



MEETING ABSTRACT

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Mometasone furoate/formoterol combination therapy increases frequency of days/nights free of short-acting β_2 -agonist use

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Objective

An important asthma therapy goal is to limit short-acting β_2 -agonist (SABA) rescue medication use. We evaluated the effect of mometasone furoate/formoterol (MF/F) combination therapy on SABA use with data from 3 phase III studies.

Methods

All studies enrolled subjects (≥ 12 y) with persistent asthma not well controlled on inhaled corticosteroids (ICS): study 1 (n=746 subjects with moderate persistent asthma randomized to 26wk MF/F-100/10 μ g, MF-100 μ g, F-10 μ g, or placebo twice daily [BID]); study 2 (n=781 subjects with moderate persistent asthma randomized to 26wk MF/F-200/10 μ g, MF-200 μ g, F-10 μ g, or placebo BID); study 3 (n=728 subjects with severe persistent asthma randomized to 12wk MF/F-400/10 μ g, MF/F-200/10 μ g, or MF-400 μ g BID). All studies included a 2-3wk MF BID run-in: P04073 (100 μ g), P04334(200 μ g), P04431 (400 μ g). Percentage of SABA-free days/nights was a pre-defined secondary endpoint in all studies.

Results

In study 1, mean change in the percentage of SABA-free days/ nights from baseline period (day -7 to 1) to overall treatment period was significantly increased for MF/F-100/10 μ g (18%) vs F-10 μ g (10%) and placebo (0% $P \leq .003$), and numerically increased for MF/F-100/10 μ g vs MF-100 μ g (14%). In study 2, change in SABA-free days/nights was significantly increased for MF/F-200/10 μ g (21%) vs MF-200 μ g (15%), F-10 μ g (11%), and placebo (5%; $P \leq .033$). In study 3, change in SABA-free days/nights was

significantly increased for MF/F-400/10 μ g and MF/F-200/10 μ g groups (25% increase for each) vs the MF-400 μ g group (13%; $P < .001$).

Conclusion

MF/F treatment resulted in significant improvement in the frequency of SABA-free days/nights vs individual MF and/or F monotherapies in subjects with persistent asthma not well controlled on ICS therapy.

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