

Regulatory Update - GSK and Valeant Respond to FDA on ezogabine

April 18, 2011

LONDON, RESEARCH TRIANGLE PARK, N.C. and MISSISSAUGA, Ontario, April 18, 2011 /PRNewswire via COMTEX/ -- GlaxoSmithKline (GSK) and Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) submitted the response on 15 April 2011 to the U.S. Food and Drug Administration (FDA) Complete Response letter received on 30 November 2010 for the New Drug Application (NDA) for ezogabine*.

Ezogabine is an investigational anti-epileptic drug being studied for the adjunctive treatment of adults with partial-onset seizures.

For announcements regarding the regulatory status, including filing and approval information, of ezogabine outside the US (where it is called retigabine*), please visit

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

and

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

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

Claire Brough

(020) 8047 5502

Stephen Rea

(020) 8047 5502

Alexandra Harrison

(020) 8047 5502

Janet Morgan

(020) 8047 5502

	David Daley	(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 initial review and assessment of the complete response letter, the ability to adequately address the issues raised in the complete response letter and the timing of any response to FDA. 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.

*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.

Registered in England & Wales:

No. 3888792

Registered Office:

980 Great West Road
Brentford, Middlesex
TW8 9GS



Investor Inquiries

ir@bauschhealth.com

877-281-6642

514-856-3855 (Canada)

Media inquiries

Corporate.communications@bauschhealth.com

908-569-3692

[LEGAL NOTICE](#)

[PRIVACY POLICY](#)

[EMAIL ALERTS](#)

[EMAIL PAGE](#)

[RSS FEED](#)

Use of this site signifies your agreement to the Legal Notice and Privacy Policy.
©2026 Bausch Health Companies Inc. All rights reserved. MTB.0230.USA.18 V2.0

CALIFORNIA RESIDENTS: DO NOT SELL MY PERSONAL INFORMATION

