

## **Abediterol, Almirall's OD LABA shows superiority vs indacaterol in Phase IIa**

- **Almirall's once daily (OD) LABA, abediterol, shows superior and sustained bronchodilation compared with indacaterol (150µg OD) in patients with COPD at specific doses from 2,5 to 10µg**
- **Abediterol is now set to move into Phase IIb trials as a once-daily fixed dose combination (FDC) with an inhaled corticosteroid (ICS), in asthma and COPD**
- **Almirall is evaluating different partnering options, to leverage the multibillion<sup>6</sup> market potential for abediterol/ICS fixed dose combination OD**

**Barcelona, June 6<sup>th</sup> 2012.-** Almirall, S.A. (ALM.MC) today announced the positive results of a single dose study where abediterol once a day (OD), delivered in the Genuair<sup>®</sup> inhaler provided significantly greater bronchodilation when compared with indacaterol and placebo in Chronic Obstructive Pulmonary Disease (COPD) patients.

In this Phase IIa study, change from baseline in trough FEV<sub>1</sub> following a single dose administration of a range of abediterol doses below 10µg once daily showed a statistically significant improvement vs placebo ( $p < 0.001$  for all abediterol doses) and, also, vs indacaterol 150µg ( $p < 0.001$  for abediterol doses of 2.5, 5 and 10µg). These comparative results reinforce abediterol as a new once-daily long acting  $\beta_2$  agonist (LABA) that potentially provides added bronchodilation effect when compared to indacaterol, the only OD LABA currently in the market. Abediterol was delivered in Almirall's multidose dry powder inhaler Genuair<sup>®</sup>.

Abediterol once-daily in fixed dose combination (FDC) with an inhaled corticosteroid (ICS) is now ready to move into Phase IIb clinical development worldwide for asthma and COPD. Pharmacokinetic and drug-drug interaction studies on the abediterol/ICS fixed dose combination in man have also been conducted and recently finalized.

Almirall is now focusing on a value development plan for the ex-USA territories that should enable a rapid market entry in this expanding therapeutic area. The company is evaluating partnering alternatives to enhance the development and commercialisation of this new respiratory treatment.

*"We are excited as we now understand the fundamental properties of the components and of the whole of our abediterol/ICS once daily combination"* said Dr. Bertil Lindmark, Chief Scientific Officer of Almirall. *"We have the opportunity to develop an excellent once daily combination in our proprietary Genuair<sup>®</sup> multidose dry powder inhaler"* he added.

The study complements a comprehensive Phase IIa program where different doses of abediterol demonstrated a fast onset (five minutes after the first administration for most of the doses tested) and long-lasting (24-hour) efficacy profile ( $p < 0.001$ , trough FEV<sub>1</sub> [23h-24h] after single doses of abediterol above 0.625µg) compared to placebo. Abediterol also showed a good safety and tolerability profile in patients with mild to moderate persistent asthma after multiple dosing (incidence of treatment-emergent adverse events with the abediterol dose of 10µg -after 7 days- was comparable to placebo [50% vs 46.7% respectively]).

In addition, abediterol (5, 10 and 25µg doses) demonstrated clinically and statistically significant improvements in trough FEV<sub>1</sub> in a head to head comparison vs salmeterol Accuhaler® 50µg BID (p<0.001) in a single-dose cross over treatment study in stable persistent asthmatic patients.

Almirall's respiratory pipeline is led by its aclidinium franchise for the treatment of COPD. In Europe, aclidinium has just received a positive opinion from the CHMP of the European Medicines Agency and final regulatory approval is due within the coming three months. Aclidinium was also recommended for approval at the FDA Advisory Board (PADAC) held in February 2012 and US regulatory feedback is expected by the middle of this year. A fixed-dose combination product (aclidinium and formoterol) is currently in phase III development for the USA and Europe.

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**Notes to editors**

**About asthma, COPD and LABAs**

Asthma is a chronic disease of the bronchi (the airways leading to and from the lungs) with an estimated 235 million affected individuals<sup>1</sup>. The global prevalence of asthma ranges from 1% to 18% of the population<sup>2</sup> and it is considered to be one of the most common chronic diseases worldwide<sup>3</sup>. In asthma management, addition of an inhaled long-acting β<sub>2</sub>-agonist to a daily regimen of inhaled glucocorticosteroids is the preferred treatment<sup>4</sup>, when the latter fails to achieve control of asthma when given alone. This greater efficacy of combination treatment has led to the development of fixed combination inhalers that deliver both glucocorticosteroid and long-acting β<sub>2</sub>-agonist, simultaneously.

COPD represents another condition where the concomitant use of a LABA and an ICS can influence both airway obstruction, and airway inflammation. They are also able to reduce the total number of bacteria adhering to the respiratory mucosa in a concentration-dependent manner without altering the bacterial tropism for mucosa, and to preserve ciliated cells. Several clinical trials support the concept of inhaled combination therapy with LABAs and corticosteroids in stable COPD patients. This type of therapy not only improves airflow obstruction but also provides clinical benefits, as manifested by sustained reduction in overall symptoms, improvements in health-related quality of life, and reductions in exacerbations<sup>5</sup>.

Fixed-dose combinations of twice daily inhaled long-acting inhaled β<sub>2</sub>-agonists with glucocorticosteroids have become the most widely used respiratory class and the introduction of highly efficacious LABA/ICS products will be the next generation in this growing therapeutic class<sup>6</sup>.

**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 products 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 the website at: [www.almirall.com](http://www.almirall.com)

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<sup>1</sup> WHO - Fact sheet N°307 - May 2011

<sup>2</sup> Masoli M, Fabian D, Holt S, et al. The global burden of asthma: executive summary of the GINA Dissemination Committee Report. Allergy 2004;59:469–78.

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<sup>3</sup> Bousquet J, Bousquet PJ, Godard P, et al. The public health implications of asthma. Bull WHO 2005;83:548–54.

<sup>4</sup> Do inhaled corticosteroid/long-acting beta2-agonist fixed combinations provide superior clinical benefits compared with separate inhalers? A literature reappraisal - Barnes, Peter J.; et al - Allergy and Asthma Proceedings, Volume 33, Number 2, March/April 2012 , pp. 140-144(5)

<sup>5</sup> Inhaled Combination Therapy With Long-Acting  $\beta$ 2-Agonists and Corticosteroids in Stable COPD\* - Mario Cazzola, MD, FCCP; and Ronald Dahl, MD - CHEST 2004; 126:220–237

<sup>6</sup> IMS World Review 2011 – Top 100 therapeutic áreas – Five Year worldwide audited sales by 3rd level therapeutic class. (ATC3).