



## **FOREST LABORATORIES AND ALMIRALL PROVIDE UPDATE ON THE FIXED DOSE COMBINATION OF ACLIDINIUM AND FORMOTEROL IN THE U.S.**

**NEW YORK & BARCELONA**, April 9, 2014 – Forest Laboratories, Inc. (NYSE: FRX) and Almirall, S.A. (ALM:MC) today announced that they have recently received feedback from the U.S. Food and Drug Administration (FDA) regarding the fixed dose combination of aclidinium and formoterol. Although no new issues have arisen, further discussion is needed with the Agency in order to address questions related to CMC (Chemistry, Manufacturing and Control) and a Type C meeting with the FDA is going to be requested, likely to be held during Q3 this year. Forest and Almirall believe that the fixed dose combination of .aclidinium and formoterol can be an important therapy for U.S. COPD patients.

### **About Aclidinium/formoterol**

Forest and Almirall completed two pivotal phase III clinical trials for aclidinium/formoterol in the spring of 2013. The combination was administered twice a day and primary end points were met which demonstrated statically significant improvements versus placebo. In addition, aclidinium/formoterol was well tolerated in both studies.

Aclidinium bromide /formoterol fumarate is an investigational fixed dose combination of two approved long-acting bronchodilators with different mechanisms of action and similar pharmacodynamic profiles. Aclidinium 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 aclidinium bromide (Tudorza<sup>®</sup>/ Eklira<sup>®</sup>) and formoterol fumarate are approved for the maintenance treatment of COPD in the United States and Europe.

## **About Almirall**

Almirall is a pharmaceutical company committed to provide valuable medicines through our own R&D efforts, which exceeded 18% on sales in 2013, together with external partnerships, licenses and collaborations. 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 3000 employees in 23 countries, Almirall generated total revenues of 825 million euros in 2013.

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](http://www.almirall.com)

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## **About Forest Laboratories**

Forest Laboratories (NYSE: FRX) is a leading, fully integrated, specialty pharmaceutical company largely focused on the United States market. The Company markets a portfolio of branded drug products and develops new medicines to treat patients suffering from diseases principally in the following therapeutic areas: central nervous system, cardiovascular, gastrointestinal, respiratory, anti-infective, and cystic fibrosis. Our strategy of acquiring product rights for development and commercialization through licensing, collaborative partnerships, and targeted mergers and acquisitions allows us to take advantage of attractive late-stage development and commercial opportunities, thereby managing the risks inherent in drug development. The Company is headquartered in New York, NY. To learn more, visit [www.FRX.com](http://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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