Press Release

Spain
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FDA approves Duaklir®, a new drug application for chronic obstructive pulmonary disease (COPD)

- **The FDA has approved Duaklir® based on the positive results of the AMPLIFY study which demonstrated significant improvements in lung function in patients with moderate to severe COPD.**
- **Duaklir® is the third product from the Almirall R&D approved by the FDA.**
- **The FDA has also approved that Tudorza® and Duaklir® reduce the annual rate of moderate or severe COPD exacerbations compared to placebo in the US Package Insert.**
- **In 2014 Almirall entered an agreement to AstraZeneca to transfer the rights for the development and commercialisation of the respiratory franchise.**

Almirall, S.A (ALM), today announced that the Food and Drug Administration (FDA) has approved the new drug application (NDA) for Duaklir® (aclidinium bromide/formoterol 400/12 mg, twice daily), for the treatment of patients with chronic obstructive pulmonary disease (COPD).

Duaklir® offers a fixed-dose combination of a novel long-acting muscarinic antagonist (LAMA), aclidinium bromide and a fast long acting beta2-agonist (LABA), formoterol fumarate, administered through the GENUAIR® inhaler device.

The FDA has approved Duaklir® based on the positive results of the AMPLIFY study, that shows Duaklir® significantly improved lung function in patients with moderate to severe COPD compared to each individual component (either aclidinium bromide or formoterol). The Phase III AMPLIFY study also proved that the efficacy, safety and tolerability profiles for aclidinium bromide and formoterol were consistent with current experience. In comparison to tiotropium bromide 18µg once-daily, both Duaklir® and aclidinium bromide monotherapy demonstrated significantly higher levels of bronchodilation during the night-time, whilst aclidinium bromide monotherapy showed non-inferior bronchodilation to tiotropium over 24 weeks.

This approval by the FDA in the US means another positive step in the partnership of Almirall and AstraZeneca.

In addition this is the third product discovered in the R&D Center of Almirall approved by the FDA.

The positive results of the Phase IV ASCENT trial for Tudorza® Pressair® (aclidinium bromide 400 µg, twice-daily) with 3.600 patients demonstrating a statistically significant reduction in the annual rate of moderate or severe COPD exacerbations compared to placebo, has been translated in a relevant change in the Package Insert of this product in the US and also reflected in the current approval of Duaklir®.

On 1st November 2014, Almirall entered an agreement to transfer the rights for the development and commercialisation of its respiratory franchise, as well as its pipeline of investigational novel therapies to AstraZeneca. This global collaboration included milestones associated to development, launch and future Duaklir® sales in US.

Almirall could receive additional milestones and royalties, which have not been disclosed.

Almirall remains positive about this partnership that has allowed to maximize the return and value of the company's assets and capabilities.

About Duaklir®

Aclidinium bromide/formoterol fumarate dihydrate 400/12 µg is an approved fixed-dose LAMA/LABA combination of two long-acting bronchodilators—aclidinium bromide, a long-acting muscarinic antagonist (LAMA), and formoterol fumarate, a long-acting beta-agonist (LABA). The fixed-dose combination was approved by the European Medicines Agency (EMA) for COPD in November 2014 and was subsequently launched in the UK (January 2015), Germany and the Netherlands (February 2015), Denmark (March 2015), and in Sweden (April 2015). DUAKLIR® is available in 18 countries globally. It is now approved in Canada, as well as being approved and marketed as BRIMICA® GENUAIR® in Australia and Italy. Both aclidinium bromide and formoterol fumarate are separately approved for the maintenance treatment of COPD in Europe and the United States. Aclidinium bromide is also currently approved in 27 countries around the world, marketed under the name Tudorza®/Eklira®, including Canada, Japan and Australia.

About Tudorza®

Tudorza® (aclidinium bromide) is a long-acting muscarinic antagonist (LAMA) indicated for the long-term maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema. Tudorza® is presented as a dry powder for inhalation. Tudorza® has been approved and marketed in the US since 2012 for the treatment of bronchospasm associated with COPD. In Europe, aclidinium bromide has been approved for the maintenance treatment of COPD since 2012 and is marketed as Eklira®.

About COPD

COPD is a progressive disease associated mainly with tobacco smoking, air pollution or occupational exposure. It can cause obstruction of airflow in the lungs resulting in extreme shortness of breath. It affects an over 329 million people worldwide and is predicted to be the third leading cause of death by 2020. COPD can be treated by improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness.

About Almirall

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying Science to provide medical solutions to patients and future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals by continuous improvement, bringing our innovative solutions where they are needed.

The company, founded almost 75 years ago with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has been key in value creation to society according to its commitment with to major shareholders and through its decision to help others, to understand their challenges and to use Science to provide solutions for real life. Total revenues in 2018 were 811 million euros. More than 1,800 employees are devoted to Science.

For more information, please visit almirall.com

Media and Investors Relations Contact:

Media contact:
bcw
Marta Gállego
marta.gallego@cohnwolfe.com
Tel.: (+34) 915 31 42 67

Investors & Corporate Communications contact:
Almirall
Pablo Divasson del Fraile
pablo.divasson@almirall.com
Tel.: (+34) 93 291 30 87