

Almirall and Forest announce positive results from the ATTAIN Phase III study of acclidinium bromide and the Phase IIb studies with the fixed dose combination with formoterol in moderate to severe COPD patients

- ATTAIN results confirm clinically significant bronchodilation and improvement of symptoms in COPD patients treated with acclidinium bromide twice daily (BID)
- Regulatory filings in Europe and USA for acclidinium bromide monotherapy are planned for mid 2011
- Positive results of two Phase IIb studies with the fixed dose combination of acclidinium bromide and formoterol will enable Phase III to start in second half 2011

Barcelona and New York, NY, January 4th, 2011 – Almirall, S.A. (ALM.MC) and Forest Laboratories, Inc. (NYSE: FRX) today announced positive top-line results of ATTAIN, a six month double-blind placebo-controlled pivotal Phase III study comparing the efficacy and safety of inhaled acclidinium bromide 200µg and 400µg twice daily (BID) versus placebo, in 828 patients with moderate to severe COPD.

Acclidinium 200µg and 400µg produced statistically significant increases from baseline in morning pre-dose (trough) FEV1 versus placebo at week 24 (99mL and 128mL, respectively; $p < 0.0001$), which was the primary endpoint of the study for Europe, and at week 12 (77mL and 105mL, respectively; $p \leq 0.0001$) which was the primary endpoint for the US.

All secondary endpoints demonstrated statistically significant differences vs placebo for both doses. These endpoints included peak FEV1, and the percentage of patients achieving a clinically meaningful reduction in breathlessness (assessed by a 1 unit improvement in Transition Dyspnea Index) and the percentage of patients with improved health status (assessed by a 4-unit improvement in the St. George's Respiratory Questionnaire).

Additionally, throughout the entire study, acclidinium produced statistically significant changes from baseline in trough FEV1 vs placebo at each time-point, which ranged from 77mL to 105mL for acclidinium 200µg and from 105mL to 140mL for acclidinium 400µg.

Acclidinium was well tolerated in this study. The incidence of adverse events and serious adverse events was similar across the three study treatment arms.

"We are very pleased with these results which demonstrate that acclidinium provided consistent bronchodilation and symptom control in COPD for patients suffering from this debilitating disease", said Jorge Gallardo, Chairman and Chief Executive Officer at Almirall. *"With these results, we anticipate regulatory filings for acclidinium BID monotherapy this year".*

Regulatory submissions in Europe and the US for acclidinium bromide monotherapy are both planned for mid 2011.

Acclidinium and formoterol fixed dose combination Phase IIb Studies

Two Phase IIb dose-ranging studies comparing fixed-dose combinations (acclidinium bromide / formoterol) to acclidinium bromide alone, formoterol alone and placebo, administered BID in patients with stable moderate to severe COPD, have also been successfully completed. Both studies showed statistically significant ($p < 0.001$) differences for the fixed dose combination

on the primary endpoint versus placebo (normalized AUC 0-12 hours FEV1). The fixed dose combinations provided improved bronchodilation compared to acclidinium and formoterol alone. Following regulatory consultations, Phase III with the fixed dose combination will commence in the second half of 2011.

"Together with our partner Almirall, we are delighted with the ATTAIN results which confirm the efficacy reported in the ACCORD COPD I study. We are also encouraged by the results achieved with the fixed dose combination of acclidinium and formoterol in the Phase IIb studies, a combination of two bronchodilators, each with a different mode of action. We believe that acclidinium, a proprietary long-acting inhaled muscarinic antagonist, and formoterol, a long-acting inhaled beta agonist may be a desired combination for the treatment of COPD," said Howard Solomon Chairman and Chief Executive Officer of Forest Laboratories.

About ATTAIN Phase III study

ATTAIN (Acclidinium To Treat Airway obstruction In COPD patients) was conducted in Europe and South Africa. It was a 24 week study, which assessed the long term bronchodilator efficacy and safety of inhaled acclidinium bromide 200µg and 400µg, both administered BID, compared to placebo in 828 moderate to severe COPD patients (mean baseline FEV1= 1480mL). In addition, it assessed the benefits of acclidinium bromide 200µg and 400µg, compared to placebo, in disease-related health status and COPD symptoms.

Acclidinium 200µg and 400µg produced statistically significant increases from baseline in morning pre-dose (trough) FEV1 versus placebo at week 24 (99mL and 128mL, respectively; $p < 0.0001$), which was the primary endpoint of the study for Europe, and at week 12 (77mL and 105mL, respectively; $p \leq 0.0001$) which was the primary endpoint for the US.

Acclidinium also demonstrated statistically significant improvement vs placebo on the three secondary endpoints assessed in the study:

- Changes from baseline in peak FEV1 observed after morning dosing with 200µg or 400µg of acclidinium at weeks 12 and 24 ($p < 0.0001$ for both doses at both time points).
- Percentage of patients experiencing a clinically meaningful improvement of greater than or equal to 1-unit from baseline in shortness of breath at week 24, as measured by the Transition Dyspnea Index (TDI), ($p = 0.032$ for acclidinium 200µg; $p = 0.004$ for acclidinium 400µg).
- Percentage of patients achieving a clinically meaningful improvement of greater than or equal to 4-units from baseline in health related quality of life, as measured by the St. George's Respiratory Questionnaire (SGRQ) at week 24 ($p = 0.0004$ for acclidinium 200µg; $p = 0.0014$ for acclidinium 400µg).

Additionally, throughout the entire study, acclidinium produced statistically significant changes from baseline in trough FEV1 vs placebo at each time-point, which ranged from 77mL to 105mL for acclidinium 200µg and from 105mL to 140mL for acclidinium 400µg.

Acclidinium was well tolerated in this study. The percentage of patients reporting adverse events and serious adverse events was similar in the placebo, 200µg and 400µg treatment arms. The most common adverse events (higher than 5% and reported more frequently with acclidinium than placebo) were headache and nasopharyngitis. Also, the incidence of anticholinergic adverse events was low and comparable to placebo (e.g. dry mouth and constipation were both $< 1\%$).

Endpoint Definitions

- **FEV1** - Forced expiratory volume in one second, or the amount of air that can be exhaled in the first second, following an inhalation.
- **Morning pre-dose (trough) FEV1** - average of two FEV1 measurements within 1 hour before morning treatment administration.
- **Normalized AUC (0-12 hours) FEV1** - Average area under the FEV1 curve over 12 hours, from dosing in the morning until pre-dose twelve hours later (0-12 hours).

About acclidinium bromide and the Genuair[®] inhaler

Acclidinium 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. Acclidinium is rapidly hydrolyzed in human plasma to two major inactive metabolites. Forest Laboratories, Inc. licensed US rights for acclidinium from Almirall, while Almirall maintains rights for the rest of the world. The companies are jointly involved in the development of the compound.

Acclidinium bromide is administered to patients using a novel, investigational, state-of-the-art multidose dry powder inhaler (MDPI), Genuair[®]. The Genuair[®] inhaler was designed with a feedback system, which through a 'colored control window' and an audible click helps confirm that the patient has inhaled correctly. It contains multiple doses of acclidinium, includes a visible dose-level indicator and also incorporates safety features such as an anti-double-dosing mechanism and an end-of-dose lock-out system to prevent use of an empty inhaler. Genuair[®] is a registered trademark owned by Almirall, S.A.

About COPD

The World Health Organization (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 is an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, it researches, develops, manufactures and commercializes 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), rheumatoid arthritis, multiple sclerosis, 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

About Forest Laboratories

Forest Laboratories' (NYSE: FRX) longstanding global partnerships and track record developing and marketing pharmaceutical products in the United States have yielded its well-established central nervous system and cardiovascular franchises and innovations in anti-infective medicine. The Company's pipeline, the most robust in its history, includes product candidates in all stages of development across a wide range of therapeutic areas. The Company is headquartered in New York, NY. To learn more, 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 Reports on Form 10-Q, and any subsequent SEC filings.

Source: Forest Laboratories, Inc.

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