

Healthcare industry BW

Nycomed: Daxas[®] included as a treatment option in COPD guidelines

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) has included roflumilast (Daxas[®]) as a new treatment option in its COPD management guidelines. A section on the new class, phosphodiesterase 4 (PDE4) inhibitors, describes the efficacy of roflumilast in patients with COPD.

'The Global Strategy for Diagnosis, Management and Prevention of COPD', provides evidence-based guidelines for COPD management and is updated annually by a committee of leading COPD experts. In the latest edition, PDE4 inhibitors have been added as a new treatment class.

The guidelines acknowledge that the principal action of PDE4 inhibitors is to reduce inflammation and its clinical implications in COPD patients. It states: «In patients with Stage III: Severe COPD or Stage IV: Very Severe COPD and a history of exacerbations and chronic bronchitis, the phosphodiesterase 4 inhibitor, roflumilast, reduces exacerbations treated with oral glucocorticosteroids. These effects are also seen when roflumilast is added to long-acting bronchodilators.»(1)

Peter Calverley, Professor of Respiratory Medicine, University of Liverpool, UK: "COPD is a chronic progressive lung disease which kills millions of people every year. Despite current maintenance therapies, COPD remains a significant area of unmet medical need. As it progresses, patients suffer exacerbations or lung attacks when breathing can become extremely difficult and they may have to be admitted to hospital."

"Studies have shown that the PDE4 inhibitor, roflumilast, significantly reduces exacerbations. The GOLD guidelines recognise its contribution to the management of this debilitating disease and it is important that physicians who treat COPD have this information," Professor Calverley added.

Daxas has been approved in the European Union and in Canada recently. It has been launched in Germany, Denmark and UK, and 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(2). Daxas, 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.

Daxas 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.

About COPD

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 or lung attacks. 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.

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