

## Press Release

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### **Advances in the understanding and treatment of Parkinson's disease discussed at the 13th EFNS Congress**

*International experts address the importance of adequate treatment strategies in Parkinson's disease and the future role of a new Mirapexin<sup>®</sup>/Sifrol<sup>®</sup> prolonged-release formulation*

**Ingelheim, Germany, 14 September 2009** – During the scientific sessions at the 13th Congress of the European Federation of Neurological Sciences (EFNS), international experts presented recent data that addresses key questions facing physicians and patients in the current and future management of Parkinson's disease (PD).

According to Dr. Werner Poewe, Professor of Neurology and Director of the Department of Neurology, University Hospital Innsbruck, Austria: "One of the key challenges in the management of PD, is that of tailored drug delivery in order to improve compliance and convenience for patients and physicians when considering their treatment strategies." Highlighting the importance of improving patient compliance through simpler treatment regimens, including new formulation developments, Professor Poewe commented: "We already know that the immediate release formulation of pramipexole is very efficacious in treating PD symptoms and that it has a simple treatment regimen. A once daily formulation could help to reduce the pill burden PD patients commonly have to cope with every day."

In June 2009, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending the approval of a once daily Mirapexin<sup>®</sup>/Sifrol<sup>®</sup> prolonged-release tablet for the treatment of PD throughout the EU/EEA countries.<sup>1</sup> The positive recommendation issued by the CHMP followed clinical trial results confirming the high therapeutic benefits of Mirapexin<sup>®</sup>/Sifrol<sup>®</sup> also when administered in a convenient once-a-day formulation.<sup>2-8</sup>

Furthermore, the expert panel pointed out that initial progression of PD begins years before symptoms are recognisable in patients, although it is not yet known how long this asymptomatic phase lasts. Current shortfalls in the early and accurate detection of PD (there is no one single reliable diagnostic test), have led to delayed treatment initiation, which potentially negatively

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impacts on the evolution of the disease.<sup>9,10</sup>

Commenting on the complexity of PD symptoms, Dr. Olivier Rascol, Professor of Clinical Pharmacology, Toulouse University Hospital, Toulouse, France, said: “Interestingly, no PD patient’s symptoms are exactly the same as another, increasing the diagnostic challenge for physicians. For example, the non-motor symptoms can often precede the more identifiable PD motor symptoms. These non-motor symptoms can have a significant impact on patients’ quality of life, but can also be indicators of an underlying progressive neurodegenerative disease such as PD. These issues raise the question of adapting PD diagnostic criteria and when and how to treat PD patients.”

A recent paper published in the *European Journal of Neurology*<sup>9</sup> cited results from a PD study led by Professor Paolo Barone, which has shown that the PD-related depressive symptoms can be improved with pramipexole, opening up new approaches to managing the non-motor symptoms in addition to controlling the motor symptoms.<sup>11</sup>

In conclusion, the lead author of the journal publication,<sup>9</sup> Professor Anthony Schapira, Chairman of the University Department of Clinical Neurosciences, Institute of Neurology, Queen Square, UCL and Professor of Neurology at the National Hospital and Royal Free Hospital, London, UK emphasised: “The individual nature of Parkinson’s disease creates broad demands on treatments. Effective control of motor and non-motor symptoms in all stages of the disease will be the primary goal of a pharmacological treatment, enabling people with PD to continue to take part in daily activities. If in addition, patient compliance can be improved by a therapy such as pramipexole that offers a simple dosing regimen and reduces the pill burden through a once daily dosing, as a physician, I am confident that this drug, once approved, can deliver benefits for PD patients beyond those seen to date with the immediate release formulation.”

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#### **Notes to Editor:**

##### **About Parkinson’s disease (PD)**

Parkinson’s disease is the second most common chronic neurological disorder in older adults after Alzheimer’s. Its worldwide prevalence is estimated to be approximately one to two percent of those over 65 years.<sup>12-16</sup> Although traditionally PD is associated with motor symptoms (such as tremor, rigidity, slowed motion, imbalance, shuffling gait, loss of facial expression), the non-motor symptoms, including depressive symptoms, pain, cognitive impairment and sleep disorders can be significant. Symptoms can vary from patient to patient, but worsen over time.

**About Mirapexin<sup>®</sup>/Sifrol<sup>®</sup> (pramipexole)**

Pramipexole (known under the trade names Mirapexin<sup>®</sup>, Sifrol<sup>®</sup>, Mirapex<sup>®</sup> and Pexola<sup>®</sup>) is a compound from Boehringer Ingelheim research first approved in 1997 and to date available in over 70 countries across the globe for the treatment of the signs and symptoms of idiopathic Parkinson's disease, as monotherapy or in combination with levodopa.<sup>17</sup> In June 2009, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending the approval of a once daily Mirapexin<sup>®</sup>/Sifrol<sup>®</sup> prolonged-release tablet for the treatment of early and advanced PD throughout the EU/EEA countries.<sup>1</sup> A new drug application (NDA) for a once daily, extended release formulation of Mirapex<sup>®</sup> is also 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). Pramipexole (immediate release formulation) is also indicated since 2006 for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS).

The most commonly ( $\geq 5\%$ ) reported adverse drug reactions in patients with Parkinson's disease treated with pramipexole were nausea, dyskinesia, hypotension, dizziness, somnolence, insomnia, constipation, hallucination, headache and fatigue.

Pramipexole may cause patients, particularly with Parkinson's disease, to fall asleep without any warning even while doing normal daily activities such as driving. When taking pramipexole hallucinations may occur and sometimes patients may feel dizzy, sweaty or nauseated upon standing up.

Patients and caregivers should be aware of the fact that abnormal behaviour (reflecting symptoms of impulse control disorders and compulsive behaviours) such as binge eating, compulsive shopping, hypersexuality and pathological gambling have been reported in patients treated with dopaminergic drugs, including pramipexole. Dose reduction/tapered discontinuation should be considered.

**Boehringer Ingelheim**

The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 138 affiliates in 47 countries and 41,300 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

In 2008, Boehringer Ingelheim posted net sales of 11.6 billion euro while spending one fifth of net sales in its largest business segment Prescription Medicines on research and development.

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### **Related links:**

Further information on Parkinson's disease and pramipexole can be found at: <http://www.boehringer-ingelheim-mediaevent.com/parkinson/>, [www.youtube.com/user/parkinsonsmatters](http://www.youtube.com/user/parkinsonsmatters) and [www.PDKnowledgeGuide.com](http://www.PDKnowledgeGuide.com)

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