

## **Almirall launches roflumilast in Spain**

- **Roflumilast is the first oral anti-inflammatory treatment for Chronic Obstructive Pulmonary Disease (COPD) patients**
- **The compound reinforces Almirall's respiratory product catalogue**

**Barcelona, 3 October 2011** - Almirall has just launched in Spain the second brand of roflumilast under the name Libertek<sup>®</sup>. Roflumilast, under licence from Nycomed, is a once daily tablet for people suffering from chronic obstructive pulmonary disease (COPD). This phosphodiesterase 4 (PDE4) enzyme inhibitor is the first anti-inflammatory oral treatment for this disease.

Enrique Domínguez, General Manager Spain, states that *"COPD is a specific inflammation that is underlying throughout the disease. Roflumilast is the first medicine that specifically treats the inflammation to prevent the appearance of exacerbations characteristic of the disease, delaying their appearance and improving lung function. All these benefits occur when the medicine is added to the patient's current treatment"*.

Roflumilast fully complements Almirall's business strategy within the respiratory area. The company has other bronchodilator products for this disease, such as acclidinium bromide, an R&D compound that was recently filed for registration in Europe and the United States.

### **About roflumilast**

Roflumilast is an orally administered selective phosphodiesterase 4 (PDE4) enzyme inhibitor, which has been shown to inhibit COPD related inflammation with a novel mode of action. Roflumilast, a once-a-day tablet, is the first drug in a new class of treatment for severe COPD and the first oral anti-inflammatory treatment specifically developed for COPD patients.

Four large randomized placebo controlled trials have shown that roflumilast significantly reduces exacerbations and improves lung function when added to first-line maintenance therapy.

Roflumilast is generally well tolerated. In clinical COPD trials involving 12,000 patients, the most commonly reported adverse reactions were diarrhoea (5.9%), weight decreased (3.4%), nausea (2.9%), abdominal pain (1.9%) and headache (1.7%). The majority of these adverse reactions were mild or moderate. These adverse reactions mainly occurred within the first weeks of therapy and mostly resolved on continued treatment.

Other pharmacological treatment for COPD patients includes the use of inhaled bronchodilators and inhaled corticosteroids.

Roflumilast has been approved in the European Union, United States and other countries. In Europe Nycomed markets roflumilast under the brand name Daxas<sup>®</sup>. In Spain, Daxas<sup>®</sup> was launched in February 2011.

### **About COPD**

The World Health Organisation (WHO) has described COPD as a global epidemic and estimates there are 210 million people around the world suffering from the disease. Over three million people died from it in 2005, which corresponds to 5% of all deaths globally that year. The total number of deaths resulting from COPD is expected to rise by over 30% over the next ten years, unless urgent measures are taken to address the risks, especially smoking.

A COPD patient's lung airways lose their elasticity, produce an excess of mucus and thicken and swell, limiting air flow. The most frequent symptoms of COPD are difficulty in breathing (or "shortness of breath"), abnormal phlegm production (a mixture of saliva and mucus in the airways) and chronic cough. Daily activities such as climbing a short set of stairs or carrying a suitcase can become extremely difficult as the disease progressively worsens. Treatment of COPD is a significant unmet medical need, with limited therapeutic options to improve lung function, reduce symptoms and control exacerbations.

#### **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), rheumatoid arthritis, multiple sclerosis, 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](http://www.almirall.com)

#### **About Nycomed, a Takeda company**

Nycomed is a Takeda company since End of September 2011. Takeda is a research-based global company with its main focus on pharmaceuticals. The combined company has an active commercial presence in the therapeutic areas of metabolic diseases, gastroenterology, oncology, cardiovascular health, CNS diseases, inflammatory and immune disorders, respiratory diseases and pain management.

Takeda's traditional strengths in North America, Japan, and the rest of Asia, are now complemented by Nycomed's position in Europe and the high growth emerging markets. The combined company has a presence in more than 70 countries worldwide, and ranked 12th by global Rx sales, 14th in the BRIC countries and 18th in Europe.

As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for patients worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, [www.takeda.com](http://www.takeda.com).

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