



FDA accepts NDA filing for Retigabine

The U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) seeking marketing approval for Retigabine. In addition, the European Medicines Agency (EMA) confirmed on November 17, 2009 that the MAA (Marketing Authorization Application) was successfully validated thus enabling the MAA review to commence.

Retigabine comprises a new way of affecting potassium channels in the central nervous system. It has been documented to treat epilepsy and has a different mechanism of action compared to current antiepileptic therapies.

Meda's partner for Retigabine, Valeant Pharmaceuticals International (Valeant), has a global collaboration agreement with the pharmaceutical company GlaxoSmithKline for the commercialization of Retigabine. Meda is entitled to receive significant royalties on sales and certain milestone payments from Valeant on Retigabine. This acceptance by the FDA triggers a milestone payment to Meda of 8 MUSD.

If questions, please contact:

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