NORGINE ANNOUNCES POSITIVE RESULTS FROM THE FIRST COMPARATIVE STUDY OF MOVICOL® (PEG 3350+E) AND PRUCALOPRIDE IN CONSTIPATED WOMEN RESISTANT TO STANDARD LAXATIVES

22 May 2013: Norgine today announced positive results of the first controlled head to head study assessing the efficacy of MOVICOL, a worldwide first-line treatment for chronic constipation compared to a newly approved treatment, prucalopride in women suffering from constipation for at least six months and who were resistant to standard laxatives.

The study was sponsored by Norgine and presented at the Digestive Disease Week® (DDW®) 2013 in Orlando, FL, US.[1]

The study which included 236 women, demonstrated that after a 4 week treatment period:

- Both treatments provided effective relief of chronic constipation in women not satisfied with standard laxatives in the past
- Women treated with MOVICOL had a higher number of spontaneous complete bowel movements ($p<0.001$) compared to prucalopride
- MOVICOL produced a profound reduction in colonic transit time (42.4 hours) comparable to the one observed in the prucalopride group (45.3 hours).

Comparison of the effect of MOVICOL (PEG+E) and prucalopride on stool weight and colonic transit time

	MOVICOL (PEG+E) (n=120)	PRUCALOPRIDE (n=116)
Mean weekly stool weight g (SD) Run-in period Week 4	 332 (182) 1208 (279)	 394 (214) 535 (253)
Mean CTT h (SD) Run-in period Week 4	102.79 (40.37) 60.38 (14.26)	106.19 (40.43) 61.12 (32.96)

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The safety and tolerability of MOVICOL and prucalopride observed in the study were generally consistent with those previously reported.

“These results of this first comparative study reinforce that newer therapies should always be compared with existing therapies rather than placebo to assess their clinical relevance” said Marc Halphen, Vice President Senior Scientific Officer at Norgine. He added; “Chronic constipation is a common digestive complaint that affect many women and proven and effective therapies such as MOVICOL that can help reduce unnecessary suffering should always be considered”.

Ends

Notes to editors

About Norgine

Norgine is a successful, independent European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2012, Norgine’s net product sales were c€250 million and the company employs over a 1,000 people.

Norgine’s focus is the development and marketing of pharmaceutical products that address significant unmet clinical needs in therapeutic areas such as gastroenterology, hepatology, critical and supportive care.

The Company currently markets a range of products in various markets in its key therapeutic areas: MOVICOL® for the treatment of constipation and faecal impaction, MOVIPREP® a bowel preparation for use prior to any procedure that requires a clean colon, KLEAN-PREP® for large bowel preparation prior to colonoscopy or surgery, XIFAXAN® (XIFAXANTA™) for the treatment of travellers’ diarrhoea and the reduction in recurrence of episodes of overt hepatic encephalopathy, ORAMORPH® for the treatment of moderate to severe pain associated with cancer and our supportive care portfolio: SAVENE®, DANTRIUM®, XEROTIN® and PROTHER®.

Norgine is active in research and development and currently has products in various stages of clinical development. Norgine manufactures most of its own products in Hengoed, UK and Dreux, France. For more information: www.norgine.com.

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References

1. Marc Halphen et al. Pharmacodynamic effects of osmotic laxative PEG 3350 +electrolytes and prokinetic agent prucalopride: a head to head comparison in a controlled environment. Digestive Disease Week® (DDW®) 2013. Sunday 19 May 2013. Presentation number 275.

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