Almirall and Forest Laboratories announce FDA approval of Tudorza™ Pressair™ for the long-term maintenance treatment of COPD

- **COPD is currently the third leading cause of mortality in the USA**
- **Tudorza™ Pressair™ (aclidinium bromide inhalation powder) will be available in the fourth quarter 2012**
- **European approval of aclidnium expected in Q3 2012**

Barcelona, Spain and New York, USA, July 24th, 2012 - Almirall, S.A. (ALM.MC) and Forest Laboratories, Inc. (NYSE:FRX) announced that the U.S. Food and Drug Administration (FDA) has approved Tudorza™ Pressair™ (aclidinium bromide inhalation powder) for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

COPD is a common, progressive, and debilitating lung disease characterized by persistent airflow limitation that makes it hard to breathe; it is currently the third leading cause of mortality in the US. Characteristic symptoms include breathlessness, excessive production of sputum, and a chronic cough.

Tudorza™ is a twice-daily inhaled long-acting anticholinergic, also referred to as a long-acting muscarinic antagonist (LAMA). Tudorza™ produces bronchodilation by inhibiting acetylcholine's effect on muscarinic receptors in the airway smooth muscle. Forest expects Tudorza™ Pressair™ to be available to wholesalers in the fourth calendar quarter of 2012.

"The FDA approval of Tudorza™ Pressair™ demonstrates our steadfast commitment to the development of respiratory compounds, such as aclidinium, innovative delivery devices, and our unfailing belief in their potential for the treatment of COPD. Today, we celebrate this achievement for our company and, most importantly, for the patients we serve," commented Jorge Gallardo, President of Almirall.

"We are pleased with the FDA approval of Tudorza. As the first long-acting inhaled anticholinergic agent approved in over 8 years for COPD, Tudorza will be an important treatment option available for the millions of patients living with this serious disease. Tudorza's approval marks an important milestone in our ongoing partnership with Almirall and advances Forest's respiratory franchise and our commitment to COPD patients," commented Howard Solomon, Chairman, Chief Executive Officer, and President of Forest Laboratories.

Professor Richard Casaburi, MD, Associate Chief for Research in the Division of Respiratory and Critical Care Physiology and Medicine, Harbor-UCLA Medical Center, stated, *"the Global Initiative for Chronic Obstructive Lung Disease 2011 guidelines recommend long-acting anticholinergics as a first-line therapy for a broad range of COPD patients with moderate to very severe disease. Tudorza will be a valuable anticholinergic option in the clinical armamentarium available to manage this serious disease."*

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Data Highlights
The Tudorza™ Pressair™ clinical development program included a dose-ranging trial and 3 confirmatory pivotal trials. The two 12-week and one 24-week pivotal placebo-controlled trials evaluated the efficacy and safety of Tudorza™ 400 mcg twice daily in 1,277 patients. Patients enrolled in these trials had a clinical diagnosis of COPD, were 40 years of age or older, had a smoking history of at least 10 pack-years, a post-bronchodilator forced expiratory volume in one second (FEV_1) of at least 30% and less than 80% of predicted normal value, and a ratio of FEV_1 over forced vital capacity (FEV_1/FVC) of less than 0.7.

In all 3 pivotal trials, Tudorza™ Pressair™ demonstrated statistically significant improvements in bronchodilation, as measured by change from baseline in morning pre-dose trough FEV_1 at 12 weeks (the primary endpoint) compared to placebo. The mean 12-week pre-dose FEV_1 improvements vs placebo were 0.12 L, 0.07 L, and 0.11 L in the 3 trials, with a 24-week improvement of 0.13 L in the 6-month trial. Mean peak improvements in lung function assessed after the first dose of Tudorza were similar to those observed at week 12 in each study. Tudorza™ had a low incidence of side effects in these trials.

The most common adverse reactions that occurred in the Tudorza™ Pressair™ group with a frequency of greater than or equal to 3% and exceeding placebo were headache (6.6% vs 5.0%), nasopharyngitis (5.5% vs 3.9%), and cough (3.0% vs 2.2%). Three long-term safety studies, evaluating 891 patients treated with Tudorza™ Pressair™ 400 mcg twice daily for 40 to 52 weeks reported similar adverse events, with no new safety findings compared to the placebo-controlled trials.

Additionally, serial spirometric evaluations of FEV_1 were performed over 12 hours in a subset of patients in the three trials. Improvement of lung function with Tudorza™ Pressair™ versus placebo was achieved for the first 12 hours on day 1 and was consistent over the 3- or 6-month treatment period evaluated.

In two of the three trials, patients treated with Tudorza Pressair also used less daily rescue albuterol compared to placebo treated patients.

About Tudorza™ Pressair™
Tudorza™ Pressair™ (aclidinium bromide inhalation powder) 400 mcg is an anticholinergic indicated for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. When given by inhalation, aclidinium produces bronchodilation by inhibiting the muscarinic M3 receptor in the airway smooth muscle. Aclidinium is rapidly hydrolyzed in human plasma into two major inactive metabolites.

Tudorza is administered using a multiple-dose dry powder inhaler, Pressair, which delivers 60 doses of aclidinium bromide powder for inhalation. The Pressair inhaler has a colored control window and audible “click” which confirm successful inhalation of the dose and a dose indicator to let patients know the approximate number of doses remaining in the inhaler.

In 2005, Forest Laboratories, Inc. licensed U.S. rights for aclidinium from Almirall, while Kyorin Pharmaceutical Co., Ltd holds marketing rights in Japan and Daewoong Pharmaceutical Co., Ltd is licensed to market aclidinium in Korea. Almirall has recently given rights of joint commercialization in the majority of European member states and a number of non-EU countries to Menarini. Almirall maintains rights for the rest of the world.

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 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. Daily activities, such as walking up a short flight of stairs or carrying a suitcase, can become very difficult as the condition gradually worsens. New therapies to treat this debilitating disease may be of value.

Important Safety Information
Tudorza™ Pressair™ is not indicated for the initial treatment of acute episodes of bronchospasm (i.e., rescue therapy).

Inhaled medicines, including Tudorza, may cause paradoxical bronchospasm. If this occurs, treatment with Tudorza should be stopped and other treatments considered.

Tudorza should be used with caution in patients with narrow-angle glaucoma or urinary retention. Instruct patients to consult a physician immediately should any signs or symptoms of narrow-angle glaucoma or prostatic hyperplasia or bladder-neck obstruction develop.

Immediate hypersensitivity reactions may occur after administration of Tudorza. If such a reaction occurs, therapy with Tudorza should be stopped at once and alternative treatments considered. Patients with a history of hypersensitivity reactions to atropine should be closely monitored for similar hypersensitivity reactions to Tudorza. Use with caution in patients with severe hypersensitivity to milk proteins.

About Almirall
Almirall is an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, it researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing. Almirall focuses its research resources on respiratory, gastrointestinal, dermatology and pain. Almirall's medicines are currently present in over 70 countries in the five continents. It has direct presence in Europe and Mexico through 12 affiliates.

For further information please visit: 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, 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 rerelease to reflect new information or future events or developments.