

Vernalis PLC launches Tuzistra™ XR (codeine polistirex and chlorpheniramine polistirex) for cough relief with 12-hour dosing

Published on September 07, 2015



Tuzistra™ XR
(Codeine Polistirex and
Chlorpheniramine Polistirex)
EXTENDED-RELEASE ORAL SUSPENSION



Tuzistra™ XR is the Only Twice-Daily, Extended-Release, Codeine-Based Cough Cold Syrup Available in the US

Vernalis plc (LSE: VER) and Tris Pharma today announce that Tuzistra™ XR (codeine polistirex and chlorpheniramine polistirex), extended-release oral suspension, CIII (DEA Schedule III) is now available to patients and physicians in the United States. Tuzistra™ XR, was approved by the U.S. Food and Drug Administration on April 30, 2015. It is indicated for the relief of cough and symptoms associated with upper respiratory allergies or a common cold in adults 18 years of age and older.

Tuzistra™ XR is the only codeine-based extended-release cough cold syrup available to patients and physicians in the United States. The US cough cold prescription market is worth in excess of \$3 billion at current brand pricing, with 30-35 million annual prescriptions. This market is dominated by short-acting treatments, which require dosing 4-6 times a day. Tuzistra™ XR was developed using Tris Pharma's liquid sustained release technology, LiquiXR®, which allows for extended drug delivery throughout a 12-hour dosing period.

Through Vernalis Therapeutics Inc, a wholly owned US subsidiary, a dedicated specialist US sales team focused on primary care has commenced promotion of Tuzistra™ XR to physicians.

Ian Garland, Chief Executive Officer of Vernalis, said "The launch of Tuzistra™ XR marks a significant milestone in the transition of Vernalis to a commercial specialty pharmaceutical company. There is a significant demand for an extended relief cough cold treatment and we are pleased to offer US physicians and patients the only 12-hourly dosed codeine-based, non-schedule II liquid product ahead of this year's cough cold season. We believe the primary care market offers Vernalis a significant commercial opportunity and we plan to leverage our specialist sales platform with complementary products, to enable us to take a share of this large and growing market."

"We are delighted that our collaboration with Vernalis has yielded its first commercial product for the cough cold market in the US. Tuzistra™ XR alone represents a significant

commercial opportunity and with further products in development as part of this alliance, we hope, over time, to be able to provide a range of extended-release liquid products that address other segments of the cough cold market where 12-hourly dosing is not currently offered” said **Ketan Mehta, President and CEO, Tris Pharma**.

About Vernalis:

Vernalis is a revenue generating, commercial stage pharmaceutical company with significant expertise in drug development. The Group has two approved products; Tuzistra™ XR targeting the US prescription cough cold market 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 <http://www.vernalis.com>.

Please [click here](#) to access the PDF of this press release.

About Tris Pharma:

Tris Pharma is a specialty pharmaceutical company focused on the research and development of technologies-driven products. Tris has pioneered the delivery of sustained release in the liquid, chewable/ODT and strip dosage forms so patients do not have to swallow a pill. Tris’ Nobuse™ technology provides abuse deterrence for opioids and other abuse-prone drugs. Tris’ R&D and manufacturing facilities are located in Monmouth Junction, New Jersey, USA.

For more information, please visit <https://www.trispharma.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 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.