## Dulera® (mometasone furoate/formoterol fumarate dihydrate) – Expanded indication, new strength

- On August 12, 2019, the FDA approved Merck's Dulera (mometasone furoate/ formoterol fumarate dihydrate) inhalation aerosol, for the twice-daily treatment of asthma in patients 5 years of age and older.
    - Dulera was previously approved for this indication in patients 12 years of age and older.
    - Dulera should be used for patients not adequately controlled on a long-term asthma-control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta$_2$-adrenergic agonist.
    - Dulera is not indicated for the relief of acute bronchospasm.
- The FDA also approved a Dulera 50 mcg/5 mcg strength (per actuation) for use in pediatric patients aged 5 to less than 12 years. Dulera was previously available in a 100 mcg/5 mcg or 200 mcg/5 mcg strength.
- The approval of Dulera for the expanded indication was based on an active-controlled study in 181 asthma patients aged 5 to less than 12 years. Patients received Dulera or mometasone furoate metered dose inhaler 50 mcg (MDI).
    - Primary endpoint results showed that patients receiving Dulera had a statistically significant change from baseline to week 12 in 60-min AM post-dose % predicted FEV$_1$ compared to mometasone furoate MDI 50 mcg (5.21, 95% CI: 3.22, 7.20).
- The recommended dose of Dulera for the treatment of asthma in pediatric patients aged 5 to less than 12 years is two inhalations of Dulera 50 mcg/5 mcg twice daily. The maximum daily dosage is 200 mcg/20 mcg.
    - Refer to the Dulera drug label for dosing for patients 12 years and older.
- Merck's launch plans for the 50 mcg/5 mcg strength of Dulera are pending.