

## **Almirall and Nycomed announce commercialization agreement for roflumilast in Spain**

- **Roflumilast is the first oral anti-inflammatory treatment for COPD patients, and has been developed by Nycomed**
- **This agreement reinforces Almirall's respiratory portfolio**
- **Agreement is part of Nycomed's strategy to complement capabilities through partnerships**
- **The launch of roflumilast by Almirall in Spain is planned for 2011**

**Zurich and Barcelona, May 5<sup>th</sup> 2011** - Almirall and Nycomed today announced that they have entered into a co-branding agreement for the commercialization of roflumilast in Spain. Roflumilast is a once-daily tablet for patients with chronic obstructive pulmonary disease (COPD). It is an orally administered phosphodiesterase 4 (PDE4) enzyme inhibitor, and the first oral anti-inflammatory treatment for COPD.

Under the terms of the agreement, Nycomed will receive an undisclosed upfront fee from Almirall, who will be exclusively promoting a second brand of roflumilast in Spain.

*"We are very pleased with this new agreement with Nycomed. It reinforces our portfolio with a first-in-class product and allows us to leverage our respiratory capabilities and expertise. This product, an entirely new class of treatment, has a strong strategic fit in our business and is fully complementary with other bronchodilator treatments in COPD such as our R&D product aclidinium bromide which is expected to be filed this year",* said Luciano Conde, Almirall's COO. *"We expect roflumilast to generate sales as of this year and could become one of Almirall's key products in the mid term",* he added.

*"We are very pleased to have entered into this collaboration with Almirall and we believe they are the best co-branding partner for roflumilast in Spain. Their respiratory expertise will contribute to successfully bring roflumilast to COPD patients and doctors,"* said Guido Oelkers, Nycomed's Executive Vice President, Commercial Operations. *"Since our local launch earlier this year, we have received a very positive response from Spanish physicians, which confirms our conviction of the potential of this important new approach for the treatment of COPD,"* he added.

### **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. This 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 received marketing authorization in the EU, the United States, and a number of other countries. In Europe, Nycomed is commercializing roflumilast under the brand name Daxas<sup>®</sup>. In Spain, Daxas<sup>®</sup> was launched in February 2011.

### **About COPD**

The World Health Organization (WHO) has described COPD as a global epidemic; an estimated 210 million people have COPD worldwide and 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.

In patients with COPD the airways in the lungs typically lose their elasticity, produce excess mucus and become thick and inflamed, limiting the passage of air. The most common symptoms of COPD are breathlessness (or a "need for air"), abnormal sputum (a mix of saliva and mucus in the airway), and a chronic cough. Daily activities, such as walking up a short flight of stairs or carrying a suitcase, can become very difficult as the condition gradually worsens. There are significant unmet needs in the treatment of COPD including 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), gastrointestinal disorders, 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**

Nycomed is a privately owned global pharmaceutical company with a diversified portfolio focused on branded medicines in gastroenterology, respiratory and inflammatory diseases, pain, osteoporosis and tissue management. A range of OTC products completes the portfolio.

Its R&D is structured around collaborations. In-licensing and expanding in emerging markets are cornerstones of the company's growth strategy.

Nycomed employs 12,500 associates worldwide, and its products are sold in more than 100 countries. It has strong platforms in Europe and in fast-growing markets such as Russia/CIS, Latin America, Asia and the Middle East. In the US and Japan its products are available through best in class partners.

Headquartered in Zurich, Switzerland, the company generated total sales of €3.2 billion in 2010 and an adjusted EBITDA of €851 million.

For further information please visit [www.nycomed.com](http://www.nycomed.com)

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