

## Healthcare industry BW

# Global market launch of Daxas® kicks off in Germany

**Stefan Brinkmann, Managing Director of Nycomed GmbH, kicked off the German market launch of Daxas® (Roflumilast) in Oranienburg today, making Germany the first country to market the medicine. Daxas® is a proprietary selective phosphodiesterase 4 (PDE4) enzyme inhibitor that was developed by Nycomed to treat the progressive, life-threatening lung disease COPD.**

“This is a very special day for Nycomed in Germany, as Daxas allows us to offer a new treatment option to 700,000 patients in Germany. However, Daxas is also a success story for the German pharmaceutical industry. The product was researched and developed at our research facility in Konstanz and we are pleased that Nycomed Oranienburg was selected as the production site to supply the global market,” said Managing Director Stefan Brinkmann.

Daxas is indicated for maintenance treatment of severe COPD (FEV1 post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as an add-on to bronchodilator treatment. COPD remains a significant area of unmet medical need. It is a progressive and irreversible lung disease resulting in difficulty in breathing. The disease is characterized by severe episodes of worsening, called exacerbations. According to World Health Organization (WHO) estimates, 80 million people have moderate to severe COPD worldwide. More than 3 million people died of COPD in 2005, which corresponds to 5% of all deaths globally. The WHO predicts that total deaths from COPD could increase by more than 30% in the next 10 years unless urgent action is taken to reduce the underlying risk factors, especially smoking.

“There is indeed a great need for new COPD treatment options,” says Prof. Helgo Magnussen, medical director of Grosshansdorf Hospital's Centre for Pneumology and Thoracic Surgery. “The aim of COPD therapy is to prevent acute exacerbations while improving lung function and easing physical strain. The reduction of exacerbations is a key objective with regard to morbidity and mortality. Medications that are currently available have limited therapy success rates for COPD, and no existing therapies slow the progression of COPD or inhibit infections of the bronchioles or pulmonary tissue. Roflumilast offers a completely new pharmacological approach and makes a real contribution to improve current COPD treatment.”

Daxas offers the production facility in Oranienburg the opportunity to build on the successful developments seen in recent years. “Today, Oranienburg is a key production site within the global Nycomed network. Over the past several years we have succeeded in bringing in a number of key projects to this location, enabling us not only to significantly expand our capacities, but also to

create jobs – 60 in the past year alone. Of course, Daxas is now our new signature product and we are proud to be able to supply the entire global market from Oranienburg,” said Plant Manager Dr. Hans-Christian Meyer.

In Germany, Daxas will be jointly marketed by Nycomed and MSD (known in the US and Canada as Merck & Co., Inc., based in Whitehouse Station, New Jersey, USA). Daxas will be launched in eight additional European countries and Canada by the end of this year. It is scheduled to be launched in other markets in 2011.

#### About Daxas® (roflumilast)

Daxas (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[1]. Daxas, a once-a-day oral tablet, is the first drug in a new class of treatment for COPD and the first oral anti-inflammatory treatment for COPD patients. Other pharmacological treatment for COPD patients includes the use of inhaled bronchodilators and inhaled corticosteroids.

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#### Press release

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