

Healthcare industry BW

ALVESCO® gains FDA approval for the U.S. market

Nycomed announced that the Food and Drug Administration (FDA) approved ALVESCO® (ciclesonide) Inhalation Aerosol in the United States for the maintenance treatment of asthma and as prophylactic therapy in adult and adolescent patients aged 12 years and older. ALVESCO® is an inhaled corticosteroid with novel release and distribution properties. Commercialisation and marketing of ALVESCO® will be achieved through a U.S. commercial partner.

The decision of the FDA allows the product to be sold in the largest pharmaceutical market in the world, where it is patent protected until 2017. Nycomed is in active negotiations with possible marketing partners for the commercialisation of ALVESCO® in the United States. The outlicensing strategy in the U.S. is consistent with Nycomed's direction to seek marketing and commercialisation partnerships for the Nycomed's assets in the U.S. market.

"The approval of ALVESCO® provides a new and effective treatment option to help patients control their asthma and improve their quality of life, and will be an important treatment option for physicians", said Myron Zitt, MD, chief of allergy and immunology at the Queens Long Island Medical Group in Babylon, N.Y., and clinical associate professor of medicine at the State University of New York, Stony Brook, School of Medicine.

"We are very much looking forward to serving patients in the United States with this innovative drug and build upon the experience we already have gained with ALVESCO®. This approval certainly adds to the respiratory area, which is a key segment for Nycomed to grow", comments Dick Söderberg, Executive Vice President of International Marketing.

About ALVESCO®

ALVESCO® (ciclesonide) Inhalation Aerosol is a new generation of inhaled corticosteroid that reduces inflammatory processes and is indicated for the use in patients with asthma. ALVESCO® has been approved in 45 countries including the U.S. and introduced in 30, with more launches expected in 2008.

ALVESCO® is based on the active ingredient ciclesonide which is Nycomed's patented corticosteroid with a novel principle of action. Ciclesonide is a prodrug that is activated by intracellular esterases following oral inhalation. ALVESCO® has wide inhibitory activities against multiple inflammatory cell types and chemicals involved in the asthmatic response.

Inhaled corticosteroids (ICS) are regarded today as the gold standard in asthma and allergic rhinitis therapy. They inhibit the activity of pro-inflammatory cells and promote the endogenous production of anti-inflammatory substances. With regular use of these corticosteroids, the inflammation in the lungs and airways that underlies the asthma is attenuated.

In clinical trials, ALVESCO® was generally well tolerated. The most common adverse reactions (>3%) were headache, nasopharyngitis, sinusitis, pharyngolaryngeal pain, upper respiratory infection, arthralgia, nasal congestion, pain in the extremities and back pain.

Treatment with orally inhaled corticosteroids may lead to signs or symptoms of hypercorticism, suppression of hypothalamic-pituitary-adrenal (HPA) function and/or suppression of growth in children. Glaucoma, increased intraocular pressure and cataracts have been reported following the administration of inhaled corticosteroids.

ALVESCO® (ciclesonide) Inhalation Aerosol is an orally inhaled corticosteroid indicated for the maintenance treatment of asthma as prophylactic therapy in adult patients 12 years of age and older. ALVESCO® is NOT indicated for the relief of acute bronchospasm.

About Asthma

Asthma is a chronic lung disease caused by airway inflammation and results in airway constriction in response to certain stimuli. It is characterized by a variety of symptoms including wheezing, coughing and a tightening of the airways, which causes shortness of breath and can be life-threatening^[i].

About Nycomed

Nycomed is a pharmaceutical company that provides medicines for hospitals, specialists and general practitioners, as well as over-the-counter medicines in selected markets.

The company is active within a range of therapeutic areas, including cardiology, gastroenterology, osteoporosis, respiratory, pain and tissue management. New products are sourced both from own research and from external partners. Operating throughout Europe and in fast-growing markets such as Latin America, Russia/CIS and the Asia-Pacific region, Nycomed has a presence in about 50 markets worldwide.

Privately owned, the combined group had annual sales of approximately € 3.4 billion and an EBITDA of € 933.4 million (2006 results).

Footnote:

[i] National Heart Lung Blood Institute (NHLBI)

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