New study provides insights into potential treatment of severe pain in Parkinson’s disease with prolonged-release oxycodone/naloxone

Cambridge, 20 October 2015 - A study published today in The Lancet Neurology has provided important insights into the analgesic effects of prolonged release oxycodone/naloxone (OXN PR) for Parkinson’s disease patients with chronic, severe pain.1 The primary endpoint of improved average 24-hour pain score with OXN PR versus placebo at week 16 was not met (p=0.058), however assessments at other time points as well as secondary endpoint data indicate some potentially positive treatment effects with OXN PR.1

The primary endpoint of the study was to demonstrate superiority of OXN PR compared to placebo for average 24-hour pain scores (11-point numerical rating scale, 0=no pain to 10=pain as bad as you can imagine) at week 16. Secondary endpoints included frequency of rescue medication intake, percentage of responders (defined by a ≥30% reduction from baseline) in average 24-hour pain at week 16, and percentage of responders (‘much improved’ or ‘very much improved’) for Clinical Global Impression – Improvement (CGI-I) and Patient Global Impression Improvement (PGI-I) at week 16.1

The study found that OXN PR was associated with numerical but not significant improvement at week 16 (p=0.058), however statistically significant differences were seen at week 4 (p=0.018), week 8 (p=0.011) and week 12 (p=0.021).1 Furthermore, the Per Protocol Population analysis revealed that when OXN PR was taken in line with the study protocol, this adherence resulted in significantly improved 24-hour average pain scores at week 16 with OXN PR as compared to placebo (p=0.010).1 Secondary endpoints also demonstrated greater improvements with OXN PR including a greater responder rate for 24-hour pain control (p=0.021), less use of rescue medication and clinically relevant improvements in CGI-I (p=0.019) and PGI-I (P=0.022). OXN PR also provided significant improvements in severe musculoskeletal (p=0.023) and severe nocturnal pain (p=0.010) as compared to placebo.1 Overall adverse events were similar between OXN PR and placebo. Treatment related adverse events seen more frequently with OXN PR compared to placebo were nausea (17% vs 9%) and constipation (17% vs 6%).1
“This study provides key learnings on the potential use of oxycodone/naloxone for the treatment of severe pain in Parkinson’s disease. The encouraging secondary endpoint data suggest that further studies may help to uncover the potential role of OXN PR in this patient population”, said Claudia Trenkwalder, principal investigator of the study. “This study adds to the very limited knowledge base on the efficacy and safety of opioid-based treatment of patients with Parkinson’s disease suffering from complex pain.”

Prof. Dr. Karen Reimer, Managing Director, Mundipharma Research, added: “To our knowledge, this is the first randomised, double-blind, controlled trial specifically designed to investigate treatment in Parkinson’s disease pain. At Mundipharma, it is our vision to set ourselves apart as pioneers in pain management. We have a proven track record of bringing pain treatment innovations to market and want to build on this heritage, in an effort to continue to provide novel treatment options that really make a difference to people living in pain.”

Parkinson’s disease is the second most common neurodegenerative disease after Alzheimer’s disease\(^2\)\(^3\), affecting over 4 million people in the world’s most populous nations.\(^4\) Pain is a common symptom, with approximately 60% of patients affected, and is one of the non-motor symptoms of Parkinson’s disease associated with a depressed mood and reduced quality of life.\(^5\)\(^6\)\(^7\) There is little awareness of the different types of Parkinson’s disease pain from both medical and patient perspectives, with disease-related pain commonly only being treated by increasing the doses of dopaminergic therapy.\(^1\)

OXN PR is currently available in 23 countries across Europe as well as other territories in Asia, North America and Oceania (Targin\(^®\)/Targinact\(^®\)/Targiniq\(^®\)) and its efficacy and safety profiles have been demonstrated in a variety of non-malignant and cancer-related pain settings.\(^8\)\(^9\)\(^10\)\(^11\)

This multi-centre, double-blind randomised placebo controlled study was funded by Mundipharma GmbH & Co.KG.

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About Mundipharma

The Mundipharma network of independent associated companies consists of privately owned companies and joint ventures covering the world’s pharmaceutical markets. The Mundipharma network has a presence in 51 countries with more than 7,800 employees across the world. These companies are committed to bringing to patients the benefits of pioneering treatment options in the core therapy areas of pain management, oncology, respiratory and inflammatory conditions.
Through innovation, design and acquisition, the Mundipharma network of independent associated companies delivers important treatments to meet the most pressing needs of patients, healthcare professionals and health systems worldwide.

About the PANDA study

PANDA (A multicentre, double-blind, randomised, placebo controlled study to determine the efficacy and tolerability of OXN PR for the treatment of severe Parkinson’s disease associated pain) was a phase II, 16-week, randomised, double-blind study, comprising treatment with OXN PR or placebo, followed by a 4-week extension phase of open-label OXN PR aimed to transition patients to subsequent pain treatment at study end. The study was performed in 47 secondary care centres in 7 countries (Czech Republic, Germany, Poland, Hungary, Romania, Spain and UK). 202 patients were randomised to take part in the study.

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References


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