## Duaklir® Pressair® (aclidinium/formoterol fumarate) – New drug approval

- On March 29, 2019, the FDA approved AstraZeneca's Duaklir Pressair (aclidinium/formoterol fumarate), for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
    - Duaklir Pressair is not indicated for the relief of acute bronchospasm or for the treatment of asthma.
- Aclidinium bromide is a long-acting antimuscarinic agent, which is often referred to as an anticholinergic. In the airways, it exhibits pharmacological effects through inhibition of $M_3$ receptors at the smooth muscle leading to bronchodilation.
- Formoterol fumarate is a long-acting selective beta$_2$-adrenergic receptor agonist (LABA). Inhaled formoterol fumarate acts locally in the lung as a bronchodilator.
- The efficacy of Duaklir Pressair was demonstrated in one active-controlled and two placebo-controlled studies enrolling 4,977 patients with moderate to very severe COPD, including chronic bronchitis and emphysema. The three studies randomized patients to Duaklir Pressair (aclidinium/formoterol fumarate) 400 mcg/12 mcg, Tudorza® Pressair® (aclidinium) 400 mcg, and formoterol fumarate 12 mcg. Studies 1 and 2 included a placebo arm, and study 3 included an active, blinded, control arm. The co-primary endpoints were change from baseline in trough forced expiratory volume in one second ($FEV_1$) and change from baseline in one-hour post-dose $FEV_1$ at week 24 vs. formoterol fumarate and Tudorza Pressair, respectively.
    - In the three trials, Duaklir Pressair demonstrated a statistically significant increase in mean change from baseline in trough $FEV_1$ and change from baseline in one-hour post-dose $FEV_1$ at week 24 vs. formoterol fumarate 12 mcg and Tudorza Pressair 400 mcg, respectively.
- The use of a LABA, including formoterol fumarate, one of the active ingredients in Duaklir Pressair, without an inhaled corticosteroid is contraindicated in patients with asthma. Duaklir Pressair is not indicated for the treatment of asthma. Duaklir Pressair is also contraindicated in patients with severe hypersensitivity to milk proteins, hypersensitivity to aclidinium bromide, formoterol fumarate, or to any component of the product,
- Warnings and precautions for Duaklir Pressair include serious asthma-related events-hospitalizations, intubations, death; deterioration of disease and acute episodes; excessive use of Duaklir Pressair and use with other LABAs; paradoxical bronchospasm; immediate hypersensitivity reactions; cardiovascular effects; coexisting conditions; hypokalemia and hyperglycemia; worsening of narrow-angle glaucoma; and worsening of urinary retention.
- The most common adverse reactions (≥ 3% and more common than with placebo) with Duaklir Pressair use were upper respiratory tract infection and headache.
- The recommended dose of Duaklir Pressair is one oral inhalation of 400 mcg/12 mcg, twice daily (once in the morning and once in the evening). Patients should not take more than one inhalation twice daily.

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- AstraZeneca's launch plans for Duaklir Pressair are pending. Duaklir Pressair will be available as a breath-actuated multi-dose dry powder inhaler with 400 mcg of aclidinium bromide and 12 mcg of formoterol fumarate per actuation.