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Title: Beclometasone/formoterol administered via extrafine dry powder inhaler in controlled asthmatic patients: Comparison with pMDI and beclometasone monotherapy

Francesco 2241 Sergio F.Sergio@chiesi.com MD , Catherine 2242 Francisco c.francisco@chiesifrance.com , Annamaria 2243 Muraro am.muraro@chiesi.com and Frank 16239 Kanniess f.kanniess@gpr-reinfeld.de MD . [1] Corporate Clinical Development, Chiesi Farmaceutici S.p.A., Parma, Italy ; [2] Corporate Clinical Development, Chiesi Farmaceutici S.p.A., Parma, Italy ; [3] Corporate Clinical Development, Chiesi Farmaceutici S.p.A., Parma, Italy and [4] Gemeinschaftspraxis Reinfeld, Gemeinschaftspraxis Reinfeld, Germany .

Body: Background: The fixed combination of beclometasone dipropionate and formoterol fumarate (BDP/FF) 100/6 µg pMDI (Foster®) is approved for treatment of adult asthmatic patients. In order to provide physicians and patients with an alternative drug delivery system for BDP/FF, a new dry powder inhaler the NEXThaler® has been developed, able to ensure consistent dosing in patients who prefer the use of dry powder inhalers. Aim: To compare efficacy and safety profile of BDP/FF NEXThaler® with BDP/FF pMDI or BDP DPI alone in adult patients with controlled asthma. Methods: 8-week randomised,double-blind, triple-dummy, 3-arm parallel-group clinical study. After 4-week run-in with BDP/FF pMDI 100/6 bid, 755 patients were randomised to receive bid BDP/FF NEXThaler® 100/6, BDP/FF 100/6 pMDI or BDP DPI 100. The primary end-point was change from baseline to the entire treatment period in average pre-dose morning PEF (mPEF). Results: Non-inferiority of NEXThaler® vs pMDI was shown for mPEF (LSmeans difference:-1.84L/min; 95%CI[-6.73;3.05]) and lower limit of the 95%CI was above the pre-defined non-inferiority margin of -15L/min. Superiority of both combinations over BDP DPI was shown ($p<0.001$) providing evidence of assay sensitivity of the study. Both BDP/FF formulations were statistically superior to BDP alone in terms of ACQ score ($p=0.009$ and 0.008) and % of rescue use-free days ($p=0.033$ and 0.006) as well as pulmonary function tests over the entire treatment period. No relevant drug related AEs were observed. Conclusion: NEXThaler® is an effective and well-tolerated alternative delivery device for treatment of asthmatic patients with BDP/FF.