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Boehringer Ingelheim Receives Approval From the European Commission for Mirapexin(R)/Sifrol(R) Prolonged-Release, Once Daily Tablet for the Treatment of Parkinson's Disease

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Ingelheim, Germany (ots/PRNewswire) - - New Formulation Brings the Established Efficacy of Mirapexin(R)/Sifrol(R) to Patients With Parkinson's Disease in the Convenience of a Once Daily Dose

Boehringer Ingelheim today announced that the Mirapexin(R)/Sifrol(R) (pramipexole) new prolonged-release , once daily tablet has been granted marketing authorisation by the European Commission in all EU/EEA(*) countries for the treatment of early and advanced idiopathic Parkinson's disease (PD). The approval was based on the submission of clinical trial results showing that the new formulation can offer an efficacy and safety profile comparable to the immediate release tablet taken three times daily.(1-6)

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In addition to clinical trial results that confirm the important therapeutic benefits of the new formulation when administered in a convenient once-a-day regimen, a further trial has shown that patients already taking Mirapexin(R)/Sifrol(R) immediate release tablets may easily be switched overnight to the Mirapexin(R)/Sifrol(R) prolonged-release tablet, at the same daily dose.(7,8)

"The European approval of the new formulation marks another big step in meeting patients' needs and represents a milestone for this worldwide highly successful treatment for Parkinson's disease. We are very pleased that due to the robust evidence base, the regulatory review experienced no delay, which will allow the first European countries to already make the once daily tablet available to patients," said Dr. Manfred Haehl, MD, Senior Vice-President Medicine at Boehringer Ingelheim Corporate Headquarters. "In addition, the data show that the prolonged-release Mirapexin(R)/Sifrol(R) tablet causes less frequent fluctuations in the plasma concentration over 24 hours compared to the three times daily administration of the immediate release tablet, an important aspect for physicians when choosing the best treatment option for their patient."

Mary Baker, MBE, President of the European Federation of Neurological Associations (EFNA) commented on the European approval of the new formulation: "Most people with Parkinson's disease take many different pills on a daily basis, to manage their PD symptoms and other concomitant conditions. Being able to reduce their pill burden without foregoing the effectiveness will be welcomed by patients as well as by their care givers as it is expected that a once-daily administration can improve patient adherence to their treatment regimen."

A new drug application (NDA) for a once daily, extended release formulation of pramipexole (marketed under the trade name Mirapex(R) in the U.S.A.) is in review with the U.S. Food and Drug Administration (FDA) for the treatment of Parkinson's disease (currently available in the U.S.A. as immediate release formulation).

(*) all 27 Member States of the European Union plus Norway and Iceland

For full version and references please visit http://www.boehringer-ingelheim.com/corporate/news/press_releases/index.asp.

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