

Almirall licenses Acclidinium to Invida in Australia and New Zealand

- **This is the fifth territorial licensing agreement for Acclidinium. Previous partnerships have been established in the US, Japan, Korea and Europe**
- **Acclidinium, a new therapeutic option for Chronic Obstructive Pulmonary Disease (COPD), was recently approved in the US and Europe where it is already on the market in Denmark and Germany**
- **It is estimated that around 2 million people in Australia suffer from COPD, where it is the sixth most common cause of death among men and seventh among women¹⁻²**

Barcelona and Singapore, 10th October 2012.- Almirall (ALM:MC) and Invida Holdings Private Limited, a member of the Menarini Group, are pleased to announce that Almirall has granted Invida commercial rights for Acclidinium in Australia and New Zealand for the treatment of COPD. Financial details of the agreement have not been disclosed. The agreement includes both Acclidinium monotherapy and its combination with Formoterol.

Invida, as a leading pharmaceutical commercialization company in Asia-Pacific, is committed to bringing innovative drugs and pharmaceutical research to doctors and patients in the region. Invida will be responsible for marketing the novel compound in Australia and New Zealand, both to primary and specialty care physicians.

This agreement further strengthens Almirall and Invida's existing partnership in the area of dermatology within the Australian market.

Eduardo Sanchiz, Chief Executive Officer of Almirall, states *"In partnership with Invida, we will be able to offer this novel therapy in Australia and New Zealand for COPD, a disease increasing in prevalence that causes mortality and poor quality of life. With this new agreement Acclidinium, via partners or Almirall's own salesforce, now has access to over 80% of the COPD world market including the US, Japan, Korea and Europe."*

John A. Graham, Chief Executive Officer of Invida, comments that *"This deal strengthens Invida's partnership with Almirall as well as its position as a leading pharmaceutical company in Asia Pacific. Acclidinium expands Invida's current product offerings into the respiratory field, which taps into our already established expertise in dermatology, consumer products and primary and speciality care."*

Acclidinium, a new therapeutic option from Almirall's respiratory R&D, was recently approved in the US and Europe where it is already available in Denmark and Germany. This paves the way for the subsequent introduction of Almirall's combination products for COPD, currently in late stage development.

About Acclidinium and the Genuair® inhaler

Acclidinium 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, Acclidinium leads to bronchodilation by inhibiting airway smooth muscle contraction. Acclidinium bromide is rapidly hydrolyzed in human plasma to two major inactive metabolites.

Acclidinium bromide was administered to patients in clinical 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 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.

Acclidinium 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 Europe, it will be marketed by Almirall under the trade name Eklira® Genuair® and by Menarini under the name Bretaris® Genuair®. 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.

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

About COPD

The World Health Organization (WHO) has described COPD as a global epidemic; an estimated 64 million people have COPD worldwide³. 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.

COPD is the sixth most common cause of death among men and seventh among women in Australia; even though it is less prevalent than asthma, COPD accounts for many more deaths. Commonly associated with other diseases such as heart disease, lung cancer, stroke, pneumonia and depression, COPD affects over two million Australians. The financial burden of COPD to the Australian community is estimated at AUD8.8 billion annually, including health and hospital costs, lost productivity, premature death and lower employment. This is of growing concern as, along with an aging population, the burden of COPD is likely to increase¹⁻².

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 medicines are currently present in over 70 countries while it has direct presence in Europe, Mexico and Canada through 13 affiliates.

For further information please visit the website at: www.almirall.com.

About Invida

Invida, a fully owned member of the Menarini Group, improves the lives of patients in Asia-Pacific by commercializing differentiated pharmaceutical and OTC brands. This is done through proven brand marketing and sales know-how, strong expertise across a number of key therapeutic categories and deep experience in all major Asia-Pacific markets. Comprehensive functional capabilities provide rapid market access delivered by a passionate team of sales and marketing professionals.

With over 3,300 employees in 13 markets in Asia Pacific, Invida operates across the commercial value chain from regulatory approval and product launch to lifecycle management. Partnering is an integral component of Invida's business model. We collaborate closely through long-term relationships with selected partners in developing effective strategies and putting our extensive experience behind maximizing the potential of the assets entrusted to us.

For further information please visit: www.invida.com.

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References:

¹ <http://www.copdx.org.au/foreword>

² http://www.internationalcopd.org/documents/english/copd_case_statement.pdf

³ The World Health Organization (WHO)