

## Press Release

September 22, 2008

### **KeyNeurotek Pharmaceuticals Receives Orphan Drug Designation of its lead compound KN38-7271 for the treatment of moderate and severe closed traumatic brain injury from EMEA**

**Magdeburg, September 22, 2008** – KeyNeurotek Pharmaceuticals AG, a biotechnology company focused on the development and marketing of drugs against auto-immune diseases and degenerative disorders of the central nervous system (CNS), today announced that the Committee for Orphan Medicinal Products (COMP) of the London-based European Medicines Agency (EMA) has approved KN38-7271 as an Orphan Medicinal Product for the orphan indication moderate and severe closed traumatic brain injury (TBI). According to the EMA, moderate and severe closed TBI was estimated to be affecting less than 4 in 10,000 persons in the European Community at the time of KeyNeurotek's application. Closed TBI is chronically debilitating and life threatening due to the high fatality rate and likelihood of permanent functional neurological impairments in surviving patients. Although satisfactory treatments of TBI have been authorized in the Europe Community, KN38-7271 may be of significant benefit to the patients.

Orphan Medicinal Products gain from a variety of incentives such as scientific advice and protocol assistance from EMA during the product development phase, a 10-year marketing exclusivity, fee reductions or exemptions as well as further national incentives. The funds made available by the European Community for fee exemptions for orphan medicinal products amounted to 6 million € in 2007.

KN38-7271 is being tested by KeyNeurotek Pharmaceuticals in an international Phase II study in more than 90 patients with severe TBI since the end of 2006. The cannabinoid receptor agonist activates both CB1 and CB2 receptors in the brain, strengthening important natural protection mechanisms and preventing overacting inflammatory reactions. Four clinical Phase I trials indicated that the product is safe well tolerated in humans.

**Dr Frank Striggow, CEO of KeyNeurotek Pharmaceuticals, said:** „We are very pleased about this very positive EMA decision. The Orphan Drug Designation will boost the further clinical development and marketing of our lead product KN38-7271.”

### **About KeyNeurotek Pharmaceuticals AG**

KeyNeurotek Pharmaceuticals, a privately held biotechnology company, was founded in 2000 within the Magdeburg, Germany, region, one of the leading centres of neuroscience in Europe.

The company pursues a number of drug candidates in various preclinical and clinical stages. The most advanced compound, KN38-7271, a cannabinoid receptor agonist, is in a Phase IIa trial in comatose patients with traumatic brain injury. At present, there is no targeted therapy for these patients.

KeyNeurotek Pharmaceuticals has unique functional and tissue-based high throughput screening platforms for compatible ex vivo and in vivo studies (TELOMICS™). Based on its know-how, KeyNeurotek develops innovative therapies for the treatment of various neurodegenerative diseases of the central nervous system, such as traumatic brain injury (TBI), stroke, Alzheimer's disease and urinary incontinence/overactive bladder.

The company has built a strong network with renowned local and international partners, including, among others, the Leibniz Association, the Max Planck Society and Fraunhofer Society, Evotec, Schwarz Pharma/UCB, Bayer Schering and Gruenthal. KeyNeurotek has been awarded the Hugo-Junckers Innovation Award of the State of Sachsen-Anhalt in 2002 and 2004 and the Innovation Award of the German Industry in 2006.

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