dose combination NEXThaler® and pMDI was equivalent in the target population. Furthermore, treatment with NEXThaler® was well tolerated with no safety concerns.