Corporate Press Release

31st May 2012

Norgine's XIFAXAN® 550 Approved in Australia in the Management of Hepatic Encephalopathy

First effective new treatment for potentially highly serious neuropsychiatric condition to be introduced in several decades

Norgine Pty Ltd (Australia) has announced the registration of XIFAXAN 550 (rifaximin α) by the Therapeutic Goods Administration (TGA) of Australia for the prevention of the recurrence of hepatic encephalopathy where other treatments have failed or are contraindicated. Hepatic encephalopathy (HE)* is a potentially highly serious neuropsychiatric condition associated with liver cirrhosis.[1, 2]

Hepatic encephalopathy, results from increased serum ammonia arising from gut bacteria, which is not efficiently removed by the diseased liver,[1] and then enters the brain and causes a spectrum of neurological disorders ranging from mild cognitive problems, such as confusion, to severe disorientation, bizarre behaviour, and even coma.[3] Also, hepatic encephalopathy is associated with poorer employment and financial status, as well as increased burden on the caregiver.[4]. Current therapy for HE is lactulose.

XIFAXAN 550 is a gut specific antibiotic which targets Gram +ve and Gram –ve ammonia producing aerobes and anaerobes to reduce the plasma ammonia load that is associated with the development of hepatic encephalopathy. In a pivotal clinical trial by Bass and colleagues (2010) [5], twice-daily (bid) treatment with XIFAXAN 550 mg plus lactulose compared with treatment with placebo plus lactulose (bid) demonstrated:

- A 58% relative and 23% absolute reduction in the risk of breakthrough episodes of overt hepatic encephalopathy
- A 50% relative and a 9% absolute reduction in the risk of hospitalisations caused by HE

In common with most countries around the world, Australia has a serious problem with the increasing incidence of liver cirrhosis,[6] with a subsequent increased incidence and cost of treatment of hepatic encephalopathy. For example, hepatic encephalopathy was estimated to be responsible for 55,000 hospitalisations at a total cost of $1.2 billion per year in the USA in 2007.[7]

Commenting on the registration of XIFAXAN 550 for hepatic encephalopathy in Australia, Peter Stein, Norgine's CEO said "Norgine is committed to improving patients' health and quality of life as well as that of those who care for them. XIFAXAN 550 has been shown to be highly effective in reducing the recurrence of episodes of hepatic encephalopathy and associated hospitalisations, which has benefits for patients, caregivers, and healthcare systems."

Norgine Australia is the first market for Norgine to enter in the hepatic encephalopathy therapy area, with a drug that has the potential to make a significant difference in treatment outcomes[5], and to improve the quality of life of suffers of hepatic encephalopathy and their caregivers.[8]

Peter Stein also added. "We are delighted to receive approval in Australia, which we anticipate will be the first of many throughout Norgine's markets"

*The indication for use of XIFAXAN 550 is "*Prevention of the recurrence of hepatic encephalopathy where other treatments have failed or are contraindicated*."

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Notes for editors

Two million Australians are, or have been, affected by liver, bile duct or gall bladder disease.[6]

More than 2,000 Australians die each year from chronic liver diseases, cirrhosis and cancers of the liver, gall bladder and bile ducts.[6]

Fatty liver, an obesity-related chronic liver condition, may affect many of the 30% of adults in Australia who are overweight.[6]

XIFAXAN® is a trademark of Alfa Wassermann Hungry KFT. Product under licence from Alfa Wassermann S.p.A.

XIFAXAN 550 is also licensed for the treatment of hepatic encephalopathy by Salix in the USA and by Alfa Wassermann in a number of other territories worldwide

About Norgine

Norgine is an independent, successful European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2011, Norgine's net product sales were €250 million and the company employs over 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 and supportive care.

The Company currently markets a range of products in various markets in its key therapeutic areas e.g. MOVICOL® for the treatment of constipation and faecal impaction, MOVIPREP® a bowel cleansing preparation, KLEAN-PREP® for large bowel preparation prior to colonoscopy or surgery, XIFAXAN® for the treatment of traveller's diarrhoea and ORAMORPH® for the treatment of moderate to severe pain associated with cancer.

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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