

Media Release

Ergonex Pharma initiates Phase II clinical trial of Terguride in pulmonary arterial hypertension

Appenzell, Switzerland, January 29, 2008 – Ergonex Pharma GmbH today announced that it has initiated a phase II clinical trial with Terguride in pulmonary arterial hypertension.

The Phase II clinical trial will be conducted in clinical centres in Switzerland, Germany, Austria, Poland and The Netherlands. It is planned to enrol a total of 84 patients with pulmonary arterial hypertension of functional class II-IV. The study is designed as a randomised, double-blind, placebo-controlled trial and will evaluate the efficacy and safety of Terguride in patients on stable treatment with best supportive care. The primary endpoint of the trial is to assess the effects of Terguride as compared to best supportive care on pulmonary artery vascular resistance (PVR) following 12 weeks of treatment.

"In October 2007 we were granted orphan drug designation for Terguride in the treatment of pulmonary arterial hypertension by the EMEA. Now we hope to translate into patients the promising anti-remodelling activity of Terguride seen in animal models of pulmonary arterial hypertension" stated Dr Rudolf Reiter, Chief Executive Officer of Ergonex Pharma GmbH. "We believe that Terguride with its anti-proliferative and anti-fibrotic activity offers the opportunity to provide a significant therapeutic benefit in pulmonary arterial hypertension by acting on serotonin signalling as a molecular target, which is not addressed by current treatment options. "

About Terguride

Terguride modulates a spectrum of neurotransmitter receptors including dopamine, serotonin, and α_2 -adrenergic receptors with high affinity. It has strong anti-serotonergic activity by acting as a potent antagonist on 5-HT_{2B} and 5-HT_{2A} receptors. Excessive vascular remodelling processes or fibrosis, respectively, in a number of tissues including liver, kidney, heart valve and lung have been associated with altered 5-HT signalling or metabolism. In pulmonary hypertension serotonin receptor signalling plays a key role in pulmonary vascular remodelling processes, which are the main driving force for the advanced stages of the disease. Excessive proliferative effects of serotonin also manifest in cardiomyocytes and contribute directly to progression towards heart failure. Terguride suppresses such processes and thereby drives reverse remodelling processes.

About Pulmonary arterial hypertension

Pulmonary arterial hypertension (PAH) is the most serious and potentially devastating chronic disorder of the pulmonary circulation. It is a progressive and fatal disease, which is characterised by abnormally high blood pressure in lungs as a result of thickening and narrowing of blood vessels in the lung. The symptoms of PAH are non-specific. Dyspnea and early fatigue is present in most PAH patients at the time of presentation. Exercise intolerance is a frequent complaint and, in most PAH patients, it has an insidious onset. Estimates of the annual incidence of primary PAH range from 1-2 cases per million people with a prevalence of 136.000 patients in major markets. According to Datamonitor, the global market for PAH drugs is rapidly growing, from USD 800 million in 2005, to an estimated USD 1.8 billion in 2010, as more patients are diagnosed and initiated on drug therapy.

About Ergonex Pharma GmbH

Ergonex Pharma GmbH is a pharmaceutical company focussed on developing and commercialising well-tolerated and effective products for novel and typically underserved indications. This is being achieved by forging collaborations with commercial and academic partners with expertise in the field of interest and through outsourcing activities to service providers.

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