Almirall starts Phase III for aclidinium and formoterol in COPD

- Almirall's respiratory franchise continues to expand in COPD

- Clinical trials of the double bronchodilator combination have commenced to satisfy European and North American regulatory requirements

Barcelona, November 16th, 2011 - Almirall, S.A. (ALM.MC) today announced that, together with its US partner Forest, initiated a Phase III clinical programme of the fixed dose combination (FDC) of aclidinium bromide and formoterol fumarate twice daily (BID) delivered in the Genuair® inhaler, for the treatment of moderate to severe chronic obstructive pulmonary disease (COPD).

The Phase III programme involves approximately 3,500 patients with moderate to severe COPD and consists of two large pivotal studies -one conducted mainly in Europe and another in North America- evaluating the efficacy and safety of the FDC of aclidinium plus formoterol during 24 weeks, as well as a long-term safety study of 52 weeks which is also performed in North America. Protocols of these clinical trials have been designed to fulfil both EMA and FDA requirements.

The studies' endpoints include bronchodilation parameters (i.e. FEV_1), symptom measurement (i.e. breathlessness assessed by Transition Dyspnoea Index -TDI-), health status (ie quality of life assessed by the St George's Respiratory Questionnaire -SGRQ-) and COPD exacerbations.

"*After the filing of aclidinium monotherapy in Europe and the USA, the start of this global Phase III programme of the fixed dose combination of aclidinium and formoterol, in more than 25 countries, means that Almirall is progressing in expanding the aclidinium franchise. We are aiming to provide innovative treatment options for patients suffering from debilitating respiratory diseases, as is the case of COPD*", said Bertil Lindmark, Chief Scientific Officer at Almirall.

In January, Almirall and Forest announced positive results of two Phase IIb dose-ranging studies comparing fixed-dose combinations to aclidinium bromide, formoterol and placebo, administered BID in patients with stable moderate to severe COPD patients. In both studies, the fixed dose combination demonstrated improved bronchodilation compared to aclidinium and formoterol alone.

Endpoint Definitions

FEV1 - Forced expiratory volume in one second, or the amount of air that can be exhaled in the first second, after an inhalation.

TDI - Multidimensional clinical instruments were developed by experts in order to provide a more comprehensive assessment of the severity of dyspnoea. The most widely used multidimensional instruments include the Transition Dyspnea Indices (TDI), which consider three components: functional impairment, magnitude of task, and magnitude of effort,

SGRG - The SGRQ is a 50-item questionnaire which measures health status (quality of life) in patients with diseases of airways obstruction. Scores are calculated for three domains: symptoms, activity and impacts (psycho-social) as well as a total score. Psychometric testing has demonstrated its repeatability, reliability and validity. Sensitivity has been demonstrated in clinical trials. A minimum change in score of 4 units was established as clinically relevant after patient and clinician testing.

About aclidinium and formoterol in the Genuair® inhaler
Aclidinium bromide is a novel, long-acting inhaled muscarinic antagonist -sometimes referred to as an anticholinergic-, which has a long residence time at M3 receptors and a shorter residence time at M2 receptors, and which is designed to be rapidly broken down in plasma, leading to high topical efficacy but low propensity for systemic anticholinergic effects. When given by inhalation, aclidinium leads to bronchodilation by inhibiting airway smooth muscle contraction. Aclidinium bromide is rapidly hydrolysed in human plasma to two major inactive metabolites.

The fixed dose combination of aclidinium and formoterol delivers improvement in bronchodilation and symptoms from both compounds and it will be administered twice daily using the novel, state-of-the-art, user-friendly multidose dry powder inhaler (MDPI), Genuair®, from Almirall. This inhaler was designed with a “click and colour” feedback system which, through a 'coloured control window' and an audible click, indicates that the patient has inhaled the dose correctly. It also incorporates significant safety features such as a visible dose indicator, an anti-double-dosing mechanism and an end-of-dose lock-out system to prevent use of an empty inhaler.

Forest Laboratories, Inc. licensed US rights for aclidinium bromide from Almirall, and Kyorin for Japan, while Almirall maintains rights for the rest of the world. Almirall and Forest are jointly involved in the development of the compound.

Genuair® is a trademark owned by Almirall, S.A. and is pending approval from the appropriate regulatory authorities.

About COPD
The World Health Organization (WHO) has described COPD as a global epidemic; an estimated 64 million people have COPD worldwide. More than 3 million people died of the condition in 2005, which is equal to 5% of all deaths globally that year. Total deaths from COPD are projected to increase by more than 30% in the next 10 years without interventions to cut risks, particularly exposure to tobacco smoke.

The most common symptoms of COPD are breathlessness (an increased effort to breathe), heaviness or a ‘need for air’, excessive mucus, and a chronic cough. Some people feel they are gasping for breath. These symptoms get worse when exercising, in case of a respiratory infection or during an exacerbation – periods of time when there is a sudden increase in symptoms and the disease is worse. COPD affects the ability to breathe and is a progressive disease, which means that COPD gets worse over time. Daily activities may become more difficult as the disease worsens. There are significant unmet needs in the treatment of COPD and new therapies may be of value.

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

Almirall focuses its research resources on therapeutic areas related to the treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), gastrointestinal disorders, psoriasis and other dermatological conditions.

Almirall’s products are currently present in over 70 countries while it has direct presence in Europe and Latin America through 12 affiliates.

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

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