

GSK and Valeant Receive European Authorisation for Trobalt (retigabine)

March 29, 2011

LONDON and MISSISSAUGA, Ontario, March 29, 2011 /PRNewswire via COMTEX/ -- GlaxoSmithKline (GSK) and Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) announced today that the European Commission has granted marketing authorisation for Trobalt(TM) (retigabine) as an adjunctive (add-on) treatment of partial onset seizures (a form of epilepsy where a seizure begins in a specific area in one side of the brain), with or without secondary generalisation in adults aged 18 years and above with epilepsy.(1)

"The European authorisation of retigabine is very welcome as it will provide neurologists within Europe with a new therapeutic option for the management of appropriate patients with uncontrolled partial onset seizures," said Dr. Tony Hoos, Senior Vice President, European Medical Affairs, GSK.

This European licence was supported by the results of the pivotal phase III studies RESTORE 1 and 2, and Study 205, a phase IIb study. The results of these three studies showed that more patients with partial onset seizures saw a reduction of 50% or more in seizure frequency compared to placebo, when a 600mg, 900mg or 1200mg dose of retigabine was added to their current anti-epileptic drug (AED) therapy.(1)

In controlled clinical studies with retigabine, urinary retention occurred at a rate of 0.9 percent in patients receiving the drug compared to 0.5 percent on placebo. Across the phase II/III safety population there were four (0.3%) serious adverse events of urinary retention, three of which were known to have resulted in withdrawal. The EU prescribing information therefore recommends that retigabine is used with caution in patients at risk of urinary retention.(1)

Retigabine also caused a prolongation of the QT interval (electrical activity of the heart) when used at the highest dose in healthy volunteers in a thorough QT study. As a precaution, the EU prescribing information recommends that an ECG is recorded before the initiation of retigabine in patients who are taking any medication that may interfere with QT intervals or who may have congestive heart failure, ventricular hypertrophy, hypokalaemia or hypomagnesaemia and in patients initiating treatment who are 65 years of age and above.(1)

In the pivotal trials, the most frequently reported adverse events with the use of retigabine in combination with other AEDs (occurring in at least 5 percent of subjects and at least twice the placebo rate) were dizziness (23 percent), fatigue (15 percent), confusion (9 percent), vertigo (8 percent), tremor (8 percent), abnormal coordination (7 percent), double vision (7 percent), disturbance in attention (6 percent), memory impairment (6 percent), and visual blurring (5 percent). In addition, somnolence occurred in 22 percent of patients on retigabine compared to 12 percent on placebo.(2-4)

Retigabine, referred to as ezogabine in the U.S. and Canada, is being jointly developed by GSK and Valeant.

"We are very pleased to have reached such an important milestone in the development of retigabine," said Susan Hall, Ph.D., Head of Research and Development at Valeant. "There is a

significant need for new AEDs and retigabine could potentially play an important role in the management of partial onset seizures in appropriate patients."

This European authorisation represents the first licence for retigabine. Preliminary authorisation was granted by the Swiss Agency for Therapeutics Products in December 2010. Applications for marketing authorisation have been submitted in six countries in addition to the EU. In December 2010, GSK and Valeant announced receipt of a Complete Response letter from the U.S. Food and Drug Administration (FDA) for the New Drug Application for ezogabine, the U.S. generic name for retigabine, and are working to submit a response to the FDA as soon as possible in 2011.

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit

<http://www.gsk.com/>

About Valeant Pharmaceuticals

Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of neurology, dermatology and branded generics. More information about Valeant can be found at

<http://www.valeant.com/>

About Trobalt(TM)(retigabine/ezogabine)

Trobalt(TM) has been developed by Valeant and GSK as an adjunctive treatment for epilepsy patients aged 18 years and above with partial onset seizures. Retigabine is the non-proprietary name adopted by the International Non-proprietary Name for Pharmaceuticals Substances Program. In the U.S. and Canada, ezogabine is the non-proprietary name adopted by the United States Adopted Name Council. GlaxoSmithKline and Valeant entered into an exclusive worldwide collaboration agreement for Trobalt(TM) in 2008.

About partial onset seizures in epilepsy

Epilepsy is a neurological condition that produces brief disturbances in the normal electrical signals of the brain(5). Partial seizures, which begin in a specific area in one side of the brain, are the most common type of seizure experienced by adults with epilepsy.(6)

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Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2010.

Valeant Pharmaceuticals Forward-Looking Statement

This press release may contain forward-looking statements, including statements regarding the development or authorisation of retigabine, providing neurologists within Europe with a new therapeutic option for the management of appropriate patients with uncontrolled partial onset seizures, and the potential role of retigabine in the management of epilepsy. Forward-looking statements may be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in the company's most recent annual or quarterly report filed with the Securities and Exchange Commission ("SEC") and other risks and uncertainties detailed from time to time in the Company's filings with the SEC and the Canadian Securities Administrators ("CSA"), which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. Valeant undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this press release or to reflect actual outcomes.

References

- Retigabine European SmPC
- Brodie, MJ. Efficacy and safety of adjunctive retigabine (ezogabine) in refractory partial epilepsy. *Neurology*. October 13, Epub ahead of print.
- Study report - Retigabine - VRX-RET- E22-301
- Porter et al. Randomized, multicenter, dose-ranging trial of retigabine for partial onset seizures. *Neurology*. 2007;68:1197-1204
- Epilepsy Foundation. About Epilepsy & Seizures/FAQ. Available at: <http://www.epilepsyfoundation.org/about/faq/> [Accessed: 15 March 2011]
- Epilepsy Foundation. Types of Seizures. Available at: <http://www.epilepsyfoundation.org/about/types/types/> [Accessed: 15 March 2011]

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