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Merck KGaA: Sarizotan Phase III Studies Did Not Meet Primary Efficacy Endpoint

Darmstadt, June 23, 2006 – Merck KGaA announced today the completion of two Phase III clinical trials of Sarizotan in advanced Parkinson’s disease patients suffering from dyskinesia.

The two placebo-controlled double-blind Phase III studies (PADDY-1 and PADDY-2) were performed in 15 countries worldwide in over 1,000 Parkinson patients with disabling dyskinesia. The treatment duration was six months with the first endpoint reached after three months. Sarizotan 1-mg tablets or a matching placebo were administered twice daily. The primary target variable of efficacy was based on the Unified Parkinson’s Disease Rating Scale (UPDRS) and included measures of severity as well as duration of patients’ dyskinesia. Treatment response was defined as a 25% improvement or greater in the primary endpoint.

The Phase III studies in the present design did not confirm the Phase II findings nor the results from preclinical studies. A statistically significant difference of the primary target variable between Sarizotan and placebo could not be demonstrated in these studies. Therefore a filing and launch in this indication will not be possible. Merck does not plan to pursue further development of this compound.

It is planned to present the results of the PADDY-1 and PADDY-2 studies at the Movement Disorder Society’s 10th International Congress of Parkinson’s Disease and Movement Disorders in Kyoto later this year.
Sarizotan is a full agonist at serotonin 5-HT$_{1A}$ receptors and also shows high affinity to dopamine D$_3$ and D$_4$ receptors.

Parkinson’s disease is the second most common neurodegenerative disease after Alzheimer’s disease. The typical clinical symptoms of Parkinson’s disease are tremor, rigidity and bradykinesia (slowing down of movements). The prevalence of Parkinson’s is estimated at approximately 1 million patients in the US and 1.3 million in the EU. In the early stage, most patients can be treated sufficiently with available anti-Parkinson drugs. However, after years of treatment, unavoidable complications occur such as motor fluctuations (unstable response to treatment) and dyskinesia, which is characterized by involuntary turning or twisting movements. To date, no drug is approved for this troubling condition.