



UCB receives U.S. FDA Complete Response Letter for Neupro® in Restless Legs Syndrome and Advanced Parkinson's disease

Brussels (Belgium), December 19, 2008 at 07:00 AM (CET) - press release, regulated information - UCB announced today that it has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for its transdermal patch, Neupro® (*rotigotine* transdermal system) to treat the signs and symptoms of advanced Parkinson's disease, and as a treatment for the signs and symptoms of moderate to severe primary Restless Legs Syndrome (RLS).

The FDA concluded that there was substantial evidence of effectiveness of Neupro® in patients with advanced Parkinson's disease and in patients with RLS. However, UCB needs to first resolve the issue of crystal formation in the patches. UCB will discuss the contents of the Complete Response Letter and the next steps with the FDA.

The FDA accepted for filing the supplemental New Drug Applications (sNDAs) for the two indications in December 2007. At that time, Neupro® was available in the U.S. for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease and had been commercially available since July 2007. The company recalled Neupro® from the U.S. market in April 2008 after ongoing monitoring revealed that specific batches of Neupro® had deviated from their approved specification.

In Europe, a complete cold-chain storage and distribution system, successfully implemented by September 2008, has helped to control the crystal formation issue and allowed existing patients to continue their therapy. Pending European regulatory authority decision, UCB aims to make Neupro® available again to all patients suffering from Parkinson's disease in Europe, and to launch the Restless Legs Syndrome indication in Europe, during the first half of 2009.

About Parkinson's disease

Parkinson's disease is a progressive disorder of the central nervous system. The patients - roughly four million worldwide, including approximately one million people in the United States - suffer primarily from a lack of dopamine, a messenger substance in the central nervous system, which is responsible for the coordination of movement.

About Restless Legs Syndrome

Restless legs syndrome (RLS) is a chronic neurological disorder that affects between 3 and 10 percent of the population. It is characterized by unpleasant feelings in the legs and an irresistible urge to move in order to relieve the discomfort. RLS sensations are frequently described as tingling, burning, tugging, gnawing and pulling. The exact cause of RLS is not known; however, recent clinical research has linked certain genes to RLS, suggesting that the disorder is biologically based.

For further information

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About UCB

UCB, Brussels, Belgium (www.ucb-group.com) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing more than 10 000 people in over 40 countries, UCB aims to achieve revenues of 3.3 billion euro in 2008. UCB is listed on Euronext Brussels (symbol: UCB).

Forward looking statement

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.