Update on Eklira® (aclidinium bromide) for chronic obstructive pulmonary disease (COPD):

Positive results in a short-term comparative trial and announcement of new Phase III studies

- **Topline positive results from a short-term comparative Phase II study vs tiotropium and placebo will be announced 1st quarter 2010, together with results from an ongoing three month trial**

- **New Phase III studies with Eklira® twice daily announced**

Barcelona, October 20th, 2009: Almirall, S.A. (ALM.MC) today announced the completion of a short-term Phase II study comparing aclidinium twice daily (BID) vs tiotropium and placebo[1] as well as the completion of the enrolment of a larger Phase III three-month study with two different BID doses of Eklira® vs placebo in patients with moderate to severe COPD[2].

«The positive outcomes from a short-term Phase II comparative study with Eklira® BID vs tiotropium and placebo[1], confirm Almirall and Forest decision to add to the ongoing twice daily development programme new Phase III clinical studies, including one of three months and one of six months duration with aclidinium vs placebo» said Per-Olof Andersson, Executive Director R&D at Almirall. Both studies will investigate the effects of aclidinium bromide in patients with moderate to severe COPD using a BID dosing regimen.

Almirall and Forest Laboratories, Inc. (NYSE:FRX) plan to disclose the results of both the short-term comparative Phase II study and the ongoing three-month Phase III study in the first quarter of 2010.

About the studies

The primary endpoint of the short term double-blind, three-way cross-over, Phase II study was to evaluate the efficacy, safety and tolerability of multiple doses of inhaled aclidinium bromide BID vs tiotropium and placebo in moderate to severe COPD patients. The primary outcome measure is change from baseline in FEV_1 (how much air can be exhaled in one second) at day 15 of the treatment.

The primary objective of the Phase III studies is to assess the efficacy and safety of aclidinium bromide compared to placebo in the treatment of moderate to severe COPD. These three-month and six-month studies have a two-week run-in period and a two-week follow-up visit, and the treatment duration will be of 12 and 24 weeks respectively. All patients meeting the eligibility criteria are randomised to either aclidinium doses or placebo. The primary endpoint will be morning pre-dose FEV_1 in all dose regimens. The program also includes trials to assess long term safety of Eklira® BID.

Eklira® and Genuair®

Eklira® (aclidinium bromide) is a novel, long-acting inhaled anticholinergic bronchodilator which has a long residence time at the M3 receptors and a shorter residence time at the M2 receptors. Aclidinium is rapidly hydrolyzed in human plasma to two major inactive metabolites.

Eklira® is administered using a novel, state-of-the-art multidose dry powder inhaler (MDPI) called Genuair®, designed with an intuitive feedback system, which through a coloured control window, an audible click, and a slightly sweet taste, indicates that the patient has inhaled correctly.

About COPD
Chronic Obstructive Pulmonary Disease (COPD) is not one single disease but an umbrella term used to describe chronic lung diseases that cause limitations in lung airflow. The more familiar terms 'chronic bronchitis' and 'emphysema' are no longer used, but are now included within the COPD diagnosis. The most common symptoms of COPD are breathlessness (or a "need for air"), abnormal sputum (a mix of saliva and mucus in the airway), and a chronic cough. Daily activities, such as walking up a short flight of stairs or carrying a suitcase, can become very difficult as the condition gradually worsens.

COPD is preventable but not curable, although treatment can slow the progress of the disease. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases. COPD has a significant impact on quality of life for patients and their families and the World Health Organisation (WHO) predicts that this disease will become the third leading cause of death worldwide by 2030[3].

About Almirall
Almirall, an international pharmaceutical company based on innovation and committed to health, headquartered in Barcelona, Spain, researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing.

The therapeutic areas on which Almirall focuses its research resources are related to the treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), rheumatoid arthritis, multiple sclerosis, psoriasis and dermatology in general.

Almirall's products are currently present in over 70 countries while it has direct presence in Europe and Latin America through 11 affiliates.

For further information, please visit www.almirall.com.

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References and Notes

1 Efficacy of aclidinium bromide administered in chronic obstructive pulmonary disease (COPD) patients. Reference in ClinicalTrials.gov: NTC00868231

2 Efficacy and safety of aclidinium bromide for treatment of moderate to severe chronic obstructive pulmonary disease (COPD). Reference in ClinicalTrials.gov: NTC00891462.

3 World Health Organisation (WHO): Chronic obstructive pulmonary disease (COPD), Fact Sheet 315. Website page available at: http://www.who.int/mediacentre/factsheets/fs315/en/