NORGINE’S MOVIPREP® GRANTED USA MARKETING APPROVAL

New 2-Litre Bowel Preparation for Colonoscopy

Norgine, the European specialty pharmaceutical company, has announced that the US Food and Drug Administration (FDA) has granted marketing approval for MOVIPREP® (PEG 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid for oral solution). MOVIPREP is indicated for bowel cleansing prior to colonoscopy.

Norgine granted exclusive marketing rights for MOVIPREP in the USA to Salix Pharmaceuticals in December 2005. Salix expects to launch MOVIPREP during the fourth quarter of 2006.

Commenting on the USA licence Peter Stein, CEO of Norgine said; “This is Norgine’s first product approval in the USA, and as such is a significant milestone for the company. It is the result of a tremendous amount of hard work from the team in Norgine. This effort has received tremendous support from our partner Salix, and we look forward to working with them to ensure a successful launch of MOVIPREP in the USA”.

Norgine’s COO, Peter Martin added “We are delighted that we are now able to anticipate the imminent launch of MOVIPREP onto the world’s largest market. We are confident that Salix will be able to maximise the opportunity for MOVIPREP in the USA. To date, in clinical trials the product has demonstrated equivalent efficacy and improved patient preference when
compared to existing 4-litre PEG products, and equivalent efficacy and improved safety compared to Fleet® Phospho-soda®. This gives us confidence that MOVIPREP can achieve great success both in the USA and Europe."

“We are very pleased to announce the approval of MOVIPREP, our 2-litre liquid bowel cleansing agent,” stated Carolyn Logan, President and CEO. “We believe that physicians who prefer PEG-based bowel preps will find MOVIPREP an excellent alternative to the currently-marketed 2-litre and 4-litre PEG products. We are pleased that we have the opportunity to work with Norgine to bring this state-of-the-art bowel cleansing agent to market in the US.”

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Notes to editor
Colorectal cancer screening
Colonoscopy is very effective in the early detection of colorectal cancer, and about 90% of colorectal cancers and deaths are preventable if detected early. The American Cancer Society estimates that more than 30,000 lives could be saved annually by widespread screening.

The majority of colonoscopies performed in the US are indicated for colorectal cancer screening, and more than 10 million uses of bowel cleansing agents were prescribed during 2005. The use of a bowel cleansing agent is a pre-requisite to a colonoscopy.

Today less than half of adults age 50 years and older in the US undergo the recommended colorectal cancer screening. Results of a study conducted by the Mayo Clinic demonstrated that patient unwillingness to take a bowel preparation is the single largest barrier to colorectal cancer screening.

MOVIPREP

MOVIPREP received marketing authorisation from the MHRA in March 2006.

Norgine

Norgine is an independent, successful European specialty pharmaceutical company that has been established for 100 years and has a presence in all the major European markets. In 2005 Norgine’s sales were €171 million, the 19th consecutive year of double-digit growth. The company employs over 900 people, of which 350 are in sales and marketing.
Norgine’s current focus is pharmaceutical products that address significant unmet clinical need in areas such as gastroenterology, hepatology and pain management. The company currently markets a range of products in its key therapeutic areas e.g. Movicol® for the treatment of chronic constipation and faecal impaction, Klean-Prep® for bowel preparation prior to colonoscopy, and Oramorph® for the treatment of moderate to severe pain associated with cancer.

Norgine has an active Research and Development effort and currently has products at various stages of clinical development. Norgine has two manufacturing sites; Hengoed in the UK and Dreux, France.

Norgine’s website is www.norgine.com

Salix Pharmaceuticals
Salix Pharmaceuticals, Ltd., headquartered in Raleigh, North Carolina, develops and markets prescription pharmaceutical products for the treatment of gastrointestinal diseases. Salix’s strategy is to in-license late-stage or marketed proprietary therapeutic drugs, complete any required development and regulatory submission of these products, and market them through the Company’s 150-member gastroenterology specialty sales and marketing team.

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