

Information on Eklira® and the device Genuair® are based on the Satellite Symposium “Taking a rounded look at COPD” on Sunday 8th September 2013 at 17:15 – 19:15 h

## The importance of 24 hours symptom relief for those suffering from COPD

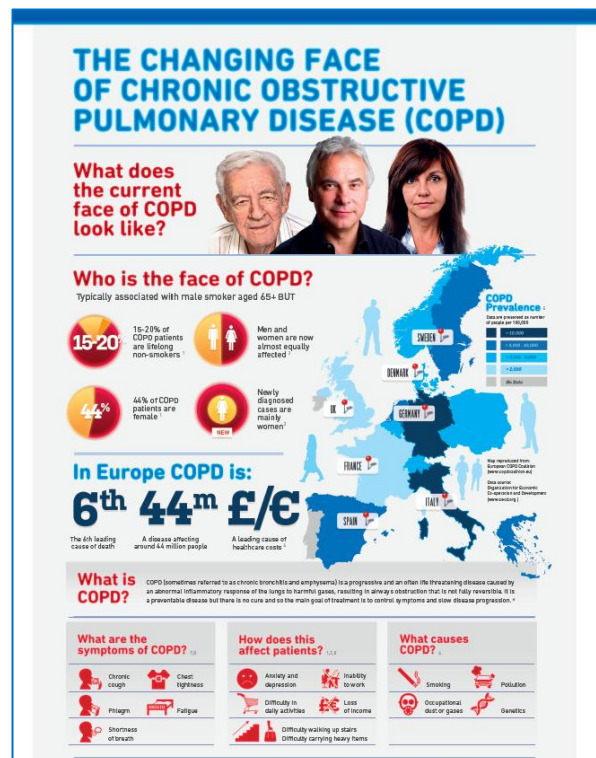
- **Chronic Obstructive Pulmonary Disease (COPD) affects around one in ten of all adults, that is around 44 million people worldwide, and approximately 200,000–300,000 people die each year in Europe because of COPD<sup>i</sup>**
- **Acclidinium provides around-the-clock symptom control (24 hours) with morning and evening administration<sup>ii</sup>**
- **Acclidinium is the first and only LAMA delivered via Genuair® a novel multi-dose, dry powder inhaler that comes pre-loaded and ready to use**

**Barcelona, European Respiratory Congress, September 9<sup>th</sup> 2013.-** COPD is a chronic and highly debilitating lung disease and the most common symptoms are breathlessness (an increased effort to breathe or a ‘need for air’), excessive mucus, and a chronic cough. These symptoms get worse when exercising during an exacerbation (periods when there is a sudden increase in symptoms and the disease is worsening). COPD limits patients’ ability to participate in daily activities and leads to poor quality of life. The disease affects around one in ten of all adults, which means around 44 million people worldwide, and is currently the sixth leading cause of death. Approximately 200,000–300,000 people die each year in Europe because of COPD.<sup>i</sup>

COPD has historically been seen as a disease that affects old men, despite the fact that, according to the World Health Organization (WHO), nowadays men and women are equally affected<sup>iii</sup>. The cause of this balance have opposite patterns according to the geographic areas. In high- and middle-income countries tobacco smoke is the biggest risk factor, meanwhile in low-income countries it is the exposure to biomass fuels for cooking and heating. Almost 3 billion people worldwide use biomass and coal as their main source of energy for cooking, heating, and other household needs.<sup>iv</sup>

In addition to the impact of the disease on a patient’s quality of life, COPD poses a significant financial burden to society. Among respiratory diseases, COPD is the leading cause of lost work days. In the EU, approximately 41,300 lost work days per 100,000 people are due to COPD every year. In Europe, productivity losses due to COPD amount to a total of €28.5 billion annually.<sup>i</sup>

Acclidinium, developed by Almirall, is amongst approved treatments helping boost patient quality of life.



## **Around the Clock COPD Symptom Control**

Acclidinium is a novel, inhaled, long-acting muscarinic antagonist (LAMA) approved in Europe and the USA as a maintenance bronchodilator treatment to relieve COPD symptoms in adult patients, providing significant and sustained bronchodilation from the first dose.<sup>v,vi</sup> The recommended dose is one inhalation of 322 mcg twice daily <sup>ii</sup>.

Acclidinium provides around-the-clock symptom control (24 hours) <sup>ii,vi</sup> leading to relief of early-morning, day and night-time COPD symptoms, including shortness of breath, cough and phlegm.<sup>ii,vii,viii</sup> Acclidinium also provides clinically meaningful improvement in quality of life<sup>v</sup> and breathlessness<sup>viii</sup>, compared with placebo.

Clinical efficacy studies showed that acclidinium significantly reduces moderate and severe exacerbations by approximately 30%<sup>viii</sup>. Patients treated with acclidinium need significantly less rescue medication than patients treated with placebo.<sup>v, viii</sup>

*"Patients with COPD have a high burden of symptom, which have important effects on their quality of life", commented Professor Paul W Jones, Professor of Respiratory Medicine and Head of the Division of Clinical Science, St George's Hospital, University of London, UK. "The reliable bronchodilation and symptom improvements demonstrated by acclidinium during the day and at night provide a valuable treatment option which can translate into benefits for patients in every-day practice", he added.*

Acclidinium is marketed in Europe by Almirall as Eklira® Genuair® and by Menarini as Bretaris® Genuair®. In the USA acclidinium is marketed as Tudorza® Pressair® by Forest Laboratories.

## **Genuair's Secrets: An Introduction To This Novel Device <sup>iv</sup>**

Acclidinium is the first and only LAMA delivered by Genuair®, a new multi-dose, dry powder inhaler that comes pre-loaded with 60 doses, for one month treatment, and ready to use.

Findings of a recent publication suggest that poor adherence to inhaled therapies is common among patients with asthma and COPD. Furthermore, patient satisfaction with their inhaler is positively correlated with improved adherence, clinical outcomes and treatment costs.<sup>ix</sup>

Genuair® was designed with a double feedback system: a 'click' sounds when the patient is inhaling correctly and a control coloured window changes from green (ready to use) to red when the patient inhaled correctly. Moreover, the device incorporates safety features such as a visible dose indicator to show patient approximately how many doses remain, an anti-double-dosing mechanism and an end-of-dose lock-out system to prevent use of an empty inhaler.

*"With acclidinium, patients are also introduced to Genuair® a new user-friendly inhaler with a novel feedback mechanism to reassure the patients that they have correctly taken their medication and which has proven patient preference vs HandiHaler<sup>x</sup>", said Dr. Carsten Niederlaender, Director of Technical Research and Development at Almirall.*

## **Acclidinium and Formoterol Combination in COPD (Phase III Results)**

Following the recent introduction of acclidinium in Europe and USA, a new combination product with acclidinium (LAMA) and formoterol (LABA – Long Acting Beta Agonist) has just finished its clinical development, aiming to provide a dual acting bronchodilator for COPD patients.

Two pivotal Phase III studies (ACLIFORM/COPD and AUGMENT/COPD) -run in 25 countries worldwide- were completed this year involving ca. 3,400 patients with moderate to severe COPD.

In these studies, the combination of acclidinium/formoterol 400/12 mcg met the co-primary endpoints showing statistically significant lung function improvement compared with each individual component. Therefore, it successfully met the required regulatory “Combination Rule” for testing two or more drugs combined in a single dosage form. Also, improvement in breathlessness (the main symptom in COPD) and health-related quality of life showed positive outcomes with acclidinium/formoterol 400/12 mcg. Additionally, the combination showed to be well-tolerated in the two pivotal studies.

*“The success of this Phase III program supports the potential of acclidinium/formoterol as a new treatment option for COPD patients who could benefit from the enhanced bronchodilation of two complementary, proven therapies”,* said Professor Alvar Agusti, Director of the Institut Clínic del Tòrax, Hospital Clínic, Universitat de Barcelona, Spain.

Acclidinium/formoterol is an Almirall inhaled COPD investigational product that combines two already approved and marketed bronchodilators, delivered twice daily in the Genuair® inhaler device.

*“COPD and asthma are amongst the world’s most important health care challenges, with increasing smoking rates and worsening air pollution in many countries. Almirall is committed to research in respiratory diseases to reduce the mortality, the morbidity and the cost burden to society from these very prevalent chronic diseases”,* said Dr. Bertil Lindmark, Almirall’s Chief Scientific Officer.

Almirall plans to submit the regulatory filing of the combination in Europe before the end of this year.

### **COPD: Impact on Patient’s Quality Of Life**

COPD (sometimes referred to as chronic bronchitis and emphysema) is a progressive and an often life threatening disease caused by an abnormal inflammatory response of the lungs to harmful gases, resulting in airways obstruction that is not fully reversible. It is a preventable disease but there is no cure and so the main goal of treatment is to control symptoms and slow disease progression<sup>xi</sup>.

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.

In the European Union, approximately 200,000–300,000 people die each year in Europe because of COPD<sup>4</sup>. Patients experiencing frequent exacerbations are at risk of increased morbidity and mortality, a faster decline in lung function, and poorer health status.

COPD also impacts adversely on economic productivity. In the EU, approximately 41,300 lost work days per 100,000 people are due to COPD every year and productivity losses due to COPD amount to a total of €28.5 billion annually.<sup>i</sup>

### **Almirall**

Almirall is a pharmaceutical company committed to provide valuable medicines through our own R&D efforts, which exceeded 23% on sales in 2012, together with external partnerships, licenses and collaborations. Through seeking innovative medicines we aim to become a relevant player in respiratory and dermatology diseases with also a strong interest in gastroenterology and pain. With more than 3,000 employees in 22 countries, Almirall generated total revenues of 900 million in 2012.

The company was founded in 1943 and is headquartered in Barcelona, Spain. The stock is traded in the Spanish stock exchange (ticker: ALM).

For more information please visit [www.almirall.com](http://www.almirall.com)

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<sup>i</sup> European Lung Foundation – 2012

<sup>ii</sup> Eklira Genuair Summary of Product Characteristics – June 2013

<sup>iii</sup> World Health Organization. Chronic obstructive pulmonary disease (COPD) Fact Sheet. 2011. Available at: <http://www.who.int/mediacentre/factsheets/fs315/en/index.html> [Accessed: October 2012]

<sup>iv</sup> <http://www.who.int/respiratory/copd/causes/en/index.html>

<sup>v</sup> Beier J, Kirsten AM, Mroz R, et al. Efficacy and safety of aclidinium bromide compared with placebo and tiotropium in patients with moderate-to-severe chronic obstructive pulmonary disease: results from a 6- week, randomised, controlled phase IIIb study. *COPD*. 2013;10:511-522.

<sup>vi</sup> Jones PW, Singh D, Bateman ED, et al. Efficacy and safety of twice-daily aclidinium bromide in COPD patients: the ATTAIN study. *Eur Respir J*. 2012; 40: 830-836

<sup>vii</sup> Beier J, Kirsten AM, Mrúz R, Segarra R, Chuecos F, Caracta C, Gil EG. Efficacy and Safety of Aclidinium Bromide Compared with Placebo and Tiotropium in Patients with Moderate-to-Severe Chronic Obstructive Pulmonary Disease: Results from a 6-week, Randomized, Controlled Phase IIIb Study. *COPD* 2013 [Epub ahead of print] doi: 10.3109/15412555.2013.814626

<sup>viii</sup> Agusti A, Jones PW, Bateman ED, et al. Improvement in symptoms and rescue medication use with aclidinium bromide in patients with COPD: results from ATTAIN. Poster presented at the European Respiratory Society annual congress. Amsterdam, Sept 24-28, 2011

<sup>ix</sup> Mika J. Mäkeläa, Vibeke Backerb, Morten Hedegaardc, Kjell Larsson d -Adherence to inhaled therapies, health outcomes and costs in patients with asthma and COPD. *Respiratory Medicine* 2013 (epub ahead to print 6th May 2013)

<sup>x</sup> Van der Palen J, Ginko T, Kroker A, et al. Preference, satisfaction and errors with two dry powder inhalers in patients with COPD [published online ahead of print June 8, 2013]. *Expert Opin Drug Deliv*. 2013;10(8):1023–1031.

<sup>xi</sup> European Lung Foundation, 2003. European Lung White Book. [pdf]. Brussels: European Lung Foundation.