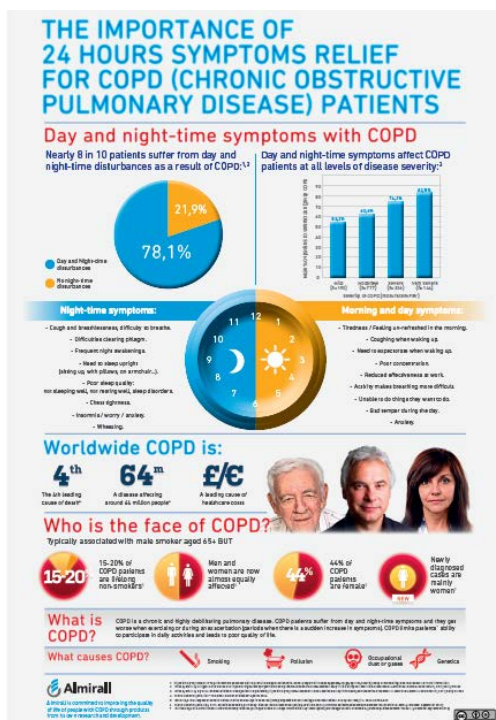


World COPD Day 2013 will take place on November 20<sup>th</sup>

## Around-the-clock symptom relief is vital to the many millions of Chronic Obstructive Pulmonary Disease (COPD) sufferers

- Most of the 64 million COPD patients around the world, including over 2 million in Spain, must contend with breathlessness, excessive mucus, chronic cough and other debilitating symptoms throughout 24 hours a day
- The World Health Organization estimates that COPD kills 3 million people each year and deaths are projected to increase by more than 30% over the next 10 years
- COPD patients suffer debilitating day and night-time symptoms, when it comes to the night-time, symptoms are frequently underreported and may cause a poor sleep quality leading to day-time fatigue and potential psychological problems

**Barcelona, November 18<sup>th</sup> 2013.-** On World COPD Day 2013, physicians and experts who study the highly-debilitating and life-threatening lung diseases are emphasizing the importance of 24hour symptoms relief of COPD as the key to provide an improved quality of life to patients. These symptoms include breathlessness, excessive mucus and chronic cough, all of which can worsen when exercising or during an exacerbation (periods when the symptoms suddenly increase).



COPD affects around 64<sup>1</sup> million people worldwide and over 2 million in Spain<sup>2</sup>. The World Health Organization estimates that COPD kills 3 million people each year and deaths are projected to increase by more than 30% over the next 10 years<sup>1</sup>.

COPD and its symptoms have a severe negative impact on a patient's ability to fully and satisfyingly take part in many daily activities, resulting in a poor quality of life. Vital to these many millions of people suffering from COPD is the relief of their symptoms in order to maintain as much as possible a regular, and even active life style.

<sup>1</sup> World Health Organization "The Global Burden of disease". Update 2004

<sup>2</sup> <http://www.conocepoc.com/prevalencia.html>

A study<sup>3</sup> with 1778 patients showed that nearly 8 out of 10 patients suffer from day and night-time disturbances as a result of COPD. Another study<sup>4</sup> showed that those patients that suffered symptoms during the day and night had the poorest sleep quality and the highest levels of anxiety and/or depression. Finally, in another study<sup>5</sup> researchers concluded that 67% of patients were bothered at night by COPD.

### **Negative Effects of Day and Night-time COPD Symptoms**

Poor sleep quality has been shown to be significantly associated with impaired health status across a variety of conditions<sup>6</sup>. These night-time disturbances can mean a poor sleep quality, resulting in a consistent lack of energy and/or tiredness during the waking hours due to lack of proper rest and even potential psychological problems.

And morning brings little or no relief. According to an internet survey taken by 803 COPD patients, shortness of breath, coughing up phlegm and persistent and/or recurring coughing were experienced by around 50% of severe COPD patients immediately after waking up all or most days<sup>7</sup>. In this same study, thirty-seven per cent of all COPD patients and 59% of those with a severe version of the disease were awoken by their symptoms in the morning at least three days a week<sup>6</sup>.

*“It is quite clear from a range of research that COPD symptoms can have a devastating impact on a patient’s well-being and quality of life whether they manifest themselves in the morning, in the afternoon or at night,”* said Professor Alvar Agusti, Director of the Institut Clínic del Tòrax, Hospital Clínic, Universitat de Barcelona, Spain. *“Sleep quality is often poor in patients with chronic obstructive pulmonary disease (COPD), but these night-time symptoms are frequently unnoticed by physicians and not reported by patients themselves”*, he added.

Night-time symptoms, therefore, are under-recognised in COPD and new treatment options may be considered to address these unmet needs in symptoms relief 24hours a day. In this regard, Professor Alvar Agusti said, *“doctors and patients now count on therapies focused on lessening COPD symptoms during the day and night, such as aclidinium, which directly brings about a better quality of life for patients and their families.”*

### **An introduction to Acclidinium bromide**

Aclidinium bromide is a novel, inhaled, long-acting muscarinic antagonist (LAMA) approved in Europe as a maintenance bronchodilator treatment to relieve COPD symptoms in adult patients, providing significant and sustained bronchodilation from the first dose<sup>8,9</sup>. Aclidinium bromide has also been approved in the USA and Canada. The recommended dose is one inhalation of 322 µg twice daily<sup>10</sup>.

---

<sup>3</sup> Price D, Small M, Milligan G. Prevalence and impact of night-time symptoms in COPD patients—results of a cross-sectional study in five European countries. Presented at: 4th World Asthma & COPD Forum; 2011; Paris, France.

<sup>4</sup> Miravittles M, Soler JJ, Worth H, et al. Observational study to characterise 24-hour COPD symptoms: interim analysis of ASSESS. Eur Respir J, 2013; 42 (suppl 57): 1040s, abstract P4907

<sup>5</sup> Price D, Small M, Sayers J. Characteristics of COPD patients experiencing night-time symptoms - results of a cross-sectional study in five European countries. Presented at: 4th World Asthma & COPD Forum; 2011; Paris, France.

<sup>6</sup> Ancoli-Israel S. The impact and prevalence of chronic insomnia and other sleep disturbances associated with chronic illness. Am J Manage Care. 2006. 12-5221-5229

<sup>7</sup> Partridge MR, Karlsson N, Small IR. Patient insight into the impact of chronic obstructive pulmonary disease in the morning: an internet survey Curr Med Res Opin 2009; 25(8):2043-2048

<sup>8</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>9</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>10</sup> Eklira Genuair Summary of Product Characteristics – May 2013

Aclidinium provides around-the-clock symptom improvement (24 hours)<sup>7,8</sup>, leading to relief of early-morning, day and night-time COPD symptoms, including shortness of breath, cough and phlegm<sup>7,8</sup>. Aclidinium also provides clinically meaningful improvement in quality of life and breathlessness, compared with placebo<sup>8</sup>.

### **An Introduction to Genuair**

Aclidinium 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>11</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.

### **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)

### **Almirall media contact:**

Sonia San Segundo / Isabel Álvarez/ Carolina Rodríguez-Solano  
[sonia.sansegundo@ketchum.com](mailto:sonia.sansegundo@ketchum.com) / [isabel.alvarez@ketchum.com](mailto:isabel.alvarez@ketchum.com) / [carolina.rodriguez@ketchum.com](mailto:carolina.rodriguez@ketchum.com)  
Phone: +34 917883200

---

<sup>11</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. *Respir Med* 2013; 107(10):1481-90