

2 October 2015

LSE: VER

**Vernalis plc acquires US rights to MOXATAG®**

*First and only approved once-a-day formulation of the antibiotic, amoxicillin*

*Exemplifies strategy for further expanding product portfolio*

Vernalis plc today announces that it has acquired the US rights to MOXATAG® (amoxicillin extended-release tablets) from Pragma Pharmaceuticals, LLC ("Pragma"). MOXATAG® is the first and only approved once-daily formulation of the antibiotic, amoxicillin.

In consideration for the acquisition, Vernalis has paid to Pragma an undisclosed up-front cash payment and will make a further payment upon successful manufacture of re-launch finished dose product, expected to be by the end of 2015. The consideration payable does not materially impact the Group's cash resources. Under the terms of the transaction, Vernalis will take over supply chain responsibility and will pay Pragma royalties on net sales and further potential sales related milestones.

Approved by the FDA in 2008, MOXATAG® is a penicillin-class antibacterial indicated for the treatment of tonsillitis and/or pharyngitis secondary to streptococcus pyogenes in adults and paediatric patients 12 years of age or older. It was approved based on a Phase III efficacy study and is protected by six Orange Book listed patents, the last of which expires in 2027. It has not been actively promoted since 2010.

Ian Garland, CEO of Vernalis commented, "The acquisition of MOXATAG® is another important step in our transition to a commercial specialty pharmaceutical company. We are delighted that we have been able to quickly expand our primary care product portfolio and leverage our newly established US commercial infrastructure following the recent US launch of TUZISTRA™ XR, our extended-release cough cold oral suspension. MOXATAG® has a strong fit with our target physician audience for TUZISTRA™ XR and we look forward to re-launching the product in early 2016 and to its contribution to our commercial business".

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**Notes to Editors**

**About MOXATAG® (amoxicillin extended-release tablets)**

**Indication**

MOXATAG® is a penicillin-class antibacterial indicated for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes* (*S. pyogenes*) in adult and pediatric patients 12 years of age or older.

**How to take MOXATAG®**

Other amoxicillin tablets must be taken 2 or 3 times a day (depending on how serious the infection is) for 10 days<sup>1</sup>. MOXATAG® requires only one dose a day for 10 days. That means fewer tablets for the patient to swallow.

***Tonsillitis and/or Pharyngitis***

The recommended dose of MOXATAG® is 775 mg once daily taken within 1 hour of finishing a meal for 10 days. The full 10-day course of therapy should be completed for effective treatment of tonsillitis and/or pharyngitis secondary to *S. pyogenes*.

Do not chew or crush tablet.

**The technology behind once-daily dosing**

Through its delivery system, MOXATAG® releases medicine in 3 separate pulses over time in different parts of the intestinal tract. This timed release of medicine throughout the day ensures that there is enough amoxicillin in your system to treat your infection with 1 dose each day for 10 days.

**Important Safety Information**

Severe life-threatening reactions can occur with MOXATAG®. Do not take MOXATAG® if you have had a previous reaction to amoxicillin or penicillin.

If you develop diarrhea that becomes severe and watery or does not go away, stop taking MOXATAG® and call your health care professional. This could be a sign of a serious medical problem.

Tell your health care professional right away if you develop other infections.

Do not take MOXATAG® if you have mononucleosis (mono).

Oral contraceptives may be less effective if you are taking MOXATAG®.

Before taking MOXATAG®, tell your health care professional if you are pregnant, plan to become pregnant or are breast-feeding. If you become pregnant while taking MOXATAG®, call your health care professional.

The most common side effects of MOXATAG® are yeast infection, diarrhea, nausea, vomiting, abdominal pain, and headache.

Call your healthcare provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

### **About Vernalis**

Vernalis is a revenue generating, commercial stage pharmaceutical company with significant expertise in drug development. The Group has three approved products: Tuzistra™ XR targeting the US prescription cough cold market; MOXATAG®, a once-a-day formulation of the antibiotic, amoxicillin, indicated for the treatment of tonsillitis and/or pharyngitis secondary to Streptococcus pyogenes in adult and paediatric patients 12 years of age or older; and frovatriptan for the acute treatment of migraine. It has an exclusive licensing agreement to develop and commercialise multiple novel products focussed on the US prescription cough cold market as well as eight programmes in its NCE development pipeline. Vernalis has also significant expertise in fragment and structure based drug discovery which it leverages to enter into collaborations with larger pharmaceutical companies. The Company's technologies, capabilities and products have been endorsed over the last five years by collaborations with leading pharmaceutical companies, including AKP, Biogen Idec, Endo, GSK, Genentech, Lundbeck, Menarini, Novartis, Servier Taisho and Tris.

For further information about Vernalis, please visit [www.vernalis.com](http://www.vernalis.com).

### **Vernalis Forward-Looking Statement**

This news release may contain forward-looking statements that reflect the Company's current expectations regarding future events including the clinical development and regulatory clearance of the Company's products, the Company's ability to find partners for the development and commercialisation of its products, as well as the Company's future capital raising activities. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors including the success of the Company's research strategies, the applicability of the discoveries made therein, the successful and timely completion of clinical studies, the uncertainties related to the regulatory process, the ability of the Company to identify and agree beneficial terms with suitable partners for the commercialisation and/or development of its products, as well as the achievement of expected synergies from such transactions, the acceptance of Tuzistra™ XR, MOXATAG®, frovatriptan and other products by consumers and medical professionals, the successful integration of completed mergers and acquisitions and achievement of expected synergies from such transactions, and the ability of the Company to identify and consummate suitable strategic and business combination transactions.

### **References:**

1. Amoxicillin package insert. <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=13bd4214-9b7f-425b-af5f-fc1ddc678230>