Mundipharma receives Positive CHMP Opinion for Targin® (oxycodone / naloxone) for the treatment of Restless Legs Syndrome

Cambridge, 24 October 2014, 14:00hrs GMT – Mundipharma today announced that the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Targin®, a fixed combination of prolonged-release oxycodone/naloxone, as a second line symptomatic treatment of patients with severe to very severe idiopathic restless legs syndrome (RLS), after failure of dopaminergic therapy.

The positive opinion adopted by the CHMP will now go through the standing committee procedure to be converted into a legally binding decision by the European Commission, a process that typically takes about 2 months. Subsequent to the European Commission decision, the national phase of the approval process will need to be completed in relevant markets before the product receives a marketing authorisation.

“This CHMP positive opinion provides new hope for patients who cannot tolerate the existing available treatments or who are not able to gain the level of symptom relief required. We look forward to continuing to work with the regulatory authorities to bring this new option to patients”, said Antony Mattessisch, Managing Director, Mundipharma International.

RLS (also known as Willis-Ekbom disease) is a neurological disorder characterised by an overwhelming urge to move, usually affecting the legs. Patients suffering from RLS may describe feelings of tingling, burning, itching or throbbing, a 'creepy-crawly' feeling or cramping in the legs. Between 5% to 10% of adults in the United States and Western Europe are affected by the condition. Symptoms occur primarily at night and can increase in severity throughout the night. Moving the legs relieves the discomfort. Restless legs syndrome is a common cause of insomnia related to problems with sleep initiation and sleep maintenance, un-refreshing sleep, and excessive daytime sleepiness, and it may signify an underlying medical condition.

Targin® is the first opioid which has been granted a positive opinion by the CHMP for the treatment of RLS. Targin® is currently licensed for the treatment of RLS in Germany only, in the same second line setting as approved today by the CHMP.

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About Targin

Targin is a combination of oxycodone (an opioid agonist) and naloxone (an opioid antagonist) in prolonged-release oral tablets. Targin has been approved in 37 countries worldwide, and in the EU it is indicated for the treatment of severe pain which, can be adequately managed only with opioid analgesics.

About Mundipharma

The Mundipharma network of independent associated companies consists of privately owned companies and joint ventures covering the world's pharmaceutical markets. These companies are committed to bringing to patients the benefits of pioneering treatment options in the core therapy areas of oncology, pain, respiratory and inflammatory conditions. They are also committed to independent thinking and ground breaking solutions. Through innovation, design and acquisition, the Mundipharma network of independent associated companies delivers cutting-edge treatments to meet the most pressing needs of healthcare professionals and patients. For further information please visit: www.mundipharma.com.

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