Laboratorios Almirall, S.A. and Forest Laboratories, Inc. complete phase III studies in COPD

Barcelona, July 7th: Laboratorios Almirall, S.A. and Forest Laboratories, Inc. (NYSE: FRX) have announced that the ACCLAIM/COPD I&II (**AC**lidinium **CL**inical Trial **A**ssessing Efficacy and Safety **I**n **M**oderate to Severe COPD Patients) studies are now closed and that the last patients have finished treatment in both of these pivotal Phase III studies.

ACCLAIM/COPD is the largest clinical development programme undertaken by Almirall, and was designed to assess aclidinium bromide for the treatment of moderate to severe chronic obstructive pulmonary disease (COPD). Both ACCLAIM/COPD trials have been fully recruited across 23 countries, with 1,647 COPD patients randomised worldwide. The final patient visits were conducted in May for ACCLAIM I and in June for ACCLAIM II. Preliminary, top-line results from both of these two studies are expected to be available during the third quarter of 2008.

About ACCLAIM/COPD studies

Two double-blind, multi-center, parallel-group, placebo-controlled Phase III studies were conducted, one in Europe and the other primarily in North America, to evaluate the efficacy and safety of aclidinium. Patients in these trials had a diagnosis of moderate to severe COPD and were at least 40 years of age with at least a 10 pack-year smoking history. Patients were randomized to receive aclidinium or placebo over a one year treatment period. The primary endpoint in both trials is pre-dose forced expiratory volume in one second (FEV_1) vs. placebo. FEV_1 is a measure of pulmonary function that is decreased in moderate to severe COPD patients.

“We are very pleased that the ACCLAIM/COPD studies have closed, and anticipate the results later this year. COPD is a very serious disease and we hope that aclidinium bromide will be a valuable treatment option for COPD patients” said Dr. Jorge Gallardo, Chairman and Chief Executive Officer of Almirall. “We are also excited by the new state-of-the-art multidose dry powder inhaler (MDPI), Genuair®[9] which has been designed to be easy and intuitive to use, offering valuable benefits for COPD patients over existing inhalation devices.”

The Aclidinium Bromide Clinical Programme

In addition to ACCLAIM/COPD studies, a range of other Phase I-III studies designed to characterise the product’s profile are included in a comprehensive clinical programme. These aclidinium studies investigate exercise tolerance and lung hyperinflation, aclidinium safety and pharmacokinetics in renal insufficiency and elderly COPD patients, peak inspiratory flow rate with the Genuair®[9] MDPI, and AM/PM dosing.

The results of Phase II clinical trials have demonstrated that aclidinium bromide achieved a significant sustained bronchodilation over 24 hours and was well tolerated.[1,2] The results of Phase I studies have shown that aclidinium bromide proved superior to placebo in improving specific airway conductance, with a greater effect obtained at

higher doses.[3] Furthermore, Phase I studies have shown that aclidinium bromide is well tolerated across a range of doses (600-6000µg)[4] and with repeated dosing (200, 400 and 800µg).[5] Dose adjustment with aclidinium is unlikely to be required in patients with renal impairment, since renal elimination plays a minor role in the overall elimination of the drug. Also, a seven day exploratory cross-over study evaluating morning or evening administration of aclidinium bromide versus placebo treatment was recently completed. At day 7 a statistical significant difference of aclidinium vs placebo in the normalized FEV_1 area under the curve (AUC 0-24/24h) was observed, but not in trough FEV_1 for both aclidinium dosing groups. No differences in FEV_1 AUC 0-24/24h or trough FEV_1 were found between the morning or evening aclidinium administrations.

About Aclidinium Bromide

Aclidinium bromide is a novel inhaled anticholinergic bronchodilator that is currently in Phase III clinical development as a once-daily maintenance treatment for COPD. Almirall licensed US rights to aclidinium to Forest Laboratories, whilst keeping rights for the rest of the world. The companies are jointly involved in the development of the compound.

Aclidinium bromide is administered to patients using Almirall's state-of-the art patient friendly Genuair®[9] MDPI, which operates on the 'one press and inhale' concept. Genuair®[9] has been designed with a novel intuitive feedback system, which through a 'coloured control window' indicates the correct use. The Genuair®[9] inhaler contains 30 doses with a visible dose level indicator and also incorporates significant safety features such as an anti-double dosing mechanism and an end-of-dose lock-out system to prevent use of an empty inhaler.

About COPD

COPD is a preventable and treatable lung disease characterized by chronic airflow limitation that interferes with normal breathing and is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases. Chronic bronchitis and emphysema are two of the most common lung diseases included under the diagnosis of COPD.[6]

COPD is an under-diagnosed and life-threatening lung disease.[7] Globally, an estimated 80 million people have moderate to severe COPD.[6] In excess of 3 million people died of the condition in 2005, accounting for 5% of all deaths worldwide.[7] There are significant unmet needs in the treatment of COPD, including limited therapeutic options to improve lung function and control exacerbations. Individual patient responses to treatment may vary and, thus, additional treatment options are needed.

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 COPD, asthma, psoriasis, rheumatoid arthritis and multiple sclerosis.

Almirall's medicines are currently present in over 70 countries with direct presence in Europe and Latin America.

For further information please visit the website at: www.almirall.com

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References and Notes

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7 World Health Organisation (WHO). Chronic obstructive pulmonary disease (COPD). Factsheet number 315; November 2006.
9 Genuair® is a registered trademark of Laboratorios Almirall, S.A. Genuair® is the proposed registered trademark for the MDPI and is pending regulatory approval.