Aclidinium bromide submitted for registration in Europe

- **In clinical trials, aclidinium has shown 24-hour symptoms control, full bronchodilatory effect from the first day and tolerability similar to placebo**

- **Further details on the Phase III programme will be presented at the ERS congress in September**

Barcelona, July 27th, 2011 - Almirall, S.A. (ALM.MC) announced today the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for aclidinium bromide, a novel long-acting inhaled muscarinic antagonist for the treatment of Chronic Obstructive Pulmonary Disease (COPD). This follows the submission of a NDA to the US Food and Drug Administration (FDA) in June.

Eduardo Sanchiz, Chief Executive Officer at Almirall said: "*Aclidinium bromide is the outcome of our strategic focus in the respiratory area and its regulatory submission, last month in US and now in Europe, is an important milestone for Almirall. Significant human and financial resources are being dedicated to research in this field, searching for innovative medicines to improve the treatment of patients suffering from respiratory diseases around the world".*

The regulatory submission is based on efficacy data from a large Phase III programme in which patients received aclidinium bromide 400 mcg or 200 mcg twice daily (BID) or placebo. In the pivotal studies, aclidinium 400 mcg twice-a-day, the proposed to-be-marketed dose, produced significant improvement in morning pre-dose (trough) FEV_1 versus placebo at week 12 ($p<0.0001$), the primary endpoint assessed as support for the U.S. NDA and at week 24 (128mL; $p<0.0001$), which was the primary endpoint assessed in the study to support the European filing.

"We are excited by this submission of aclidinium BID in Europe, because it has shown to provide COPD patients with true 24-hour symptoms control and full bronchodilatory effect from the first day of therapy in a comprehensive phase III programme," said Bertil Lindmark, Chief Scientific Officer at Almirall.

Aclidinium also demonstrated statistically significant differences vs placebo, achieving a clinically meaningful reduction in breathlessness (assessed by a 1 unit improvement in Transition Dyspnoea Index [p=0.004] at week 24) and in the percentage of patients with improved health status [p=0.001] (assessed by a 4-unit improvement in the St George's Respiratory Questionnaire).

"*There are significant unmet needs in the treatment of COPD including limited therapy options to improve lung function, reduce symptoms, improve quality of life and prevent exacerbations*," said Professor Paul Jones, St George's Hospital, University of London, UK. "*In the Phase III ATTAIN*[i] *study, aclidinium provided consistent bronchodilation and symptoms control resulting in clinically significant improvement in health status*."

Additionally, safety data collected from the Phase III programme demonstrated that aclidinium 400 mcg twice-a-day was generally well tolerated, with an incidence of systemic anticholinergic effects in the range of placebo, similar across the study treatment arms. The most commonly reported adverse reactions were headache and nasopharyngitis (inflammation of the nose and throat).

Further details of the Phase III clinical programme will be presented at the ERS congress in Amsterdam, September 24-28th 2011.

About aclidinium bromide and the Genuair® inhaler
Aclidinium bromide is a novel, long-acting inhaled muscarinic antagonist (sometimes referred to as an anticholinergic) that has a long residence time at M3 receptors and a shorter residence time at M2 receptors. When given by inhalation, aclidinium leads to bronchodilation by inhibiting airway smooth muscle contraction. Aclidinium is rapidly hydrolyzed in human plasma to two major inactive metabolites. Forest Laboratories, Inc. licensed US rights for aclidinium from Almirall, while Almirall maintains rights for the rest of the world. The companies are jointly involved in the development of the compound.

Aclidinium bromide was administered to patients in the trials using a novel, state-of-the-art, user-friendly multidose dry powder inhaler (MDPI), Genuair®. 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.

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. It is a progressive disease, which means that COPD gets worse over time. This means that the ability to breathe is affected, and because of this, 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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[i] **A**clidinium **T**o **T**reat **A**irway obstruction **I**n COPD patients