Barcelona, April 1st 2019

SIGNIFICANT EVENT

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

Almirall, S.A. (ALM.MC), as per section 228 of the Royal Legislative Decree 4/2015, of 23 October 2015, approving the Restated Text of the Securities Market Act, hereby announces that:

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, 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.

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.

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

In 2014 Almirall entered an agreement to AstraZeneca to transfer the rights for the development and commercialisation of the respiratory franchise.

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

Sincerely,

Pablo Divasson del Fraile
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