DUAKLIR GENUAIR APPROVED IN THE EU FOR COPD

DUAKLIR® GENUAIR® approved in the EUROPEAN union FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE

AstraZeneca today announced that Duaklir® Genuair® (aclidinium bromide/formoterol fumarate 340/12 mcg) has been granted Marketing Authorisation by the European Commission (EC) to be used as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Approximately 300 million people1 around the world live with COPD, a progressive and chronic disease where people find breathing difficult due to limited airflow. Improving the lung function and managing daily symptoms such as breathlessness are important to the management of COPD.

Duaklir is a fixed-dose combination of already-approved Eklira® (aclidinium bromide), a long-acting muscarinic-antagonist (LAMA), with the long-acting beta-agonist (LABA) formoterol. The twice-daily therapy is the only LAMA/LABA combination to show statistically significant improvement in breathlessness compared to individual therapies and is administered by the Genuair® dry powder inhaler device.

AstraZeneca owns the rights to develop and commercialise Duaklir Genuair in the European Union (EU) following the strategic business combination of Almirall's respiratory portfolio, which was completed last month. The EU approval of Duaklir Genuair marks an important further step in AstraZeneca's inhaled therapy strategy of providing physicians and patients a choice of products uniquely available in both dry powder and pressurised metered dose devices.

"We are pleased to receive European regulatory approval for Duaklir Genuair as an innovative treatment for patients with COPD. Patients need treatments that can help to improve their lung function and allow them to better manage the daily and debilitating symptoms of their condition, in turn improving their overall quality of life." said Briggs Morrison, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca.

The EU approval of Duaklir Genuair was based on efficacy and safety data from more than 2,000 patients in 11 clinical studies, conducted in 29 countries worldwide. Results showed that Duaklir Genuair demonstrated statistically significant and sustained improvement in the lung function compared to monotherapy, providing a favourable benefit-to-risk profile.

The EC marketing authorisation applies to all member states of the EU and the European Economic Area. Aclidinium bromide/formoterol fumarate will be marketed in Europe by AstraZeneca under the trade name Duaklir® Genuair®.

About Duaklir® Genuair®
Duaklir Genuair (aclidinium bromide/formoterol fumarate 340/12 mcg) is a fixed dose combination of two approved long-acting bronchodilators with different mechanisms of action and similar pharmocodynamic profiles. Aclidinium bromide is an anticholinergic or long acting muscarinic antagonist (LAMA) that produces bronchodilation by inhibiting the muscarinic M3 receptor in the airway smooth muscle. Formoterol fumarate is a long-acting beta-agonist (LABA) that stimulates the β2-receptors in the bronchial smooth muscle resulting in bronchodilation. Both aclidinium bromide (Eklira®) and formoterol fumarate are separately approved for the maintenance treatment of COPD in the United States and Europe.

AstraZeneca owns the rights for the development and commercialisation of Almirall's proprietary respiratory business as well as its pipeline of investigational novel therapies.

About Genuair®
Genuair is a multi-dose, pre-loaded dry powder inhaler with a unique combination of optical and acoustic signals to reassure patients that the dose has been taken correctly. The inhaler's safety features ensure high levels of reliability while its easy-to-use features and design minimise the potential for misuse and are expected to increase patient acceptance and compliance.

About Phase III Studies AUGMENT and ACLIFORM
The Phase III clinical development programme included approximately 4,000 patients with a clinical diagnosis of COPD. The programme comprised of two 6-month randomised, control- and active-controlled studies, ACLIFORM-COPD (LAC 30) - (ACLIdinium/FORMoterol fumarate combination for Investigative use in the treatment of moderate to severe COPD) and AUGMENT (LAC 31) - (Aclidinium/formoterol FUmurate Combination for InvestiGative use in the TreatMENT of Moderate to Severe COPD); a 6-month extension of the AUGMENT study (LAC 36); and a further long-term 12-month randomised controlled study comparing aclidinium/formoterol 340/12 to formoterol (LAC 32).

About COPD
Chronic obstructive pulmonary disease (COPD) is a progressive and chronic disease which encompasses a number of lung conditions, including chronic bronchitis, emphysema and chronic obstructive airways disease. People with COPD have difficulty breathing due to persistent airflow limitation.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

1 Decision Resources 2013 for G7 prevalence: http://www.decisionresources.com/Products-and-Services/Report?r=dbasim0213.

Buist SA, McBurnie MA, et al. International variation in the prevalence of COPD (The BOLD Study), a population-based prevalence study; The Lancet (2007): http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)61377-4/abstract,

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