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**SCOTTISH MEDICINES CONSORTIUM ACCEPTS TARGAXAN<sup>®</sup> 550<sup>†</sup>  
(RIFAXIMIN- $\alpha$ ) COST-EFFECTIVENESS<sup>i</sup> – A NEW TREATMENT FOR A LIFE-  
THREATENING CONDITION LINKED TO LIVER DISEASE**

**LONDON. 9 September 2013:** Norgine today announced that the Scottish Medicines Consortium (SMC) has accepted the use, within NHS Scotland, of TARGAXAN<sup>®</sup> 550 (rifaximin- $\alpha$ ), a treatment licensed for the reduction in recurrence of episodes of overt hepatic encephalopathy in patients of 18 years of age and over.<sup>ii</sup>

This is the second acceptance for use made by a health technology assessment (HTA) body. In May 2013, the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia recommended listing of rifaximin on the basis of high clinical need, improved clinical benefit over the existing treatments and acceptable cost-effectiveness.<sup>iii</sup>

**Professor Peter Hayes Professor of Hepatology at the University of Edinburgh and the Scottish Liver Transplant Unit** said: “Being able to use TARGAXAN<sup>®</sup> 550 in Scotland is important as liver disease has been on the rise over the past decade<sup>iv</sup> - so we’re seeing far more cases of hepatic encephalopathy. In 2012, in Scotland alone almost 5,000 people were diagnosed with chronic liver disease,<sup>v</sup> which can progress to cirrhosis, and of which 80 per cent can go on to develop hepatic encephalopathy.<sup>vi, vii</sup>”

He added: “Hepatic encephalopathy is a serious and potentially fatal disease, it develops when the liver stops functioning properly, so the toxins build up in the blood and then enter the brain and can present as serious neurological symptoms.<sup>viii</sup> In the UK, it is estimated that over 10,000 patients suffer from hepatic encephalopathy,<sup>ix</sup> but unfortunately one year survival rates are less than 50 per cent.<sup>x, xi</sup>”

**British Liver Trust’s Chief Executive Andrew Langford** said: “When there is no cure for hepatic encephalopathy apart from liver transplantation, TARGAXAN<sup>®</sup> 550 offers a huge advance after decades of no new treatments. For patients struggling with liver disease, hepatic encephalopathy is a double whammy of both liver disease and related mental health problems. For the person with hepatic encephalopathy and also for their family and friends, this treatment offers the potential of improved quality of life by reducing the recurrence of breakthrough overt episodes and/or hospitalisations for the patient.”

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**Peter Martin Chief Operating Officer at Norgine** said: “Norgine welcomes the positive decision of the SMC which further establishes the clinical and cost-effectiveness of TARGAXAN<sup>®</sup> 550. This new treatment can reduce the treatment cost of cirrhotic patients by reducing the number of breakthrough episodes of hepatic encephalopathy and subsequent hospitalisations.”

**Ends**

### **Notes to editors**

The SMC<sup>i</sup> announced its final decision as follows:

**ADVICE:** following a full submission

**rifaximin (Targaxan<sup>®</sup>)** is accepted for use within NHS Scotland.

**Indication under review:** reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients ≥18 years of age.

In a double-blind randomised controlled study of six months duration, rifaximin was superior to placebo for the primary outcome of time to first overt breakthrough episode of HE.

### **XIFAXAN<sup>®</sup> / TARGAXAN<sup>®</sup> 550 Pivotal Clinical Trial<sup>xii</sup>**

The pivotal clinical trial by Bass *et al*,<sup>xii</sup> in which patients in remission from recurrent episodes of hepatic encephalopathy due to cirrhosis who were treated with rifaximin α 550mg twice-daily (bid) with or without lactulose\*, were compared with patients given placebo (bid) 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.

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### **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 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 critical and supportive care.

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Norgine owns a manufacturing and development site in Hengoed, UK and a manufacturing site in Dreux, France. For more information: [www.norgine.com](http://www.norgine.com).

### **About Alfa Wassermann**

Alfa Wassermann is a private pharmaceutical group with headquarters 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 1,300 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<sup>®</sup>, XIFAXAN<sup>®</sup> 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<sup>®</sup>), a heparinoid for thromboembolic diseases, and parnaparin (FLUXUM<sup>®</sup>), a low molecular weight heparin for the treatment and prophylaxis of deep-vein thrombosis. For more information, please visit Alfa Wassermann's website at [www.alfawassermann.it](http://www.alfawassermann.it).

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  - ii TARGAXAN 550 SmPC. <http://www.medicines.org.uk/emc/>
  - iii PBAC decision. April 2013. <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2013-04/positive-recommendations>
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