GSK and Valeant Announce New U.S. FDA PDUFA Goal Date for Ezogabine

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LONDON, RESEARCH TRIANGLE PARK, N.C., and ALISO VIEJO, Calif., Aug. 30 /PRNewswire-FirstCall/ -- GlaxoSmithKline (NYSE: GSK [1]) and Valeant Pharmaceuticals International (NYSE: VRX [2]) announced today the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date for ezogabine* to 30 November 2010. The original goal date was 30 August 2010.

The FDA has not yet completed the review of the New Drug Application (NDA) for ezogabine due to the recent submission of a formal REMS (Risk Evaluation and Mitigation Strategy) for ezogabine, an investigational anti-epileptic drug being studied for the adjunctive treatment of adults with partial onset seizures. The REMS was requested by FDA in correspondence dated 16 August 2010 and submitted to the FDA on 26 August 2010.

The NDA was submitted to the FDA on 30 October 2009. The companies will continue to work closely with FDA as the Agency completes its review.

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 [3]

Valeant Pharmaceuticals – Valeant Pharmaceuticals International (NYSE: VRX [2]) 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 www.valeant.com [4].

GlaxoSmithKline cautionary statement re
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