Airsupra™ (albuterol/budesonide) – New drug approval

- On January 11, 2023, the FDA announced the approval of AstraZeneca's Airsupra (albuterol/budesonide), for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older.

- Airsupra is a combination of albuterol (a beta-2 adrenergic agonist) and budesonide (a corticosteroid). It is the first approved combination of an inhaled corticosteroid (ICS) and a short-acting beta-agonist (SABA). Additionally, Airsupra is the first product containing an ICS to be approved as a reliever treatment (rather than as a controller) for asthma.

- The efficacy of Airsupra was established in two studies: MANDALA and DENALI. While patients 12 to 17 years were included in these trials, Airsupra is not approved in this age group; therefore, efficacy results are presented for adults only.

- MANDALA was a randomized, double-blind, event-driven study evaluating the efficacy of Airsupra compared to albuterol on the time to first severe asthma exacerbation in 2,940 adults with moderate to severe asthma taking ICS alone or in combination with a range of asthma maintenance therapies. Patients were randomized to one of the following three treatment groups: Airsupra 180 mcg/160 mcg, albuterol/budesonide 180 mcg/80 mcg or albuterol 180 mcg, taken as an as-needed rescue medicine. The primary endpoint was the time to first severe asthma exacerbation.

    — Compared with albuterol 180 mcg, adult patients receiving Airsupra experienced a statistically significant 28% reduction (hazard ratio 0.72; 95% CI: 0.60, 0.86; $p < 0.001$) in the risk of a severe asthma exacerbation.

- DENALI was a randomized, double-blind, placebo-controlled study evaluating the efficacy of Airsupra compared to its components albuterol and budesonide on improvement in lung function in 964 adults with mild to moderate asthma previously treated either with SABA as-needed alone or in addition to regular low-dose ICS maintenance therapy. Patients were randomized to one of the following five treatment groups: Airsupra 180 mcg/160 mcg, albuterol/budesonide 180 mcg/80 mcg, albuterol 180 mcg, budesonide 160 mcg, or placebo, all administered four times daily.

    — In the adult population, the onset of bronchodilation was observed in 51% of patients treated with Airsupra 180 mcg/160 mcg and 43% of patients treated with albuterol 180 mcg.
    — Following a single dose on day 1, the median time to onset and mean duration of bronchodilation were 7.5 minutes and 186.9 minutes with Airsupra 180 mcg/160 mcg and 10.0 minutes and 167.9 minutes with albuterol 180 mcg, respectively.

- Warnings and precautions for Airsupra include deterioration of asthma; paradoxical bronchospasm; cardiovascular effects; do not exceed recommended dosage; hypersensitivity reactions, including anaphylaxis; risk of sympathomimetic amines with certain coexisting conditions; hypokalemia; immunosuppression and risk of infections; oropharyngeal candidiasis; hypercorticism and adrenal suppression; reduction in bone mineral density; glaucoma and cataracts; drug interactions with strong cytochrome P450 3A4 inhibitors; and effects on growth in pediatric patients.

- The most common adverse reactions (≥ 1%) with Airsupra use were headache, oral candidiasis, cough, and dysphonia.

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- The recommended dosage of Airsupra is albuterol 180 mcg and budesonide 160 mcg (administered as 2 actuations of Airsupra [albuterol/budesonide 90 mcg/80 mcg]) as needed for asthma symptoms by oral inhalation. More than 6 doses (12 inhalations) should not be taken in a 24-hour period.

- AstraZeneca's launch plans for Airsupra are pending. Airsupra will be available as a pressurized metered dose inhaler that delivers a combination of albuterol 90 mcg and budesonide 80 mcg per actuation (the canister has an attached dose indicator which indicates how many inhalations remain).