

## Media Release

### **Terguride receives FDA orphan drug designation for the treatment of pulmonary arterial hypertension**

*Appenzell, Switzerland, May 15, 2008:* Ergonex Pharma today announced that the United States Food and Drug Administration (FDA) has granted orphan drug designation to Terguride for the treatment of pulmonary arterial hypertension (PAH). Terguride is currently being evaluated for PAH in a pivotal Phase II trial in Europe.

“The FDA’s grant of orphan drug designation to Terguride for PAH encourages and strengthens our development program by offering regulatory, clinical development and commercial benefits,” said Dr Rudolf Reiter, CEO of Ergonex Pharma. “We believe that Terguride can provide a significant therapeutic benefit in PAH by inhibiting excess serotonin signalling.”

The U.S. Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases, which affect 200.000 persons or less in the United States. Under the Orphan Drug Act, upon marketing authorization, the FDA does not accept or approve other applications to market the same medicinal product for the same indication for a seven-year period. In addition to potential market exclusivity, orphan drug designation provides protocol assistance, advice on the conduct of clinical trials, tax credits for clinical research expenses, grant funding for research of rare disease treatments and waiver of the Prescription Drug User Fee Act filing fee.

#### About Terguride

Terguride has strong anti-serotonergic activity by acting as a potent antagonist on 5-HT<sub>2B</sub> and 5-HT<sub>2A</sub> receptors: It has anti-proliferative and anti-fibrotic activity and drives reverse remodelling processes. Serotonin is a signal molecule in the body with many functions. In the blood vessel walls of the lung it stimulates proliferation of smooth muscle cells and narrowing of the blood vessels, which leads to PAH. Excessive proliferative effects of serotonin on the heart contribute directly to progression towards heart failure.

Terguride is clinically approved in Japan for hyperprolactinemia acting as partial dopamine agonist on the pituitary.

#### About Pulmonary arterial hypertension

Pulmonary arterial hypertension is a disorder of the blood vessels in the lung, in which the pressure in large blood vessel rises above normal. Walls of the blood vessels are thickened and hardened, becoming less elastic and decrease in lumen leading to increases the pressure. Patients with PAH suffer from extreme shortness of breath as the heart struggles to pump against these high pressures causing such patients to ultimately die of heart failure. PAH can occur with no known underlying cause, or it can occur secondary to diseases such as connective tissue disease, congenital heart defects, cirrhosis of the liver and HIV infection.

#### About Ergonex Pharma

Ergonex Pharma 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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