

Almirall and Forest Laboratories announce positive results for the second Phase III study for acclidinium and formoterol combination in COPD

- **Acclidinium/formoterol demonstrates consistent, statistically significant lung function improvement in the second pivotal efficacy trial**
- **Positive outcomes also were seen in TDI (breathlessness) and SGRQ (quality of life) in this study**
- **Regulatory filings in the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) are planned in Q4 2013**

Barcelona and New York, May 2nd, 2013 - Almirall, S.A. (ALM:MC) and Forest Laboratories, Inc. (NYSE:FRX) today announced positive topline results from AUGMENT/COPD, the second six-month pivotal phase III clinical trial evaluating the efficacy and safety of investigational fixed dose combinations of acclidinium bromide (LAMA) and formoterol fumarate (LABA) for the treatment of Chronic Obstructive Pulmonary Disease (COPD), delivered in the Pressair™ inhaler (Genuair® outside the USA).

The 400/12mcg combination of acclidinium/formoterol given twice daily demonstrated statistically significant improvements in change from baseline for the co-primary endpoints of Forced Expiratory Volume (FEV₁) at 1 hour post-dose versus acclidinium 400mcg ($p < 0.0001$), and morning predose trough FEV₁ versus formoterol 12mcg at week 24 ($p < 0.05$). The 400/6mcg combination demonstrated statistically significant improvements in (FEV₁) at 1 hour post-dose versus acclidinium 400mcg ($p < 0.0001$). For the change from baseline in morning pre-dose trough FEV₁, the 400/6mcg combination did not reach significance versus formoterol 12mcg at week 24 ($p > 0.05$).

Both combinations of acclidinium/formoterol (400/12mcg and 400/6mcg) provided statistically significant improvements versus placebo in the above two comparisons (both $p < 0.0001$).

The positive results of the acclidinium/formoterol 400/12mcg combination in this study are consistent with the statistically significant improvement in lung function demonstrated by acclidinium/formoterol 400/12mcg in the previously completed ACLIFORM/COPD Phase III study. In both studies, the 400/12mcg dose successfully met the required regulatory "Combination Rule" for testing two or more drugs combined in a single dosage form.

Both studies included secondary endpoints. The endpoints analyzed to date were change from baseline vs placebo at 24 weeks in TDI (Transitional Dyspnea Index, which measures breathlessness) and in SGRQ (St. George's Respiratory Questionnaire, a respiratory-specific disease-related quality of life assessment). Positive outcomes were seen with the two combinations achieving the MCID (Meaningful Clinical Important Difference) of a one point change ($p < 0.0001$) in TDI in both studies, and a four point change ($p < 0.0001$) in SGRQ in the AUGMENT/COPD study. Additional analyses, including those on pooled data, will be presented at future scientific meetings.

Additionally, both acclidinium/formoterol treatment arms were well-tolerated in this study. The most common adverse events (greater than or equal to 3% and reported more

frequently with either acclidinium/formoterol 400/12mcg or acclidinium/formoterol 400/6mcg than placebo respectively) were: cough (5.1%, 3.9% and 3.6%); nasopharyngitis (4.8%, 5.1% and 3.6%); headache (4.8%, 4.2% and 3.3%); urinary tract infection (4.5%, 2.1% and 3.0%); upper respiratory tract infection (3.0%, 3.9% and 1.5%); back pain (3.0%, 1.5% and 2.7%); diarrhea (2.7% 3.0% and 2.4%); nausea (1.5%, 4.5% and 1.2%); and dyspnea (1.5%, 3.3% and 1.8%).

“We are very pleased with these results which confirm the efficacy and safety profile of the novel combination of acclidinium/formoterol”, commented Dr. Bertil Lindmark, Chief Scientific Officer at Almirall. “The positive results in breathlessness and quality of life measures combined with the patient preferred Pressair/Genuair multidose device could place this new combination as a treatment option for patients suffering from COPD. The successful completion of both pivotal studies marks an important milestone towards achieving an innovative global respiratory franchise around acclidinium and the Almirall’s Genuair inhaler.”

“By successfully achieving the primary endpoints in these two pivotal trials, we have demonstrated that acclidinium/formoterol, 400/12mcg, delivers statistically significant improvement in lung function” said Dr. Marco Taglietti, President of Forest Research Institute. “The success of this Phase III program supports the potential of acclidinium/formoterol as a new treatment option for COPD patients who could benefit from the enhanced bronchodilation of two complementary, proven therapies.”

Regulatory filings in the USA (FDA) and Europe (EMA) are planned in Q4 2013.

About AUGMENT/COPD Phase III Study

AUGMENT (Acclidinium/formoterol FUMurate Combination for Investigative use in the Treatment of Moderate to Severe COPD) was a 24-week randomized double-blind trial evaluating the 400/12mcg and 400/6mcg fixed dose combinations of acclidinium bromide/formoterol fumarate compared with acclidinium bromide 400mcg, formoterol fumarate 12mcg and placebo administered BID through the Pressair inhaler (Genuair outside the USA) in 1,692 patients with moderate to severe COPD in the USA, Australia and New Zealand.

Two co-primary endpoints, designed to take in account the different contributions of the individual components in terms of efficacy, were developed in consultation with FDA/EMA to meet the “Combination Rule” (i.e., showing superiority in FEV1 at week 24 of the fixed dose combination over acclidinium at one hour post-dose and over formoterol at morning pre-dose trough):

1. The first co-primary endpoint consisted of the comparison between the fixed dose combinations of acclidinium/formoterol 400/12mcg and 400/6mcg versus acclidinium alone in change from baseline in FEV1 at 1 hour post-dose at week 24. The acclidinium/formoterol 400/12mcg and 400/6mcg achieved statistically significant improvements compared with acclidinium 400mcg (108mL and 87mL, respectively).
2. The second co-primary endpoint consisted of the comparison between the fixed dose combinations of acclidinium/formoterol 400/12mcg and 400/6mcg versus formoterol alone in change from baseline in morning pre-dose trough FEV1 at week 24. The acclidinium/formoterol 400/12mcg demonstrated statistically significant improvement versus formoterol 12mcg (45mL). Acclidinium/formoterol 400/6mcg did not demonstrate statistically significant improvement versus formoterol 12mcg (26mL).

In this AUGMENT/COPD study, the acclidinium/formoterol 400/12mcg and 400/6mcg also demonstrated superior efficacy in the secondary efficacy comparison for each co-primary parameter as compared to placebo, achieving statistically significant benefits 1-hour post-dose FEV1 (284mL and 263mL, respectively) and in trough FEV1 (130mL and 111mL, respectively).

The positive results of the acclidinium/formoterol 400/12mcg combination in this study are consistent with the statistically significant improvement in lung function demonstrated by

acclidinium/formoterol 400/12mcg in the previously completed ACLIFORM/COPD Phase III study.

About the ACLIFORM/COPD Phase III Study

ACLIFORM/COPD (ACLIdinium/FORMoterol fumarate combination for Investigative use in the treatment of moderate to severe COPD) was a 24-week randomized double-blind trial evaluating the 400/6mcg and 400/12mcg fixed dose combinations of acclidinium bromide/formoterol fumarate compared with acclidinium bromide 400mcg, formoterol fumarate 12mcg and placebo administered BID through the Genuair[®]/Pressair[™] inhalers in 1,729 patients with moderate to severe COPD, in 22 countries including Europe, Korea and South Africa.

The full results of both studies will be presented at future scientific meetings.

About acclidinium/formoterol

Acclidinium bromide /formoterol fumarate (400/12mcg and 400/6mcg) are investigational fixed dose combinations of two approved long-acting bronchodilators with different mechanisms of action and similar pharmacodynamic profiles. Acclidinium bromide is an anticholinergic or long-acting muscarinic antagonist (LAMA) that produces bronchodilation by inhibiting the muscarinic M3 receptor in the airway smooth muscle. Formoterol fumarate is a long-acting beta-agonist (LABA) that stimulates the B2-receptors in the bronchial smooth muscle resulting in bronchodilation. Both acclidinium bromide (Tudorza[™]/Elkira[®]) and formoterol fumarate are approved for the maintenance treatment of COPD in the United States and Europe.

Acclidinium/formoterol was administered using a multiple-dose dry powder inhaler, Pressair[™] (outside of the United States the inhaler is marketed as Genuair[®]), which delivers 60 doses of acclidinium bromide/formoterol powder for inhalation. The Pressair[™] inhaler has a colored control window which confirms successful inhalation of the full dose and a dose indicator to let patients know approximately how many doses remain in the inhaler. The Pressair[™]/Genuair[®] inhaler is approved in the United States and Europe for the administration of Tudorza[™]/Elkira[®].

Acclidinium/formoterol combines two effective bronchodilators with complementary mechanisms of action and is being evaluated as a potential treatment for COPD patients who could benefit from two bronchodilators administered in a single multi-dose inhaler.

About COPD

Chronic Obstruction Pulmonary Disease (COPD), or chronic obstructive pulmonary disease, is a common, progressive, and debilitating lung disease characterized by persistent airflow limitation that makes it hard to breathe. 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. WHO predicts that COPD will become the third leading cause of death worldwide by 2030. COPD is already the third leading cause of death in the U.S.

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 chronic cough. As the condition worsens and breathlessness increases, daily activities, such as walking up a short flight of stairs or carrying a suitcase, can become very difficult. New therapies to treat this debilitating disease may be of value.

About Almirall

Almirall is a pharmaceutical company committed to provide valuable medicines from its own R&D, external partnerships, licenses and collaborations. In 2012, Almirall invested over 23% of its sales in R&D. Through seeking innovative medicines we aim to become a relevant player in respiratory and dermatology diseases with also a strong interest in gastroenterology and pain. With around 3,000 employees in 22 countries, Almirall generated total revenues of 900 million Euros in 2012.

The company was founded in 1943 and is headquartered in Barcelona, Spain. The stock is traded in the Spanish stock exchange (ticker: ALM). For more information please visit www.almirall.com

Tudorza™, Eklira®, Genuair® and Pressair™ are registered trademarks of Almirall S.A.

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, respiratory, gastrointestinal and pain management medicine. Forest'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. Forest assumes no obligation to update forward-looking statements contained in this release to reflect new information or future events or developments.

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