COPD patients experienced benefits from the first dose when treated with aclidinium, as shown in the ATTAIN Phase III study

- **Aclidinium demonstrates improved lung function, symptom control and quality of life for Chronic Obstructive Pulmonary Disease (COPD) patients**

Amsterdam, September 27th, 2011 - Almirall, S.A. (ALM.MC) today announced results from the ATTAIN study at the Annual Congress of the European Respiratory Society (ERS) showing the safety and efficacy of aclidinium bromide for the treatment of COPD. The findings demonstrate that from the first dose, aclidinium bromide 200 µg and 400 µg twice daily significantly improved airflow limitation measure by forced expiratory volume in one second (FEV_1), compared to placebo.[1] The ATTAIN study lasted for six months and involved 828 patients with moderate to severe COPD. Top line results of the study were announced in January 2011 but this is the first time the full data are presented to the scientific community.

"*COPD can be a debilitating disease due to a number of symptoms, particularly breathlessness. This has a large impact on the patients' quality of life,"* said Professor Paul Jones, St George's Hospital, University of London, UK. "*These findings from the ATTAIN programme are very promising as they demonstrate that aclidinium bromide can improve breathlessness and reduce the impact of symptoms throughout the day, as well as improving lung function*."

Treatment with aclidinium provided 24 hour symptom relief[2] according to the newly presented ATTAIN data which shows improvement in COPD symptoms, as assessed by the Transitional Dyspnoea Index (TDI) and the EXAcerbations of Chronic Pulmonary Disease Tool (EXACT).

Along with improved lung function and reduction of symptoms, patients treated with aclidinium in the ATTAIN study also experienced improvements in markers of quality of life as measured by the St George's Respiratory Questionnaire (SGRQ) and the EuroQuol questionnaire (EQ-5D).[3] The study authors noted that this may translate into noticeable benefit for patients in routine practice. In particular, with aclidinium 400 µg, the improvement in the SGRQ was seen as early as 12 weeks after the start of treatment. Aclidinium bromide 400 µg also significantly improved EQ-5D (weighted index and VAS score) at week 24, compared with placebo.[3]

"*There is an unmet need for new therapeutic options to improve the health and quality of life of patients living with COPD,*" said Bertil Lindmark, Chief Scientific Officer at Almirall. "*Based on the findings of the comprehensive ATTAIN programme, aclidinium bromide has shown great potential for addressing this need by offering 24 hour improvement in symptoms along with improved health status and lung function*."

The data presented at ERS also confirm that aclidinium bromide has a favourable safety and tolerability profile at both the 200 µg and 400 µg doses.[4] In particular, the data demonstrate a low incidence of anticholinergic adverse events across all treatment groups.

Other communications presented at the ERS

1. An assessment of the functional profile of aclidinium in human bronchi and left atria - J Milara, E Garbarda, A Gavalda, M Miralpeix, J Beleta, E Morcillo, J Cortijo - Abstract 2916 - Poster Session Translational models of disease - Sunday 25 September 12:50-14:40 in Hall 2-18

2. Patient assessments of ease of use of Genuair® versus Aerolizer® and HandiHaler® - R Fuhr, H Magnussen, D Singh, G de Miquel, C Caracta, E Garcia Gil - Abstract 2090 - Poster Session Drug delivery and pharmacokinetics 2 - Tuesday 27 September 12:50-14:40 in Hall 2-22

3. The ATTAIN study: bronchodilatory effect of aclidinium bromide in chronic obstructive pulmonary disease (COPD) - D Singh, ED Bateman, PW Jones, A Agusti, R Lamarca, G de Miquel, C Caracta, E Garcia Gil - Abstract 2095 - Poster Session Bronchodilators in asthma and COPD - Sunday 25 September 12:50-14:40 in Hall 2-19

4. The ATTAIN study: safety and tolerability of aclidinium bromide in chronic obstructive pulmonary disease - ED Bateman, D Singh, PW Jones, A Agusti, R Lamarca, G de Miquel, C Caracta, E Garcia Gil - Abstract 2097 - Poster Session Airways disease co-morbidities and general aspects - Tuesday 27 September 12:50-14:40 in Hall 2-23

5. Aclidinium bromide in patients with chronic obstructive pulmonary disease: improvement in health status in ATTAIN - PW Jones, A Agusti, ED Bateman, D Singh, R Lamarca, F de Miquel, C Caracta, E Garcia Gil - Abstract 2091 - Poster Session Bronchodilators in asthma and COPD - Sunday, 25 September 12:50 to 14:40 in Hall 2-19

6. Improvement in symptoms and rescue medication use with aclidinium bromide in patients with chronic obstructive pulmonary disease: results from ATTAIN - A Agusti, PW Jones, ED Bateman, D Singh, R Lamarca, C Caracta, E Garcia Gil - Abstract 2092 - Poster Session Bronchodilators in asthma and COPD - Sunday 25 September 12:59-14:40 in Hall 2-19

7. ACCORD COPD I: Improvements in nighttime symptoms and rescue medication use in COPD with twice daily aclidinium bromide - E Kerwin - Poster Session Bronchodilators in asthma and COPD - Sunday 25 September 12:50-14:40 in Hall 2-19

About aclidinium and 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 hydrolyzed in human plasma to two major inactive metabolites. 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.

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 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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[1] The ATTAIN study: bronchodilatory effect of aclidinium bromide in chronic obstructive pulmonary disease. Singh, D et al. European Respiratory Association Annual Congress, Amsterdam, The Netherlands, 24th – 28th September, 2011
[2] Efficacy of aclidinium bromide administered in chronic obstructive pulmonary disease (COPD) patients. Reference in ClinicalTrials.gov: NTC00868231
[3] Aclidinium bromide in patients with chronic obstructive pulmonary disease: improvement in health status in ATTAIN. Jones P. et al. European Respiratory Association Annual Congress, Amsterdam, The Netherlands, 24th – 28th September, 2011
[4] The ATTAIN study: safety and tolerability of aclidinium bromide in chronic obstructive pulmonary disease. Bateman, E. et al. European Respiratory Association Annual Congress, Amsterdam, The Netherlands, 24th – 28th September, 2011