



Almirall and Menarini sign a licence agreement and commercial alliance for Acclidinium in the majority of European member states and a number of non-EU countries

- **Partnership fulfills Almirall's key criteria: territorial complementarity, non-competing portfolio assets, strong primary care capabilities and proven track record**
- **Acclidinium, a new therapeutic option, is awaiting regulatory feedback in the US and Europe, while partnerships have already been established in the US, Japan and Korea**
- **Chronic Obstructive Pulmonary Disease (COPD) affects nearly 44 million people in Europe¹ and is considered by the World Health Organization (WHO) a global epidemic**

Barcelona and Firenze, 26 March 2012. - Almirall and Menarini announce an agreement by which Almirall grants Menarini marketing rights for Acclidinium in most EU and other European countries for the treatment of COPD. The agreement includes both Acclidinium monotherapy and its combination with Formoterol.

Menarini will have joint commercialisation rights across the majority of EU member states (excluding the UK, the Netherlands and the Nordic countries where Almirall retains sole marketing rights for the product) as well as Russia, Turkey and other CIS countries.

In the territories for which Menarini holds rights to market Acclidinium, it currently has a commercial infrastructure of over 5,000 sales representatives. These strong commercial capabilities and excellent track record in partnering have been key for Almirall in selecting Menarini. The commercial capabilities of Menarini are especially strong in Germany, Italy and France as well as Turkey, Central and Eastern Europe.

Eduardo Sanchiz, Chief Executive Officer of Almirall, commented: "*Amongst a number of interested partner candidates, Menarini stood out as it combines a powerful commercial platform with an impressive track record in successfully commercialising distinctive medicines. This brings a strong commitment to maximizing the value of the Acclidinium franchise. Our joint efforts will extend Acclidinium and its combination as a new therapeutic option to a broad range of physicians and patients*", he said.

COPD affects nearly 44 million people in Europe¹ and is considered by WHO a global epidemic.

Alberto Giovanni Aleotti, Member of the Board of Menarini Group stated: "*We are proud to have undertaken this agreement with Almirall, a company which represents an EU gold standard of leadership, scientific value, and efficiency. We are pleased that the cooperation between our two companies on Acclidinium will bring improvement to the quality of life of COPD sufferers in Europe*".

¹ European Lung Foundation

Aclidinium, a new therapeutic option coming from Almirall's respiratory R&D, was filed for registration in the US and Europe in 2011, and regulatory feedback is expected within 2012. With this new licence-out agreement, Almirall extends the global reach of its research respiratory compound. Previous partnerships have been already established in the US, Japan and Korea.

Additionally, Phase III of the combination of Aclidinium + Formoterol BID² in COPD is underway with global clinical trials to meet regulatory requirements for both North American and European authorities.

About Aclidinium and the Genuair[®] inhaler

Aclidinium bromide is a novel, long-acting inhaled muscarinic antagonist -sometimes referred to as an anticholinergic-, which has a long residence time at M3 receptors and a shorter residence time at M2 receptors, and which is designed to be rapidly broken down in plasma, leading to high topical efficacy but low propensity for systemic anticholinergic effects. When given by inhalation, aclidinium leads to bronchodilation by inhibiting airway smooth muscle contraction. Aclidinium bromide is rapidly hydrolyzed in human plasma to two major inactive metabolites. Almirall has licensed-out aclidinium bromide to Forest for USA, Kyorin for Japan and Daewoong in Korea. Almirall and Forest are jointly involved in the development of the compound.

Aclidinium was administered to patients in the trials using a novel, state-of-the-art, user-friendly multidose dry powder inhaler (MDPI), Genuair[®]. This inhaler was designed with a "click and colour" feedback system which, through a 'coloured control window' and an audible click, indicates that the patient has inhaled the dose correctly. It also incorporates safety features such as a visible dose indicator, 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.

The most common symptoms of COPD are breathlessness (an increased effort to breathe), heaviness or a 'need for air', excessive mucus, and a chronic cough. Some people feel they are gasping for breath. These symptoms get worse when exercising, in case of a respiratory infection or during an exacerbation – periods of time when there is a sudden increase in symptoms and the disease is worse. COPD affects the ability to breathe and is a progressive disease, which means that COPD gets worse over time. Daily activities may become more difficult as the disease 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 commercialises 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 the website at: www.almirall.com.

² BID: twice daily

About Menarini

Menarini is an international pharmaceutical company which, with a 2011 consolidated worldwide turnover of more than **3 billion Euro**, ranks **15th in Europe and 34th world-wide***.

Menarini's territorial presence covers more than 100 countries in Europe, Africa, Asia, Australia and Latin America, with a **headcount of more than 13,000**. Menarini was founded 125 years ago and currently markets products for the most important therapeutic fields: respiratory, cardiovascular, gastroenterology, oncology, metabolism, antibiotics, diabetes, anti-inflammatories and analgesics. The Menarini Group has always pursued two strategic objectives: **Research and Internationalisation**, both of which have allowed them to achieve outstanding results in today's global market and invest in the research of innovative drugs, making them available to patients all around the world.

For further information please consult www.menarini.com

*Sources: IMS World Review 2010

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