FDA approves Glaxo, Valeant's epilepsy drug

Singapore, June 16, 2011: Valeant Pharmaceuticals International and GlaxoSmithKline announced that the US Food and Drug Administration has approved Potiga (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.

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 percent) 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).