Asmanex HFA® (mometasone furoate) – Expanded indication, new strength

- On August 12, 2019, the FDA approved Merck's Asmanex HFA (mometasone furoate) inhalation solution, for the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older.
    - Asmanex HFA was previously approved for this indication in patients 12 years and older.
    - Asmanex HFA is NOT indicated for the relief of acute bronchospasm
- The FDA also approved an Asmanex HFA 50 mcg strength (per actuation) for use in pediatric patients aged 5 to less than 12 years. Asmanex HFA was previously available in a 100 mcg and 200 mcg strength.
- The approval of Asmanex HFA's expanded indication was based on a 12-week, double-blind study in 583 patients aged 5 to less than 12 years with persistent asthma. Patients were randomized to Asmanex HFA 50 mcg dose, two other doses of Asmanex HFA, Asmanex dry-powder inhaler or placebo.
    - Primary endpoint results show that after 12 weeks of treatment, Asmanex HFA 50 mcg was statistically superior to placebo with respect to the improvement from baseline in AM pre-dose percent predicted FEV_1 at the end of the dosing interval (6.29%, 95% CI: 3.05, 9.53).
- The recommended dose of Asmanex HFA for the maintenance treatment of asthma in patients aged 5 to less than 12 years is two inhalations of Asmanex HFA 50 mcg twice daily. The maximum daily dosage is 200 mcg.
    - Refer to the Asmanex HFA drug label for dosing for patients 12 years and older.
- Merck's launch plans for the 50 mcg strength of Asmanex HFA are pending.