



Study results of prucalopride in elderly patients with chronic constipation published in June 2010 issue of 'Neurogastroenterology and Motility'

Turnhout (Belgium) – 29 June 2010 (5:45 PM CET) – Movetis NV (MOVE), the European gastrointestinal (GI) speciality pharmaceutical company, announces that the renowned medical journal 'Neurogastroenterology and Motility' has published the results of a double-blind, placebo-controlled study of prucalopride in elderly patients with chronic constipation in its June 2010 issue.¹ The authors of this study conclude that "prucalopride (...) has beneficial effects on bowel movements, symptoms and quality of life (QoL), and is safe and well-tolerated in elderly patients with chronic constipation".

Chronic constipation is of particular concern to the elderly, for whom the authors indicate an estimated prevalence of 15-50%. This explains why Movetis also ran a clinical study in this specific patient population. In total, 461 patients were screened and the intention-to-treat population comprised 300 patients who took prucalopride and provided follow-up data. Patients were recruited from 48 study centres throughout the world. The study population had a mean age of 76 years (range 64-95) and 70% of the patients were female. The median duration of constipation was around 15 years and around 30% of the patients had no spontaneous complete bowel movement (SCBM) at run-in. More than 70% of patients were dissatisfied with previous treatment, mainly laxatives.¹

The study revealed that the weekly frequency of SCBM after 4 weeks of treatment was significantly higher than at baseline in patients receiving prucalopride ($p \leq 0.05$), but not in the placebo group. The proportion of patients with an improvement in PAC-quality-of-life satisfaction score of ≥ 1 was significantly higher for the group treated with 1 mg prucalopride once daily compared with the group receiving placebo ($p \leq 0.05$). The authors of the article note that "the importance of these patient perceptions are not always fully appreciated by many of the treating physicians, who may often be more concerned with the patients' stool frequency. However, especially in the elderly patient group, perceived effectiveness of treatment and relief of constipation symptoms beyond just bowel movement frequency are particularly relevant to address".¹

This study¹ is part of the clinical development programme in which over 3,000 patients (adults and elderly, predominantly female) were treated for the equivalent of more than 2,600 patient years and which demonstrated the favourable risk/benefit profile of this novel enterokinetic agent in chronic constipation.²

Neurogastroenterology and Motility is the official journal of the European Society of Neurogastroenterology and Motility, the American Neurogastroenterology and Motility Society and the Functional Brain-Gut Research Group.

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About Resolor® (prucalopride)

Resolor (prucalopride) is a selective, high-affinity 5-HT₄ receptor agonist specifically developed to target impaired motility associated with chronic constipation, thereby restoring normal bowel movement. Resolor (prucalopride) is currently approved in thirty European countries (EU27, Norway, Iceland and Liechtenstein) for the symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.

About chronic constipation

Chronic constipation is characterised by infrequent and difficult passage of stools over a prolonged period and a range of bothersome symptoms. Traditional treatment options for chronic constipation consist mainly of dietary and lifestyle changes in combination with laxatives.³ However, traditional therapies such as fibre or osmotic and stimulant laxatives do not address the underlying cause(s) of chronic constipation⁴. This may explain why there is an important subgroup of patients who are not fully satisfied with their current constipation relief therapy.⁴

About Movetis

Movetis is a European specialty GI company that is focused on improving the lives of millions of patients – both adults and children – by discovering, developing and commercialising innovative treatments targeting GI conditions with a high unmet medical need. Movetis NV was founded in Belgium in November 2006 as a spin-off of Johnson & Johnson.

Movetis has a broad portfolio of GI products. Beside Resolor, Movetis has two products in Phase II development and two prioritised compounds in preclinical development, all addressing important GI areas including ascites, paediatric reflux, refractory GERD (gastroesophageal reflux disease) and severe forms of irritable bowel syndrome. In addition, Movetis has rights to a large library of qualified lead compounds with potential for development in different GI indications and access to know how for compounds in secretory diarrhoea. The current portfolio is licensed from Janssen Pharmaceutica NV, Belgium and Ortho-McNeil Pharmaceutical Inc., two Johnson & Johnson companies. Movetis shares are listed on Euronext Brussels under the ticker MOVE.

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¹ Mueller-Lissner S, Rykx A, Kerstens R, Vandeplassche L. A double-blind, placebo-controlled study of prucalopride in elderly patients with chronic constipation. *Neurogastroenterol Motil.* 2010; Jun 7. DOI 10.1111/j.1365-01533.x

² SmPC. Summary of product characteristics Resolor (prucalopride). October, 2009

³ WGO Practice Guidelines – <http://www.medscape.com/>

⁴ Johanson Kralstein. Chronic constipation: a survey of the patient perspective. *Aliment Pharmacol Ther* 2007; 25:599-608