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Press Release

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Phase IV ASCENT trial shows *Tudorza* reduces COPD exacerbations and demonstrates cardiovascular safety

- **Phase IV ASCENT trial meets primary endpoints in COPD patients with cardiovascular risk factors**
- **These positive top-line results represent another milestone for Almirall, which receives sales-related milestones from AstraZeneca associated to sales in US**

Almirall, S.A (ALM), today announced positive top-line results from the Phase IV, ASCENT trial for Tudorza (aclidinium bromide 400µg, twice-daily), a long-acting muscarinic antagonist (LAMA). Tudorza met the primary endpoints, demonstrating a statistically significant reduction in the annual rate of moderate or severe chronic obstructive pulmonary disease (COPD) exacerbations in patients with moderate to very severe COPD, with a history of cardiovascular disease and/or significant cardiovascular risk factors compared to placebo. These positive top-line results represent another milestone for Almirall, which receives sales-related milestones from AstraZeneca associated to sales in US.

Tudorza also achieved its primary safety endpoint of demonstrating time to a first major adverse cardiovascular event (MACE) comparable to placebo in the same patient population. The 36-month ASCENT post-marketing trial included more than 3,500 patients from Canada and the United States.

Peter Guenter, Chief Executive Officer, Almirall said: *"These positive top-line results from ASCENT study represent another significant milestone for Almirall's respiratory business transferred to AstraZeneca, and will reinforce the marketplace positioning of Tudorza, while Almirall keeps strengthening its financial position".*

On 17th of November 2017, AstraZeneca notified Almirall of a sales milestone achievement for $80 million– expected to be paid in December– related to the aclidinium bromide franchise. In September 2017, Almirall and AstraZeneca had announced positive top-line results from Duaklir Phase III AMPLIFY trial, demonstrating a statistically significant and clinically relevant improvement in lung function in moderate to very severe stable COPD patients.

On 1st of November 2014, 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. This global collaboration included milestones associated to development, launch and future Duaklir sales in US. To date, Almirall has received four additional payments from milestones of 280 million dollars, in addition to the upfront payment of $900 million.

In April 2017, AstraZeneca entered a strategic collaboration with Circassia Pharmaceuticals plc for the development and commercialisation of *Tudorza* and *Duaklir* in the US.

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 ASCENT

ASCENT is Phase IV trial that is double-blind, randomised, placebo-controlled, parallel-group. It is designed to evaluate the effect on long-term cardiovascular safety of Tudorza (aclidinium bromide 400 µg, twice-daily), the long-acting muscarinic antagonist (LAMA). It evaluates the time to a first major adverse cardiovascular event (MACE), as well as the reduction of moderate or severe COPD exacerbations in moderate to very severe COPD patients. The trial was a mandatory, post-approval trial requested by the US Food and Drug Administration (FDA). It was conducted in 3,500 patients and concluded after 122 patients had experienced an adjudicated MACE.

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 & future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals in its continuous improvement, bringing our innovative solutions where they are needed.

The company, founded in 1943 and with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key element of value creation to society according to its commitment with its major shareholders and its decision to help others, to understand their challenges and to use Science to provide them with solutions for real life. Total revenues in 2016 was 859.3 million euros and more than 2,000 employees are devoted to Science.

For more information, please visit almirall.com linkedin.com/company/almirall

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