Phase III AMPLIFY study shows *Duaklir* significantly improves lung function in moderate to very severe stable COPD

- *Duaklir* achieved the primary endpoints according to the AMPLIFY data, which will be valuable to support an NDA submission to the US FDA
- Almirall will receive sales-related milestones from AstraZeneca associated to *Duaklir* sales in US, according to the global collaboration between both companies

Barcelona, 7th September 2017

Barcelona, 7th September, 2017.- Almirall has announced positive top-line results, which shows that *Duaklir** (aclidinium bromide/formoterol 400µg/12µg twice-daily) met the primary endpoints in the AMPLIFY high-level read-out, demonstrating a statistically significant and clinically relevant improvement in lung function in moderate to very severe stable chronic obstructive pulmonary disease (COPD) patients compared to each individual component (either aclidinium bromide or formoterol).

The Phase III AMPLIFY study proves that the efficacy, safety and tolerability profiles for aclidinium bromide and formoterol were consistent with current knowledge. 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.

Eduardo Sanchiz, Chief Executive Officer at Almirall said: *"These results represent a significant milestone for Almirall's respiratory business transferred to AstraZeneca, as they support the previous regarding of Duaklir and will contribute to making this combination treatment available to COPD patients in the US".* Based on the positive results of the AMPLIFY study, AstraZeneca is preparing a New Drug Application (NDA) submission to the US FDA for *Duaklir* (aclidinium bromide/formoterol 400/12mg).

The global collaboration between Almirall and AstraZeneca includes milestones associated to development, launch and future *Duaklir* sales in US. "*This agreement has allowed us to evolve our respiratory strategy to maximise the return and value of our assets and capabilities while it will keep improving the financial position of Almirall and contributing to the company's long-term growth,"* commented Eduardo Sanchiz.

Almirall entered an agreement to transfer to AstraZeneca the rights for the development and commercialisation of its respiratory franchise, as well as its pipeline of investigational novel therapies in November 2014. The franchise includes products such as *Duaklir*, the combination of aclidinium with formoterol (LAMA/LABA) approved by the European Medicines Agency (EMA) as a maintenance treatment for patients with chronic obstructive pulmonary disease.

About *Duaklir*

Aclidinium bromide/formoterol fumarate 400µg/12µg twice-daily is an approved fixed-dose LAMA/LABA combination of two long-acting bronchodilators – aclidinium bromide is a long acting muscarinic antagonist (LAMA) and formoterol fumarate is a long-acting beta-agonist (LABA). The fixed-dose combination was approved by the European Medicines Agency (EMA) in November 2014 as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). *Duaklir* and aclidinium are inhaled via the easy to use multi-dose, breath activated Pressair inhaler.

Pressair is a registered trademark of AstraZeneca.

**Duaklir is a registered trademark of aclidinium bromide/formoterol fumarate in Europe and other markets. The US trademark is subject to review and approval by the FDA.*

About Almirall

Almirall is a global pharmaceutical company with a strong focus in Dermatology and Aesthetics with the mission of providing valuable medicines and medical devices to you and future generations. Our R&D is focused on Dermatology, with a wide range of programs including key indications. Through our innovative products, agreements and alliances, our work covers the entire drug value chain. Almirall is continually growing as a specialist company in a wide range of skin diseases, in order to cover our customers unmet needs.

Founded in 1943, headquartered in Barcelona, Spain, Almirall is listed on the Spanish Stock Exchange (ticker:ALM) and it has become a source of value creation for society due to its vision and the commitment of its long-standing major shareholders. In 2016, its revenues totaled 859.3 million euros and, with more than 2,000 employees, it has gradually built up a trusted presence across Europe, as well as in the US.

For more information, please visit www.almirall.com

About AMPLIFY

AMPLIFY is a 24-week treatment, multicentre, randomised, double-blind, double dummy, parallel-group trial to assess the efficacy and safety of aclidinium bromide/formoterol 400µg/12µg twice-daily compared to its component parts (aclidinium bromide 400µg twice-daily or formoterol fumarate 12µg twice-daily) and once-daily tiotropium 18µg in moderate to very severe stable COPD patients.

The primary outcome measures were to demonstrate;

- a change from base-line morning pre-dose (trough) FEV1 for aclidinium bromide/formoterol 400µg/12µg versus formoterol 12µg at week 24
- a change from base-line in morning one-hour post-dose FEV1 for aclidinium bromide/formoterol 400µg/12µg versus aclidinium bromide 400µg at week 24
- a change from baseline in morning pre-dose (trough) FEV1 at week 24 comparing aclidinium bromide 400µg versus tiotropium 18µg to demonstrate non-inferiority

Other objectives were to assess the safety of aclidinium bromide/formoterol fumarate 400µg/12µg, as well as to further characterise the effect of the combination on bronchodilation and health related quality of life.

About COPD

Chronic obstructive pulmonary disease (COPD) is a progressive disease associated mainly with tobacco smoking, air pollution or occupational exposure, which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. It affects an estimated 329 million people worldwide and is predicted to be the third leading cause of death by 2020. Improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness are important to the management of COPD.

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