PBAC APPROVES XIFAXAN® (RIFAXAMIN α) 550 mg COST EFFECTIVENESS IN AUSTRALIA

LONDON. 24 May 2013: Norgine today announced that the Australian assessment body the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended the use of XIFAXAN 550 mg in the prevention of the recurrence of hepatic encephalopathy (HE) where other treatments have failed or are contraindicated; a potentially life-threatening neuropsychiatric condition associated with liver disease.

XIFAXAN 550 mg is the only treatment that has demonstrated a reduction in the recurrence of episodes of overt HE and hospitalisation due to HE compared with placebo in a 6-month randomised, double blind, placebo-controlled study[i] in which ~91% patients were taking concomitant lactulose in both arms, in patients who were in remission from HE, resulting from chronic liver disease.

The PBAC announced its final decision as follows:

The PBAC recommended listing of rifaximin on the basis of high clinical need, improved clinical benefit over the existing treatments and acceptable cost effectiveness.

On the basis of the information available to it at the April 2013 meeting, the PBAC considered that there was no longer a requirement for a managed entry scheme approach.

This outcome represents the first acceptance for use made by a health technology assessment (HTA) process for XIFAXAN 550 mg in their healthcare system based on cost effectiveness review. Norgine and Alfa Wassermann are working closely with other HTA bodies across Europe including the National Institute for Health and Care Excellence (NICE) and The Scottish Medicines Consortium (SMC) to ensure patients have appropriate access to this important medicine. The review processes are currently underway and Norgine expects these bodies to make their decision in the second half of 2013.

'It's critical that we deliver medicines that treat serious conditions and improve quality-of-life as well as alleviate the cost burden on healthcare systems caused by hospital admissions," said Peter Martin, Norgine Chief Operating Officer.

"XIFAXAN 550 mg provides healthcare professionals with a world-leading treatment option for patients with hepatic encephalopathy, which is a recognised growing problem that may lead to premature death," added Peter Martin.

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Norgine currently holds marketing rights for XIFAXAN 550* in: Australia, Belgium, Denmark, Egypt, Finland, France, Germany, Ireland, Luxembourg, the Netherlands, New Zealand, Norway, Switzerland, Sweden and the UK.

In Europe, XIFAXAN® 550 mg /TARGAXAN® 550 mg is already available in Denmark, Germany and in the UK for healthcare professionals to prescribe in accordance with local guidance.

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Notes to editors

About the PBAC

The PBAC is the independent, expert advisory body comprising doctors, other health professionals and a consumer representative, which makes recommendations to the Australian Government about Pharmaceutical Benefits Scheme (PBS) listings. The Government cannot list a medicine on the PBS unless the PBAC makes a recommendation in favour of its listing.

About Hepatic Encephalopathy

Hepatic encephalopathy is the term used to describe a complex and variable neuropsychiatric condition of patients with acute or chronic liver disease, more commonly associated with cirrhosis. Patients with hepatic encephalopathy may experience symptoms ranging from subtle, clinically indiscernible neurological abnormalities, to severe neurological impairment.

XIFAXAN 550 mg Pivotal Clinical Trial

The pivotal clinical trial by Bass et al (2010), in which patients in remission from recurrent episodes of hepatic encephalopathy due to cirrhosis who were treated with XIFAXAN 550mg twice-daily (bd) with or without lactulose*, were compared with patients given placebo (bd) with or without lactulose* over 6 months, demonstrated:

- A 58% relative reduction in the risk of breakthrough episodes of overt hepatic encephalopathy over 6 months (Hazard ratio 0.42; $p<0.001$). Thus the numbers needed to treat (NNT) = 4
- A 50% relative reduction in the risk of hospitalisations caused by HE over 6 months (Hazard ratio 0.50; $p=0.01$). Thus the numbers needed to treat (NNT) = 9

*91% of patients in both groups were taking lactulose.

About Norgine

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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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About Alfa Wassermann

Alfa Wassermann is a private pharmaceutical group with Head Quarters in Bologna, Italy with its own Research, Development and Manufacturing facilities. In 2012, Alfa Wassermann net sales were above €360million and the company employs over 1300 people. It has a growing number of affiliate companies in both Europe as well as in emerging markets such as Russia, China and Mexico. Its main product Rifaximin-alpha is a gut-selective antibiotic which has been prescribed for 24 years, under the Trade Names of NORMIX®, XIFAXAN® and others, in 33 countries, including the USA where Salix Pharmaceuticals is the exclusive licensee. Alfa Wassermann has also developed other important products: Sulodexide (VESSEL®), a heparinoid for thromboembolic diseases, and Parnaparin (FLUXUM®), a low molecular weight heparin for the treatment and prophylaxis of deep-vein thrombosis. For more information, please visit ALFA WASSERMANN's web site at www.alfawassermann.it

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References

[i] Bass, N.M. *et al.* N Engl J Med, 2010: 362(12): 1071-81)

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