Almirall launches Eklira® Genuair® (aclidinium) in Europe

- **Denmark is the first country to market Eklira® Genuair®, a long acting muscarinic antagonist (LAMA) for the treatment of COPD**
- **Next countries to launch in Europe will be Germany and the UK**
- **Eklira® Genuair® provides meaningful and sustained bronchodilation from the first dose. It improves COPD symptoms control and patients' quality of life[1]**

Barcelona, September, 20th 2012 – Almirall, S.A. (ALM:MC) announced that the Danish Health and Medicines Authority has granted general reimbursement to Eklira® Genuair® (aclidinium 322µg twice daily), as a maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD) in adult patients, following the positive recommendation by the Danish Reimbursement Committee and the marketing approval from the European Commission.

"The launch of Eklira® Genuair® in Denmark is the first step in the European roll out of this new therapeutic option for COPD. We also expect to make this medicine available to patients in the UK and Germany soon", said Eduardo Sanchiz, Chief Executive Officer at Almirall*. "With this medicine, Danish patients are also introduced to Genuair® a new user-friendly inhaler which is easy to use and has a novel feedback mechanism to reassure the patients that they have correctly taken their medication."*

Patients with COPD suffer a high burden of symptoms with different severity levels of dyspnea (shortness of breath), cough, sputum production, wheezing (sound produced in the respiratory airways), chest tightness and exacerbations (acute worsening of COPD symptoms that might require hospitalization).[2]

"It is good news that we now have a new treatment option available for Danish COPD patients," says Peter Lange, Professor and Chief Physician at the Pulmonary Section at Hvidovre Hospital in Denmark.

Forthcoming launches are expected in the UK and Germany which, together with the Nordic countries, account for almost half of the European COPD market.

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Clinical efficacy data[1,3]

Clinical efficacy studies showed that aclidinium provides significant and sustained bronchodilation and symptoms control from the first dose. These benefits were evident within 30 minutes of the first dose. It also reduced moderate and severe exacerbations by approximately 30%. In pivotal studies, patients treated with aclidinium needed less rescue medication than patients treated with placebo (p=0.005). It also improved COPD symptoms such as dyspnoea, cough and sputum production.

In addition, the studies demonstrated that aclidinium provided clinically meaningful improvements in breathlessness (assessed using the Transition Dyspnoea Index [TDI] [4]) and disease-specific health status (assessed using the St. George's Respiratory Questionnaire [SGRQ])[5].

Aclidinium showed a good safety profile, with the most frequently reported adverse reactions being headache (6.6%) and nasopharyngitis (5.5%). Importantly, the incidence of typical anticholinergic adverse events was low and comparable to placebo (e.g. dry mouth and constipation were both <1%).[1]

About Eklira® Genuair®

Aclidinium is a novel, long-acting inhaled muscarinic antagonist (sometimes referred to as an anticholinergic) that has a long residence time at M3 receptors and a shorter residence time at M2 receptors. When given by inhalation, aclidinium leads to bronchodilation by inhibiting airway smooth muscle contraction. Aclidinium is rapidly hydrolysed in human plasma to two major inactive metabolites.

Aclidinium is administered to patients using the novel, 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 used the inhaler correctly. It also incorporates significant 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.

Aclidinium is being developed worldwide and has been recently approved in the USA by the FDA where it will be marketed by Forest Laboratories and marketed under the name of Tudorza™ Pressair™. In Japan the product is in development in partnership with Kyorin and with Daewoong in Korea. Almirall holds the rights for the rest of the world.

In Europe, Almirall retains sole marketing rights for the product in the UK, the Netherlands and the Nordic Countries. Menarini will have joint commercialisation rights across the rest of EU member states as well as Russia, Turkey and other CIS countries under the brand name Bretaris® Genuair®, whilst Almirall will market the product in Europe as Eklira® Genuair®

Eklira® Genuair® and Bretaris® Genuair® are trademarks owned by Almirall, S.A.

About COPD

COPD is the occurrence of chronic bronchitis or emphysema, a pair of commonly co-existing diseases of the lungs in which the airways become narrowed. This leads to a limitation of the flow of air to and from the lungs, causing shortness of breath (dyspnoea). In clinical practice, COPD is defined by its characteristically low airflow on lung function tests. 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.

The World Health Organization (WHO) has described COPD as a global epidemic, and it is estimated that 210 million people suffer COPD' worldwide.

In the European Union, the total direct costs of respiratory diseases are estimated to be approximately 6% of the total healthcare budget, with COPD accounting for more than half (56%) of this expenditure, equating to €38.6 billion[6]. Approximately 200,000–300,000 people die each year in Europe because of COPD[4]. Patients experiencing frequent exacerbations are at risk of increased morbidity and mortality, a faster decline in lung function, and poorer health status.

In the EU, approximately 41.3% lost work days are due to COPD every year and productivity losses due to COPD amount to a total of €28.5 billion annually.

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, Mexico and Canada through 13 affiliates.

Almirall's respiratory franchise is complemented by aclidinium combination products for COPD, currently in late stage development and abediterol (a once daily LABA combined with an ICS) for asthma and COPD, currently under development, set to move into Phase IIb development worldwide (excluding USA).

For further information please visit: www.almirall.com

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