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Ezogabine, an Investigational Anti-Epileptic Drug, Receives Positive Vote from FDA Advisory Committee

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GlaxoSmithKline (NYSE: GSK) and Valeant Pharmaceuticals International (NYSE: VRX) announced today that a U.S. Food and Drug Administration (FDA) advisory committee voted unanimously that clinical studies had provided substantial evidence of the effectiveness of ezogabine as adjunctive treatment for adults with partial-onset seizures.

After a review of the safety data, including urinary retention, infection and kidney stones, the majority of Committee members voted that urinary retention could be mitigated by patient monitoring and discussed how this could be addressed. The Committee also voted unanimously that monitoring should not be instituted for infection and kidney stones.

"We are encouraged by the Advisory Committee's assessment of the efficacy and safety of ezogabine and await a decision by the FDA," said Atul Pande, MD, senior vice president, Neurosciences Medicines Development Center, North America Pharmaceuticals, GlaxoSmithKline. "For appropriate patients, we believe ezogabine could offer an important adjunctive treatment option for partial-onset seizures that are not well-controlled."

The Peripheral and Central Nervous System Drugs Advisory Committee reviewed efficacy data from three pivotal studies of ezogabineand an integrated safety data base including all patients who had at least one dose of ezogabine. Overall, ezogabine, as adjunctive therapy at a daily dose of 600, 900 or 1200 mg, reduced the median number of partial-onset seizures in adults with epilepsy not adequately controlled on one to three concomitant anti-epileptic drugs compared to placebo (standard therapy).

"We are pleased with the Advisory Committee's evaluation of ezogabine," said Susan Hall, PhD, Head of Neurology Research and Development at Valeant. "There is a significant need for additional anti-epileptic drugs because approximately one-third of patients with epilepsy continue to experience seizures despite treatment."

The FDA specifically asked the Committee to comment on risks associated with urinary retention. In the pivotal trials, urinary retention occurred at a rate of 0.9 percent in patients receiving ezogabine compared to 0.5 percent on placebo. In all studies of patients with partial-onset seizures, including open-label studies, five patients required catheterization (four on ezogabine and one on placebo). The Committee recommended that patient monitoring for these events would be appropriate, with special attention given to specific groups that may be predisposed to urinary retention.

In the pivotal trials, the most frequently reported adverse events with the use of ezogabine 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 ezogabine compared to 12 percent on placebo.

The FDA does not have to follow the advice of the Advisory Committee, though it usually does. The Prescription Drug User Fee Act goal date for the FDA to complete its review of the ezogabine application is August 30, 2010. The product, known as retigabine outside the U.S., also is under review by the European Medicines Agency.*

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 go to
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Valeant Pharmaceuticals - Valeant Pharmaceuticals International (NYSE: VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of neurology and dermatology. More information about Valeant can be found at
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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 efficacy and safety of ezogabine, its role in the management and treatment of epilepsy, and the review by the FDA with respect to, and the timing of, any marketing approval

for ezogabine. 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"). Forward-looking information contained in this press release does not take into account or give effect to the impact of the proposed merger with Biovail. Additional uncertainties relating to the proposed merger with Biovail are discussed under the heading "Risk Factors" in the preliminary joint proxy statement/prospectus contained in the registration statement on Form S-4 filed by Biovail on July 21, 2010 with the SEC and will be included in the definitive version thereof when it becomes available. 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 nonproprietary name adopted by the International Nonproprietary Name for Pharmaceuticals Substances Program for use in the rest of the world.

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