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Title: Safety of once-daily QMF149 in patients with persistent asthma

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Body: QMF is an investigational once-daily (QD), fixed-dose combination of indacaterol (IND) and mometasone furoate (MF). This study assessed the long-term safety of QMF in patients (pts) with persistent asthma. In this randomized, double-blind, multi-centre, Phase II study, pts (12–70 y) received QMF (IND maleate 500µg/MF 400µg) or MF (400µg), both administered QD via the Twisthaler®* for 6–21 months. Systemic exposure data show that this QMF dose is comparable to 150µg IND/160µg MF in the Concept1 (Breezhaler®) inhalation device, the delivery device that will be used in future studies. The primary endpoint was time to first serious exacerbation (resulting in hospitalisation, intubation or death). A key secondary endpoint was the cumulative incidence of serious exacerbations. AEs and SAEs were recorded. 8 of 1519 randomised pts (QMF, 756; MF, 763) were hospitalised for a serious exacerbation (QMF, 2; MF, 6); none required intubation or resulted in death. QMF reduced the risk of a serious exacerbation vs MF by 69% (hazard ratio=0.31; 90% CI 0.08, 1.19; p=0.076). The difference in cumulative incidence was -0.52 percentage points (90% CI -1.14, 0.09) in favor of QMF, meeting the pre-specified, non-inferiority margin of 1 percentage point. Similar proportions of pts experienced AEs and SAEs in both groups (QMF, 74.0% and 4.0%; MF, 73.4% and 5.8%). Most frequent AEs with QMF and MF were cough and asthma, respectively. There was one death (MF group), which was not treatment or asthma related. Mean plasma MF concentrations were similar in both groups. QMF QD was not associated with additional safety concerns vs MF monotherapy in pts with persistent asthma. * Twisthaler® is a registered trademark of Schering-Plough LTD.