Valeant and GlaxoSmithKline Announce U.S. FDA Approval of Potiga(TM) (ezogabine)

June 13, 2011

MISSISSAUGA, Ontario, LONDON, and RESEARCH TRIANGLE PARK, N.C., June 13, 2011 /PRNewswire via COMTEX/ -- Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) and GlaxoSmithKline (NYSE: GSK) announced today that the U.S. Food and Drug Administration (FDA) has approved Potiga(TM) (ezogabine) Tablets, a potassium channel opener, as adjunctive treatment of partial-onset seizures in patients aged 18 years and older.

"We are so pleased to reach such an important milestone with the U.S. approval of *Potiga* by the FDA," stated Susan Hall, PhD, head of research and development at Valeant. "We believe this product will play a needed role in the management of partial onset seizures in appropriate patients who are uncontrolled on their current medications."

FDA has recommended that ezogabine be scheduled as a controlled substance under the Controlled Substances Act (CSA). Final classification is still under review by the Federal Drug Enforcement Administration (DEA) and ezogabine will not be available until this process is complete.

Ezogabine is expected to be available in U.S. pharmacies by the end of the year. Full Prescribing Information and a Medication Guide will be available at
http://www.gsk.com/
once scheduling is complete.

The efficacy of ezogabine as adjunctive therapy in partial onset seizures was established in 3 controlled clinical studies involving 1,239 adult patients. The primary endpoint was percent change in seizure frequency from baseline in the double-blind treatment phase.

FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) will be necessary for ezogabine, with the goal of informing healthcare professionals of the risk of urinary retention and the symptoms of acute urinary retention. Ezogabine caused urinary retention in clinical trials. Urinary retention was reported as an adverse event in 29 out of 1,365 (approximately 2%) patients treated with ezogabine. In all studies of patients with partial-onset seizures, including open-label studies, five patients required catheterization (four on ezogabine and one on placebo).

In 3 controlled clinical studies, 25% of patients receiving ezogabine (199/813) and 11% of patients receiving placebo (45/427) discontinued treatment because of treatment-emergent adverse reactions.

The most frequently reported adverse reactions in patients receiving ezogabine vs placebo (greater than or equal to 4% and occurring approximately twice the placebo rate) were dizziness (23% vs 9%), somnolence (22% vs 12%), fatigue (15% vs 6%), confusional state (9% vs 3%), vertigo (8% vs 2%), tremor (8% vs 3%), abnormal coordination (7% vs 3%), diplopia (7% vs 2%), disturbance in attention (6% vs <1%), memory impairment (6% vs 3%), asthenia (5% vs 2%), blurred vision (5% vs 2%), gait disturbance (4% vs 1%), aphasia (4% vs <1%), dysarthria (4% vs <1%), and balance disorder (4% vs <1%).

Outside of the U.S., ezogabine is known as retigabine (brand name Trobalt(TM)), and received marketing authorization in the European Union (EU) on March 28th 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 - 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/
.

GlaxoSmithKline Enquiries:

UK Media enquiries:	David Mawdsley	(020) 8047 5502
	Stephen Rea	(020) 8047 5502
	Sarah Spencer	(020) 8047 5502
	Janet Morgan David Daley	(020) 8047 5502 (020) 8047 5502
US Media enquiries:	Nancy Pekarek	(919) 483 2839
	Mary Anne Rhyne	(919) 483 2839
	Kevin Colgan	(919) 483 2839
	Sarah Alspach	(919) 483 2839
European Analyst/Investor enquiries:	Sally Ferguson	(020) 8047 5543
	Gary Davies	(020) 8047 5503
	Ziba Shamsi	(020) 8047 3289

US Analyst/ Investor enquiries:	Tom Curry	(215) 751 5419
	Jeff McLaughlin	(215) 751 7002
Valeant Enquiries:	Laurie W. Little	(949) 461 6002

GlaxoSmithKline 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, but not limited to, statements regarding the efficacy and safety of Potiga, Potiga's role in the management and treatment of epilepsy, the timing and classification of Potiga as a controlled substance and the timing of Potiga's availability. 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 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 and the Canadian Securities Administrators, which risks and uncertainties 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.

*Editor's note: Ezogabine is the non-proprietary name adopted by the United States Adopted Name Council for use in the U.S. and Canada. Retigabine is the non-proprietary name adopted by the International Nonproprietary Name for Pharmaceuticals Substances Program for use in the rest of the world.

877-281-6642
514-856-3855 (Canada)

EMAIL ALERTS EMAIL PAGE RSS FEED

Media inquiries
Corporate.communications@bauschhealth.com
908-569-3692