Press release, 12 August 2010

Ezogabine receives positive vote from FDA advisory committee

The U.S. Food and Drug Administration (FDA) advisory committee voted unanimously that clinical studies had provided substantial evidence of the effectiveness of Ezogabine (known as Retigabine outside of the U.S.) 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.

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

"This positive recommendation from the advisory committee is a significant step in the registration process for Retigabine. The clinical evidence demonstrates that Retigabine can be an important option when treating patients with epilepsy", said Anders Lönner, CEO Meda.

The FDA does not have to follow the advice of the Advisory Committee, though it usually does. Retigabine is also under review by the European Medicines Agency.

Meda's partner for Retigabine, Valeant Pharmaceuticals International, has a collaboration agreement with the pharmaceutical company GlaxoSmithKline for the commercialization of Retigabine. Meda is entitled to receive significant royalties on global sales and certain milestone payments from Valeant on Retigabine.

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