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GSK and Valeant announce receipt of U.S. FDA Complete Response letter for ezogabine

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London, UK, Research Triangle Park, NC and Mississauga, Ontario, December 1, 2010 /PRNewswire via COMTEX/ -- GlaxoSmithKline (NYSE: GSK) and Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) announced receipt of a Complete Response letter from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) for ezogabine*, an investigational anti-epileptic drug being studied for the adjunctive treatment of adults with partial-onset seizures.

A Complete Response letter is issued by the FDA's Center for Drug Evaluation and Research when the review of a file is completed and questions remain that preclude the approval of the NDA in its current form. GSK and Valeant are evaluating the Complete Response letter in which FDA cited non-clinical reasons for this action. GSK and Valeant believe that these items can be addressed and the two companies are working for a timely response to the FDA as soon as possible in 2011.

The NDA was submitted to the FDA on 30 October 2009.

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 www.gsk.com
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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 www.valeant.com
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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 2009.

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.

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