Press release, 1 December 2010

Complete Response letter for ezogabine

Valeant Pharmaceuticals International, (Meda's partner for ezogabine - known as retigabine outside of the U.S.) has received a Complete Response letter from the U.S. Food and Drug Administration (FDA) 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.

A Complete Response letter is issued by the FDA's Center of 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. Valeant and their global collaboration partner for ezogabine, GlaxoSmithKline, 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.

For questions, please contact:

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