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## Press Release

### **Nycomed and Forest Laboratories to collaborate on US commercialisation of Daxas<sup>®</sup> in COPD**

- Forest Laboratories acquires exclusive commercialisation rights to Daxas<sup>®</sup> in the United States in treatment of symptomatic COPD
- Nycomed to receive US\$100 million upfront payment plus significant milestones and royalties
- Daxas filed for approval in US and Europe following encouraging results from four Phase III studies
- Access to Forest Laboratories' 2,700-strong US sales force completes global marketing strategy for Daxas

**Nycomed and Forest Laboratories, Inc. (NYSE: FRX) today announced that they have entered into an exclusive development, manufacturing and commercialisation agreement in the United States for Daxas<sup>®</sup> (roflumilast), a once-daily oral treatment for patients suffering from symptomatic Chronic Obstructive Pulmonary Disease (COPD). Nycomed will retain marketing rights to Daxas in Europe and the rest of the world.**

Under the terms of the agreement, Forest Laboratories will make an upfront payment of US\$100 million and additional milestone payments to Nycomed based on defined regulatory and commercialisation achievements. Nycomed will also receive royalties on US net sales typical for a product, which is in registration. Forest will assume responsibility for the US regulatory approval and commercialisation of Daxas in the United States and the companies will collaborate on future development programs. Other details of the financial terms of the agreement were not disclosed.

Daxas is an orally-administered phosphodiesterase 4 (PDE4) enzyme inhibitor targeting cells and mediators in the body believed to be important in the COPD disease process. A New Drug Application (NDA) was filed with the US Food and Drug Administration (FDA) in July and a Marketing Authorisation Application (MAA) was filed with the European Medicines Agency (EMA) in May 2009.

Commenting on today's announcement, Howard Solomon, Chairman and Chief Executive Officer of Forest Laboratories, said: "We are pleased to have entered into this collaboration with Nycomed. Nycomed has demonstrated great dedication in bringing Daxas to its current NDA stage of development and we are looking forward to working with such a talented and committed group as we consider ways to further develop and expand the use of Daxas. Daxas represents the first in a new class of agents to treat COPD and would be the first oral agent to be approved for this debilitating disease. If approved, Daxas will give physicians and patients a much needed new treatment option in a unique oral dosage form that can augment the existing armamentarium of inhaled therapies."

Håkan Björklund, Chief Executive Officer of Nycomed, said: "We have received considerable interest in the marketing rights to Daxas and we believe Forest Laboratories is the best possible partner for Nycomed in the United States. Forest Laboratories has a significant national sales force, an increasing focus on respiratory products and an unrivalled track record of partnering with European companies to build hugely successful franchises. We believe their absolute commitment to Daxas will help to bring this innovative new therapy to as many patients in the United States as possible who suffer from COPD, a disease which is predicted to become the third-leading cause of death worldwide by 2030."

Nycomed submitted MAA and NDA filings earlier this year following encouraging results from a preliminary analysis of four Phase III trials of Daxas (roflumilast) in the treatment of symptomatic COPD. Two pivotal 12-month studies showed positive effects on exacerbation rates and pulmonary function (FEV<sub>1</sub>). Two supporting six-month studies also confirmed the efficacy of Daxas when used with standard bronchodilator treatments. Full data from all four studies are to be published in a leading peer-reviewed journal later this year and will be presented at the annual European Respiratory Society (ERS) Congress in Vienna, Austria, in September.

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 characterised 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 three 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.

(See <http://www.who.int/respiratory/copd/burden/en/index.html>)

## About Daxas<sup>®</sup>

Nycomed's Daxas is an orally administered phosphodiesterase 4 (PDE4) enzyme inhibitor targeting cells and mediators in the body believed to be important in the COPD disease process. Daxas is expected to act on the underlying mechanism of COPD and related inflammatory diseases. If approved, Daxas, a once-a-day tablet, will be the first drug in its class. It will also be the first new approach to the management of COPD in a generation. Current treatment for COPD patients includes the use of inhaled bronchodilators and inhaled corticosteroids.

## About Forest Laboratories

Forest Laboratories (NYSE: FRX) is a U.S.-based pharmaceutical company with a long track record of building partnerships and developing and marketing products that make a positive difference in people's lives. In addition to its well-established franchises in therapeutic areas of the central nervous and cardiovascular systems, Forest's current pipeline includes product candidates in all stages of development and across a wide range of therapeutic areas. The company is headquartered in New York, NY. To learn more about Forest Laboratories, visit [www.FRX.com](http://www.FRX.com).

Except for the historical information contained herein, this release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in Forest Laboratories' Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and any subsequent SEC filings.

SOURCE Forest Laboratories, Inc.

## About Nycomed

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

Its R&D is structured around partnerships and in-licensing is a cornerstone of the company's growth strategy.

Nycomed employs 12,000 associates worldwide, and its products are available in more than 100 countries. It has strong platforms in Europe and in fast-growing markets such as Russia/CIS and Latin America. While the US and Japan are commercialised through best-in-class partners, Nycomed plans to further strengthen its own position in key Asian markets.

Headquartered in Zurich, Switzerland, the company generated total sales of € 3.4 billion in 2008 and an adjusted EBITDA of € 1.2 billion.

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

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