



Almirall and Forest announce regulatory submission of acclidinium bromide for the treatment of COPD in the USA

- Regulatory filing in Europe is on-track as planned

Barcelona and New York, June 30th, 2011.- Almirall, S.A. (ALM.MC) and Forest Laboratories, Inc. (NYSE: FRX) announced today the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for acclidinium bromide, a long-acting inhaled antimuscarinic agent developed for the treatment of Chronic Obstructive Pulmonary Disease (COPD).

The submission includes efficacy data from a large Phase III double-blind placebo-controlled program in which patients received acclidinium bromide 400 mcg or 200 mcg twice daily or placebo. In the pivotal studies, acclidinium 400 mcg twice-a-day, the proposed to-be-marketed dose, produced significant improvement in morning trough FEV₁ versus placebo at week 12 ($p < 0.0001$), the primary endpoint assessed as support for the U.S. NDA, and at week 24 ($p < 0.0001$), which was the primary endpoint assessed in one study as support for a European filing.

Additionally, safety data collected from the Phase III program demonstrated that acclidinium 400 mcg twice-a-day was generally well tolerated, with an incidence of adverse events that was low and similar across the study treatment arms. The most commonly reported adverse reactions were headache and nasopharyngitis.

About acclidinium bromide

Acclidinium bromide is a novel, long-acting inhaled antimuscarinic agent, which is often referred to as an anticholinergic that has a long residence time at M3 receptors and a shorter residence time at M2 receptors. When given by inhalation, acclidinium leads to bronchodilation by inhibiting airway smooth muscle contraction. Acclidinium is rapidly hydrolyzed in human plasma to two major inactive metabolites. Forest Laboratories, Inc. licensed U.S. 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 was administered to patients in the trials using a novel, investigational, state-of-the-art multidose dry powder inhaler (MDPI). This 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.

About COPD

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.

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 and new therapies may be of value.

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), gastrointestinal disorders, 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: 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 and respiratory 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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