

## **New strategic direction for Almirall's OD LABA, following successful Phase IIa completion**

- **Almirall's OD LABA (Abediterol) is set to move into Phase IIb development worldwide (ex-US) as a fixed dose OD LABA/ICS in the Genuair® inhaler**
- **Almirall and Forest have agreed to conclude the US development due to the increasingly challenging LABA market environment in the US**
- **Abediterol targets the largest product category in the asthma and COPD respiratory markets which are currently valued (ex-US) at € 5.8 Bn and growing at +6% yearly**

**Barcelona, May 18th 2012.-** Almirall, S.A. (ALM.MC) today announced the positive conclusion of Abediterol's Phase IIa, which is now set to move into Phase IIb worldwide (ex-US) as a fixed dose OD LABA/ICS in the Genuair® inhaler.

Additionally, the collaboration with Forest to develop, market and distribute Abediterol in the US has been discontinued. The basis of this joint decision is the increasingly challenging market environment in the US for LABA based products.

Abediterol is a highly potent novel once daily LABA which, combined with an ICS, recently completed Phase IIa testing. Abediterol demonstrated fast onset and long-lasting (24-hour) efficacy with a very good tolerability profile in patients with stable asthma after single and multiple dosing. Abediterol has also demonstrated clinically and statistically significant improvements in lung function in direct head to head comparisons with other LABA's such as Salmeterol (BID), high dose Salbutamol and Indacaterol (OD). The compound is now ready to move forward into Phase IIb.

Abediterol is delivered through the novel and patient friendly multidose dry powder inhaler - Genuair®.

*"Based on Phase II clinical evidence, Abediterol has the potential to become the key component in a best-in-class once daily LABA/ICS treatment option for Asthma and COPD"* said Dr. Bertil Lindmark, Chief Scientific Officer of Almirall. *"The excellent efficacy and safety profile, together with the 24h coverage and the novel Genuair® device provides a strong basis to offer a new effective treatment to millions of patients".*

Almirall intends to continue the development of Abediterol combined with an ICS outside the US where it is evaluating partnering options. Almirall's value development plan for the ex-US territories should enable a rapid market entry in this expanding therapeutic area.

Almirall's respiratory pipeline is led by its acclidinium bromide franchise for COPD. The monotherapy was filed for registration in the US and Europe in 2011 and is expecting regulatory feedback by the middle of this year while acclidinium plus formoterol is now in phase III.

### **About asthma, COPD and LABAs**

Asthma is a public health problem worldwide, with an estimated 300 million affected individuals. The global prevalence of asthma ranges from 1% to 18% of the population in different countries. In asthma management, addition of an inhaled long-acting  $\beta$ 2-agonist to a daily regimen of inhaled glucocorticosteroids is the preferred treatment, 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  $\beta$ 2-agonist, simultaneously.

Despite the high efficacy of fixed-dose combinations of LABA and ICS in controlling asthma for the majority of patients, there is still a significant unmet need to effectively achieve full asthma control, and this is in part believed to be due to poor compliance with the currently available LABA/ICS products, which require twice daily dosing.

COPD represents another condition where the use of inhaled long-acting  $\beta$ 2-agonists combined with inhaled glucocorticosteroids is well established.

Fixed-dose combinations of twice daily inhaled long-acting inhaled  $\beta$ 2-agonists with glucocorticosteroids have become the most widely used respiratory class and the introduction of once daily LABA/ICS products will be the next generation in this growing therapeutic class.

### **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)

**More information:**

Ketchum Pleon

Sonia San Segundo

[sonia.sansegundo@ketchumpleon.com](mailto:sonia.sansegundo@ketchumpleon.com)

Tel.:34 91 788 32 00