SAFETY AND EFFECTIVENESS OF FLUTICASONE FUROATE/VILANTEROL DPI IN ASTHMA: RESULTS OF A 12-WEEK POST MARKETING SURVEILANCE (PMS) IN INDIA.

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Introduction: The FDC of Fluticasone Furoate and Vilanterol trifenatate (FF/VI) is an ultra-long-acting ICS/LABA indicated for asthma. This PMS evaluated the safety and effectiveness of FF/VI 100/25 or 200/25 via DPI in asthma.

Methods & Materials: We conducted a 12-week open label, multicentre, surveillance of 200 participants, (≥12 years), prescribed FF/VI. Primary endpoint was incidence of adverse events (AEs). Secondary endpoints were change in ACQ-5 score and PEFR recorded at sites from baseline to week 4, 8 and 12.

Results: Of the 200 enrolled participants, 195 completed the surveillance (51% women; mean age 37 years, duration of asthma 2 years). Five AEs were reported in five participants: cough and nasopharyngitis in FF/VI 100/25, and pruritus (related and led to discontinuation), headache, and myocardial infarction (MI) in FF/VI 200/25, of which MI was a serious event reported as unassessable by the Investigator. No clinically significant changes were observed in vitals, physical examination, or laboratory parameters. At week 12, ACQ-5 LS Mean (95%CI) decreased by -1.57(-1.79, -1.34) and -1.76(-2.01, -1.51) from baseline ($p<0.0001$), exceeding MCID (0.5) and PEFR increased from baseline by 144.58(122.66, 166.49) L/min and 141.27(120.53, 162.01) L/min for FF/VI 100/25 and FF/VI 200/25, respectively ($p<0.0001$). Significant improvements in ACQ-5 and PEFR were observed as early as 4 weeks.

Discussion and Conclusion: The FF/VI FDC demonstrated a favourable safety profile and was effective in significantly improving PEFR and asthma control over 12 weeks in Indian asthmatics.

Keywords: Asthma, ACQ-5, PEFR.