Almirall and Forest Laboratories Announce Positive Results of Clinical Studies for Aclidinium Bromide, A Novel Long-Acting Anticholinergic for the Treatment for COPD

- **Data Presented at the 2008 International Conference of the American Thoracic Society**

Toronto, May 20th, 2008 – Laboratorios Almirall, S.A. and Forest Laboratories, Inc. today presented results from four clinical trials assessing the efficacy and safety of aclidinium bromide, an investigational treatment for chronic obstructive pulmonary disease (COPD). Data from four preclinical studies further describing the properties of aclidinium were also presented at the meeting.

Presentations included data from a 464-patient randomized, double-blind, four-week, Phase IIb study that evaluated both the efficacy and tolerability of once-daily aclidinium (25 mcg, 50 mcg, 100 mcg, 200 mcg or 400 mcg) or placebo in patients with moderate to severe COPD. An open-label tiotropium (18 mcg) arm was included as an active control. The study demonstrated aclidinium (200 mcg and 400 mcg), administered via a multi-dose dry powder inhaler, significantly increased trough (24 hour) forced expiratory volume in one second (FEV_1) - an important measure of lung function - on Day 29 compared with placebo ($p<0.05$ vs placebo).[1] There was a dose response observed for lung function improvement with once-daily aclidinium. Aclidinium was well-tolerated, with no dose-dependent effect on ECG, laboratory parameters, or adverse events.[1] Overall, the most frequently reported adverse events were headache (4.1% of patients), dry mouth (2.8% of patients), exacerbation of chronic obstructive airways disease (1.7% of patients) and cough (1.7% of patients). Based on these results, aclidinium 200 mcg administered once every 24 hours was selected as the dose for investigation in the two ongoing Phase III clinical trials, ACCLAIM COPD I and II, which are expected to report out during the second half of this year.[1]

"These clinical data suggest that aclidinium may be a valuable treatment option for patients suffering from COPD," said Dr. Jorge Gallardo, Chairman and Chief Executive Officer of Almirall. "We remain committed to our partnership with Forest Laboratories to jointly develop aclidinium."

Additional Clinical Data

Three additional clinical trials assessing the safety and pharmacokinetics of aclidinium were also presented at this meeting.

A randomized, double-blind, placebo- and active-controlled clinical trial evaluating the cardiovascular safety and pharmacokinetics of aclidinium (200 or 800 mcg) in 272 healthy subjects, showed no effect on QT interval at doses up to 800 mcg.[2] Furthermore, aclidinium was well-tolerated, with most adverse events being of mild intensity, related to electrode attachment, and of similar incidence across treatment groups.[2] Maximum concentration of aclidinium was reached 5 to 30 minutes post-dose and aclidinium was not detectable in the plasma after one hour.

Results of two other randomized, placebo-controlled studies, each in 16 healthy subjects, were presented. In the first, subjects were exposed to single doses of aclidinium (600-6000

mcg) and placebo to determine pharmacokinetics, safety and tolerability, and maximum tolerated dose. For all doses, aclidinium was undetectable in plasma beyond 3 hours post-dose.[3] Aclidinium was well tolerated across this dosage range, with headache (n=10) and fatigue (n=5) being the most frequently reported adverse events. No serious adverse events were reported.[3] The second study assessed the safety, tolerability, and pharmacokinetics of aclidinium after multiple doses. Subjects received 5 days of treatment with aclidinium 200, 400, and 800 mcg or placebo. Aclidinium was undetectable in plasma after all studied doses beyond 1 hour post-dose.[4] Aclidinium was well tolerated at all doses and the majority of AEs were considered mild. The most commonly reported adverse events were coughing (n=2) and dysphagia (n=1). One serious AE (hospitalization due to severe diarrhea) occurred after the last dose of 800 mcg and was judged by the investigator as unrelated to treatment. There were no clinically relevant changes in laboratory parameters, vital signs or ECG.[4]

"There are still significant unmet needs in the treatment of COPD. These efficacy and safety data from the Phase II trials are very encouraging," said Lawrence S. Olanoff, M.D., Ph.D., President and Chief Operating Officer of Forest Laboratories. "We look forward to the completion of ACCLAIM I & II trials and continuing the clinical development of aclidinium for the treatment of COPD."

Results of pre-clinical animal and *in vitro* studies announced at the meeting showed that aclidinium exhibited low potential for cardiovascular effects and was broken down in the plasma within 1.8 to 38 minutes, across the models studied.[5] In addition, aclidinium had a potent and long-lasting effect on preventing bronchoconstriction in both the human bronchi and several animal models assessed. [6,7]

Abstracts from ATS 2008 will be available upon request.

About Aclidinium Bromide
Aclidinium bromide is a novel inhaled anticholinergic bronchodilator that is currently in phase III clinical development as a once-daily maintenance treatment for COPD. Almirall licensed US rights to aclidinium to Forest Laboratories, whilst keeping rights for the rest of the world. The companies are jointly involved in the development of the compound.

About COPD
COPD is a preventable and treatable lung disease characterized by chronic airflow limitation that interferes with normal breathing and is not fully reversible.[8] Globally, an estimated 80 million people have moderate to severe COPD. In excess of 3 million people died of the condition in 2005, accounting for 5% of all deaths worldwide.[9]

About Almirall
Almirall, an international pharmaceutical company based on innovation and committed to health, headquartered in Barcelona, Spain, researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing.

The therapeutic areas on which Almirall focuses its research resources are related to the treatment of COPD (Chronic Obstructive Pulmonary Disease), asthma, psoriasis, rheumatoid arthritis and multiple sclerosis.

Almirall's medicines are currently present in over 70 countries with direct presence in Europe and Latin America.

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About Forest Laboratories

Forest Laboratories is a U.S.-based pharmaceutical company dedicated to identifying, developing, and delivering products that make a positive difference in people's lives. Forest Laboratories' growing product line includes Lexapro(R) (escitalopram oxalate), an SSRI indicated for adults for the initial and maintenance treatment of major depressive disorder and generalized anxiety disorder; Namenda(R) (memantine HCl), an N-methyl-D-aspartate (NMDA)-receptor antagonist indicated for the treatment of moderate to severe Alzheimer's disease; Campral(R)* (acamprosate calcium), indicated in combination with psychosocial support for the maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation; and Bystolic(R) (nebivolol), a beta-adrenergic receptor blocking agent indicated for the treatment of hypertension. For more information, visit www.frx.com.

* Campral is a registered trademark of Merck Santé s.a.s., a subsidiary of Merck KGaA, Darmstadt, Germany.

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.

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2 Lasseter KC, Aubets J, Gil E Garcia. Aclidinium bromide, a novel long-acting anticholingergic, does not affect QT interval in health subjects. American Thoracic Society, May 2008. Poster.
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9 World Health Organisation (WHO). Chronic obstructive pulmonary disease (COPD). Factsheet number 315; November 2006.