Almirall and Forest announce positive results from the ACCORD COPD I Phase III study of aclidinium bromide in Chronic Obstructive Pulmonary Disease (COPD)

- Top line results of ACCORD COPD I, the first three-month Phase III pivotal study with aclidinium twice daily (BID) in patients with COPD, met primary endpoint[1].

- These results are consistent with findings from a Phase II study comparing aclidinium vs tiotropium and placebo[2]

Barcelona, January 7th, 2010 - Almirall, S.A. (ALM.MC) and Forest Laboratories, Inc. (NYSE: FRX) today announced positive top-line results from ACCORD COPD I, a three-month Phase III study comparing aclidinium 200µg and 400µg BID versus placebo. Aclidinium bromide produced statistically significant ($p<0.0001$) changes from baseline in morning pre-dose (trough) FEV_1 versus placebo at week 12, which was the primary endpoint for the study.[1] Changes from baseline values in morning trough FEV_1 compared to placebo were 86mL and 124 mL for the 200µg and 400µg BID groups, respectively. This is the first of three pivotal Phase III studies investigating the BID administration of aclidinium in COPD patients.

Aclidinium was well tolerated in this study. The percentage of patients reporting adverse events and serious adverse events was similar across the study treatment arms. The most frequent adverse event observed was COPD exacerbation**,** which occurred in 9.2%, 7.4% and 12.4% of patients receiving aclidinium 200µg, aclidinium 400µg and placebo, respectively. Other frequently observed adverse events included dyspnea, headache and nasopharyngitis and occurred at similar rates across the treatment groups..

"*We are very pleased with the results of this study which confirm the decision made by Almirall and Forest to investigate a BID dosing regimen for aclidinium",* said Lawrence S. Olanoff, President and Chief Operating Officer of Forest Laboratories*. "Together, these data suggest that aclidinium administered BID provides a clinically important bronchodilatory effect with good tolerability in patients with COPD."*

These top-line results are consistent with previously announced positive findings from a 15 day, Phase II study comparing aclidinium bromide 400µg BID, tiotropium 18µg once daily (QD) and placebo. In this Phase II study, both products showed a statistically significant difference in normalized AUC (0-12 hours) FEV_1 compared to placebo (both $p<0.0001$). Improvements versus placebo for aclidinium and tiotropium in terms of normalized AUC (12-24 hours) FEV1 on Day 15 were also statistically significant and the effect was significantly higher for aclidinium than tiotropium during the 12-24 hour period ($p=0.020$).

«We are encouraged by the positive top-line results shown in this Phase III study. Taken together with the Phase II study vs tiotropium, it indicates that aclidinium bromide BID provides significant bronchodilation and is well tolerated in patients with moderate to severe COPD» said Per-Olof Andersson, Executive Director Research and Development at Almirall. *«We look forward to presenting full results from both studies at upcoming scientific meetings and in publications»*.

The Phase II and III studies above are part of Almirall and Forest's ongoing development program for aclidinium bromide. Two additional placebo-controlled Phase III studies (ACCORD COPD II and ATTAIN) assessing efficacy and safety in patients with COPD are currently underway, one in North America and the other in Europe and the rest of the world. Results from these studies are expected to be available between the second half of 2010 and early 2011.

About the studies:

- Phase III ACCORD COPD I Study
  This study was a twelve week randomized, double-blind, placebo controlled trial that evaluated the efficacy and safety of aclidinium bromide 200µg or 400µg or placebo, administered twice daily by inhalation, in patients with moderate to severe COPD. The study was conducted in North America and randomized a total of 561 patients. Mean baseline FEV_1 at randomization ranged from 1,332 to 1,376mL.

  The primary endpoint, which was significant ($p<0.0001$) at both aclidinium doses, assessed morning trough FEV_1 after twelve weeks of treatment. Aclidinium administration at both doses also produced a significant ($p<0.0001$) change from baseline versus placebo in peak FEV_1, the secondary endpoint, as early as day 1 which was sustained for the duration of the study with week 12 values of 146mL and 192mL for 200µg and 400µg versus placebo, respectively. Further analysis of the results of this study is ongoing.

- Phase II Study
  In this Phase II study, moderate to severe COPD patients were randomized in a double-blind and double-dummy fashion to a cross-over sequence of three 15 day treatment periods with aclidinium bromide 400µg BID, tiotropium 18µg QD, or placebo. The study was conducted in Europe and randomized a total of 30 patients. The primary endpoint was change from baseline in normalized AUC (0-12 hours) FEV_1 at day 15. Both aclidinium and tiotropium showed a statistically significant ($p<0.0001$) difference on this endpoint.

  Key secondary endpoints include change from baseline in normalized AUC (12-24 hours) FEV1 at Day 15 along with peak and trough FEV1 at Day 15. Both aclidinium and tiotropium produced a statistically significant difference versus placebo ($p<0.05$) on all secondary measures assessed with the exception of nighttime use of relief medication and sputum scores for both treatments, and breathlessness, cough and nighttime symptoms with tiotropium. The improvement in normalized AUC (12-24 hours) FEV_1 was significantly higher for aclidinium than tiotropium ($p=0.020$).

Endpoint Definitions

- **FEV_1** - Forced expiratory volume in one second, or the amount of air that can be exhaled in the first second, following an inhalation.

- **Morning trough FEV_1** - average of two FEV_1 measurements within 1 hour before morning treatment administration.

- **Normalized AUC (0-12 hours, 12-24 hours) FEV_1** - Average area under the FEV_1 curve over 12 hours, from dosing in the morning until pre-dose twelve hours later (0-12 hours), and from dosing in the evening through the night until pre-dose the next morning (12-24 hours), respectively.

About aclidinium bromide and the Genuair® inhaler[3]

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. 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 is administered to patients using a novel, state-of-the-art multidose dry powder inhaler (MDPI), Genuair®. The Genuair® inhaler was designed with an intuitive feedback system, which through a 'colored control window' and an audible click confirms that the patient has inhaled correctly. It contains multiple doses of aclidinium, and includes 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[4]

The World Health Organisation (WHO) has described COPD as a global epidemic; an estimated 210 million people have COPD worldwide and 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.

In patients with COPD the airways in the lungs typically lose their elasticity, produce excess mucus and become thick and inflamed, limiting the passage of air. 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. There are significant unmet needs in the treatment of COPD including limited therapeutic options to improve lung function, reduce symptoms and control exacerbations.

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.

About Forest Laboratories

Forest Laboratories, Inc. (NYSE: FRX) is a U.S.-based pharmaceutical company with a long track record of building partnerships and developing and marketing products that make a positive difference in people's lives. In addition to its well-established franchises in therapeutic areas of the central nervous and cardiovascular systems, Forest's current pipeline includes product candidates in all stages of development and across a wide range of therapeutic areas. The company is headquartered in New York, NY. To learn more about Forest Laboratories, visit www.FRX.com.

Except for the historical information contained herein, this release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in Forest Laboratories' Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and any subsequent SEC filings.

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References:

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

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

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

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