Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/nycomed-and-merck-co-inc-announce-commercialization-agreements-for-daxas-in-europe-and-canada

Nycomed and Merck & Co., Inc., announce commercialization agreements for Daxas® in Europe and Canada

Nycomed and Merck & Co., Inc. announced that they have entered into a co-promotion agreement for Canada and certain European countries for the commercialization of Daxas® (roflumilast), an investigational once-daily tablet for patients with chronic obstructive pulmonary disease (COPD). Merck & Co., Inc. is based in Whitehouse Station, New Jersey and known as MSD outside the USA and Canada.

In addition, the two companies have signed an exclusive distribution agreement for the commercialization of Daxas® in the United Kingdom.

"This agreement with Nycomed for a late-stage PDE4 inhibitor candidate represents a strong strategic fit for Merck," said Kevin Ali, senior vice president and general manager Bone, Respiratory, Immunology and Dermatology franchise at Merck & Co., Inc. "This builds upon Merck's leadership in the asthma and allergy marketplace and positions the company to leverage our well-trained sales force to target the rapidly growing unmet medical need of COPD."

"We are very pleased to have entered into this collaboration with Merck and we believe it's the best partner for us," said Håkan Björklund, Chief Executive Officer of Nycomed. "Nycomed's expertise in development of roflumilast, an important new approach for the treatment of COPD, Merck's customer oriented interactive commercial model and the regional synergies between the two companies will contribute to successfully bring Daxas to patients and doctors."

Under the terms of the agreement, Nycomed will receive an undisclosed upfront fee from Merck and is eligible for certain payments based on defined regulatory and commercialization milestones for Daxas. If approved by the relevant regulatory authorities, Merck and Nycomed will co-promote Daxas in France, Germany, Italy, Spain, Portugal, and Canada. Nycomed will manufacture and distribute the finished product in all countries covered by the co-promotion agreement. In the United Kingdom Merck will have exclusive commercialization rights and Nycomed will supply finished product and has retained a co-promotion option. Further details of the agreement were not disclosed.

Nycomed filed marketing applications for Daxas with the European Medicines Agency (EMA) and Health Canada in 2009. In addition, Nycomed submitted a New Drug Application (NDA) to the US

Food and Drug Administration (FDA) in July 2009. On April 23, 2010, Nycomed announced that it had received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), recommending the approval of Daxas in the European Union.

About Roflumilast (Daxas®)

Roflumilast 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 and related inflammatory diseases. If approved, roflumilast, a once-a-day oral tablet, will be the first in an entirely new class of treatment for COPD. It will also be the first oral anti-inflammatory treatment for COPD patients. Current treatment for COPD patients includes the use of inhaled bronchodilators and inhaled corticosteroids.

Press release

29-Apr-2010
Source: Nycomed 26.04.10 - mst (P)