

Almirall strengthens its focus on the twice-daily dosing of Eklira[®] in Chronic Obstructive Pulmonary Disease (COPD)

- Improved efficacy (trough FEV₁) values and good tolerability in the recent Phase III study have triggered the strategic decision to focus on twice daily (BID) development.
- Almirall's strategy is aligned with the opinion of European regulatory experts consulted.
- Regulatory filing of Eklira^{®1} (aclidinium bromide) BID is targeted for 2011.

Barcelona, January 27th, 2010 - Following the positive top-line results from the first Phase III study of Eklira[®] twice daily (ACCORD COPD I) versus placebo and the positive findings from a Phase II study announced early this month², Almirall, S.A. (ALM.MC) today announced its decision to give full priority to the development and filing of the BID dosing of Eklira[®] (aclidinium bromide), putting on hold the filing of the once daily regimen.

«This strategic decision has been taken following discussions with European regulatory experts and key opinion leaders from which it became clear that BID dosing is likely to provide a superior benefit for COPD patients. Focusing on BID also has the benefit to increase the likelihood of product approval and long-term value for shareholders» said Jorge Gallardo, President – Chief Executive Officer, Almirall. *«We believe that this decision strengthens the opportunity for the Eklira[®] franchise (both monotherapy and in combination with formoterol) to generate worldwide blockbuster potential»* he added.

Two additional placebo-controlled Phase III studies (ACCORD COPD II and ATTAIN) assessing efficacy and safety in patients with COPD are currently underway. Results from these studies are expected to be available between the second half of 2010 and early 2011.

This decision also keeps on track the current development plan of registering a fixed dose combination of aclidinium with formoterol BID, which continues as planned. In line with this, two Phase IIb studies of aclidinium and formoterol are ongoing and top-line results expected at the end of the year.

Summary of the latest positive results with Eklira[®] BID

Earlier in January 2010, positive top-line results were announced from ACCORD/COPD I comparing Eklira 200µg and 400µg twice-daily versus placebo which produced statistically significant ($p < 0.0001$) changes from baseline in morning pre-dose FEV₁ (trough) vs placebo at week 12. Changes from baseline values were 86mL and 124mL for 200µg and 400µg twice-daily, respectively. Eklira[®] was well tolerated and the percentages of patients reporting adverse events and serious adverse events were similar across the study treatment arms.

Consistent with these Phase III results, positive findings from a Phase II study comparing aclidinium 400µg twice-daily, tiotropium 18µg once-daily and placebo demonstrate that both products showed a statistically significant difference in normalised AUC (0-12 hours) FEV₁ compared to placebo ($p < 0.001$), but in terms of normalised AUC (12-24 hours) FEV₁ Eklira[®] was significantly higher ($p = 0.020$) than tiotropium.

Endpoint Definitions

- **FEV₁** - Forced expiratory volume in one second, or the amount of air that can be exhaled in the first second, following an inhalation.
- **Morning trough FEV₁** - average of two FEV₁ measurements within 1 hour before morning treatment administration.

- **Normalized AUC (0-12 hours, 12-24 hours) FEV₁** - Average area under the FEV₁ curve over 12 hours, from dosing in the morning until pre-dose twelve hours later (0-12 hours), and from dosing in the evening through the night until pre-dose the next morning (12-24 hours), respectively.

About Eklira[®] and the Genuair[®] inhaler

Eklira[®] (acridinium bromide) is a novel, long-acting inhaled anticholinergic bronchodilator which has a long residence time at the M3 receptors and a shorter residence time at the M2 receptors. It is rapidly hydrolyzed in human plasma to two major inactive metabolites. Forest Laboratories, Inc. licensed US rights for Eklira[®] from Almirall, while Almirall maintains rights for the rest of the world. The companies are jointly involved in the development of the compound.

Eklira[®] is administered to patients using a novel, state-of-the-art multidose dry powder inhaler (MDPI), Genuair[®]. The Genuair[®] inhaler was designed with an easy-to-use intuitive feedback system, which through a 'colored control window' and an audible click confirms that the patient has inhaled correctly. It contains multiple doses of Eklira[®], and includes a visible dose level indicator and also incorporates significant 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 COPD³

The World Health Organisation (WHO) has described COPD as a global epidemic; an estimated 210 million people have COPD worldwide and 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 including limited therapeutic options to improve lung function, reduce symptoms and control exacerbations.

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 asthma, COPD (Chronic Obstructive Pulmonary Disease), rheumatoid arthritis, multiple sclerosis, psoriasis and dermatology in general.

Almirall's products are currently present in over 70 countries while it has direct presence in Europe and Latin America through 11 affiliates.

For further information, please visit www.almirall.com

¹ Eklira and Genuair[®] are trademarks owned by Almirall, S.A. and is pending approval from the appropriate regulatory authorities.

² Press release: 07/01/2010 - Almirall and Forest announce positive results from the ACCORD COPD I Phase III study of acridinium bromide in Chronic Obstructive Pulmonary Disease (COPD) – URL: http://www.almirall.com/webcorp2/cda/comunicacion_detalle_noticia.jsp?id=1306.

³ World Health Organisation (WHO): Chronic obstructive pulmonary disease (COPD), Fact Sheet 315. Website page available at: <http://www.who.int/mediacentre/factsheets/fs315/en/>