

Almirall and Forest Laboratories announce positive results of a Phase III Study for acclidinium and formoterol combination in COPD

- **Acclidinium / formoterol fixed dose combinations twice daily show statistically significant improvements in the two co-primary endpoints in the first pivotal COPD study**
- **A second pivotal Phase III study is still ongoing, results expected in coming weeks**

Barcelona and New York, April 16th, 2013 - Almirall, S.A. (ALM:MC) and Forest Laboratories, Inc. (NYSE:FRX) today announced positive topline results from a six month pivotal phase III clinical trial evaluating the efficacy and safety of fixed dose combinations of acclidinium bromide (LAMA) and formoterol fumarate (LABA) delivered by Almirall's inhaler Genuair[®] (Pressair[™] in the USA).

Both combinations of acclidinium/formoterol (400/6mcg and 400/12mcg twice a day) demonstrated statistically significant improvements in the co-primary endpoints of change from baseline in morning predose trough FEV1 versus formoterol 12mcg and in FEV1 at 1 hour post-dose versus acclidinium 400mcg both at week 24 ($p < 0.01$ and $p \leq 0.0001$, respectively). In addition, both combinations of acclidinium/formoterol (400/6mcg and 400/12mcg) provided statistically significant improvements versus placebo in the above two variables (both $p < 0.0001$).

Both fixed-dose combination treatment arms were well tolerated in this study. The most common adverse events (greater than or equal to 3% and reported more frequently with acclidinium/formoterol than placebo) were nasopharyngitis (7.9% for 400/6mcg and 7.8% for 400/12mcg fixed-dose combinations and 7.2% for placebo) and back pain (3.4% for 400/6mcg and 4.7% for 400/12mcg fixed-dose combinations and 4.6% for the placebo group).

Results from a second pivotal Phase III clinical study are expected in the coming weeks. The successful completion of the second clinical trial combined with the positive results of this study will support our intention to file an NDA to the FDA and a MAA to the EMA.

"We expect this novel combination of acclidinium/formoterol to offer patients a new option in COPD treatment. In addition to the improved efficacy shown in this study, the safety profile was comparable to placebo", commented Bertil Lindmark, Chief Scientific Officer at Almirall. "Indeed, these positive results confirm Almirall's potential to build an innovative worldwide respiratory franchise around our Genuair[®] device and acclidinium bromide (Eklira[®]/Bretaris[®])".

"By successfully achieving the primary endpoints in this pivotal trial, we have demonstrated the superior improvement in lung function that can be achieved by combining two proven bronchodilators with complementary modes of action," said Dr. Marco Taglietti, President of Forest Research Institute. "Acclidinium/formoterol has the potential to further expand the success of the Forest respiratory franchise, which includes Tudorza[™] Pressair[™] (acclidinium bromide 400mcg), as a treatment option for COPD patients who could benefit from additional bronchodilation".

About the 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 1729 patients with moderate to severe COPD, in 22 countries including Europe, Korea and South Africa.

For the co-primary efficacy endpoint of change from baseline in morning pre-dose trough FEV1 at week 24, acclidinium/formoterol 400/6mcg and 400/12 mcg demonstrated statistically significant improvements versus formoterol 12mcg (53mL and 85mL, respectively) and placebo (111mL and 143mL, respectively). For the second co-primary endpoint of change from baseline in FEV1 at 1 hour post-dose also at week 24, acclidinium/formoterol 400/6mcg and 400/12 mcg demonstrated statistically significant improvements versus acclidinium 400mcg (69mL and 125mL, respectively) and placebo (244mL and 299mL, respectively).

The full results of this study will be presented at future scientific meetings.

About Acclidinium/Formoterol

Acclidinium bromide/formoterol fumarate (400/6mcg and 400/12mcg) 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[™]/Eklira[®]) 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 fumarate 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[™]/Eklira[®].

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

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 2030¹. 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 our 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 more than 3,000 employees in 22 countries, Almirall generated total revenues of 900 million 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.

Contact Almirall:

Media information:

Ketchum

Bianca Daneshfar-Nia
bianca.daneshfar-nia@ketchumpleon.com
Tel.: +44 20 76113510

Investor Relations enquiries:

Almirall

Jordi Molina
jordi.molina@almirall.com
Tel.: +34 93 291 30 87

Contact Forest:

Forest Laboratories, Inc.
Frank J. Murdolo, 212-224-6714
Vice President - Investor Relations
media.relations@frx.com

ⁱ WHO Burden of COPD