

Announcement

NeuroSearch's license partner Astellas initiates clinical Phase Ib study with ACR16 in patients with schizophrenia

NeuroSearch's development and license partner Astellas Pharma (Astellas) has enrolled and dosed the first patients in a clinical Phase Ib study with the drug candidate ACR16 for the treatment of schizophrenia.

The Phase Ib study is a placebo-controlled, multiple-dose escalating study to evaluate the safety and tolerability of ACR16 in patients with schizophrenia. The study will be performed in the US and include up to 60 patients. While this study assesses primarily the safety and tolerability, scores on the PANSS (Positive and Negative Symptoms' Scale) will be included as an efficacy measure.

ACR16 is a novel compound in the pharmacological class of CNS active agents called dopaminergic stabilizers. Dopaminergic stabilizers are compounds that can both enhance and counteract dopamine-dependent functions in the brain, depending on the initial level of dopaminergic activity. ACR16 also enhances the glutamatergic function and the compound has shown promising behavioural effects in preclinical models for psychoses including schizophrenia.

Astellas holds the rights to ACR16 for all indications except for Huntington's disease, where NeuroSearch has the rights in North America and Europe. NeuroSearch is preparing for the initiation of clinical Phase III studies with ACR16 for the treatment of Huntington's disease.

The initiation of the Phase Ib study with ACR16 in schizophrenia does not change NeuroSearch's financial expectations for 2007 of a loss before tax of DKK 80 – 100 million.

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NeuroSearch is a Scandinavian biopharmaceutical company listed on the Copenhagen Stock Exchange (NEUR). Our core business covers the development of novel drugs, based on a broad and well-established drug discovery platform focusing on ion channels and diseases of the central nervous system (CNS). A substantial part of the company's activities are partner financed through a broad alliance with GlaxoSmithKline (GSK) and collaborations with among others Abbott and Astellas. Eight drug programmes are in clinical development: ACR16 for the treatment of Huntington's disease (under preparation for Phase III), tesofensine for the treatment of obesity/type 2 diabetes (Phase II), NS2359 for the treatment of depression (Phase II) and ADHD (Phase II) in partnership with GSK, NS1209 for the treatment of epilepsy and pain (Phase II), ABT-894 for the treatment of ADHD (Phase II) and neuropathic pain (Phase I) in partnership with Abbott, ACR16 for the treatment of schizophrenia (Phase I) in partnership with Astellas, and ACR325 for the treatment of psychoses and bipolar disorder (Phase I). In addition, NeuroSearch has a broad portfolio of preclinical drug candidates and has equity interests in several biotech companies.