

## PRESS RELEASE

### **7TM Pharma successfully conducts clinical Phase I trial of its first in class peripheral CB1 receptor antagonist TM38837 demonstrating restriction from the human CNS**

**Hoersholm – November 11, 2010:**

7TM Pharma today announced that it has successfully conducted and completed a Phase I clinical trial confirming that the drug candidate TM38837 is restricted to the periphery of the human body. TM38837 was discovered internally at 7TM Pharma and is being developed for treatment of obesity and type 2 diabetes.

TM38837 is a first in class peripheral CB1 receptor antagonist. It was designed to be restricted to peripherally located CB1 receptors in the body. This approach is in contrast to first generation CB1 receptor antagonists, which primarily targeted CB1 receptors within the central nervous system. Although clinically effective, these earlier CB1 antagonists had unfavorable psychiatric side effects.

TM38837 is highly efficacious in animal models of obesity and type 2 diabetes. In addition, TM38837 has completed a spectrum of preclinical in vivo studies supporting the thesis of peripheral restriction.

The double-blind placebo controlled cross-over Phase I clinical trial in 24 subjects assessed the ability of TM38837 to attenuate the centrally mediated side effects of an administered dose of a CB1 agonist,  $\Delta 9$ -tetrahydrocannabinol (THC), the active ingredient in cannabis. The study was performed at the Centre for Human Drug Research (CHDR) in Leiden, The Netherlands. The responsible investigator, Prof. Joop van Gerven explains: "CHDR has examined several different centrally acting CB1 agonists. These compounds all caused a strong inhibition of typical THC-induced centrally mediated effects like feeling high and postural instability. You wouldn't expect to see this suppression with a purely peripheral CB1 antagonist like TM38837. Indeed, this study confirmed that TM38837 did not reduce any THC-effect in a dose that is considered to be therapeutically relevant".

Christian E. Elling, Vice President, Development, commented: "The CNS active CB1 antagonists showed great promise as therapy for obesity and related diseases such as diabetes. However, those compounds were troubled by risks of psychiatric side effects. With TM38837 we have engineered a new first in class compound which aims to circumvent exactly those issues, to realize the clinical beneficial effects already proven by the CB1 pharmacology. The data from this Phase I

clinical pharmacology study clearly demonstrated lack of human CNS effects of TM38837 even at doses higher than those predicted to be efficacious in humans. This is very encouraging, as it suggests that TM38837 will not have the same undesirable side effect profile as CB1 antagonists that are active within the CNS. We intend to partner this program during clinical development to further accelerate the progression to market to the benefit of the growing number of obese and type 2 diabetic patients requiring safe and effective medicines".

7TM Pharma

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**About TM38837**

TM38837 is a small molecule CB1 receptor antagonist discovered and developed internally at 7TM Pharma. This compound is highly efficacious in animal models of obesity and type 2 diabetes. In addition, TM38837 has completed a spectrum of preclinical in vivo studies supporting the thesis of peripheral restriction. TM38837 is enabled for 28-days studies in humans.

**About obesity**

Globally, obesity and related metabolic diseases are considered to be major health problems and causes significant expenses in healthcare budgets. Obesity significantly increases the risk of diseases such as cardiovascular diseases, type 2 diabetes and osteoarthritis. According to WHO, there are more than 400 million clinically obese people worldwide with a BMI of more than 30 kg/m<sup>2</sup>, and the prevalence of obese subjects is increasing rapidly from the pool of approximately 2 billion overweight subjects. Centers for Disease Control and Prevention, CDC, estimated that medical costs associated with obesity in 2006 in USA alone was as much as \$147 billion. The currently marketed medicinal products for obesity have limited effect and significant side effects and there is consequently a large, unmet need for new and better therapies.

**About Type 2 Diabetes**

In the seven major markets, 31 million people suffer from Type 2 diabetes. Worldwide, this number exceeds 100 million. Type 2 diabetics carry a substantial risk of developing cardiovascular diseases, blindness, neuropathies and kidney disease. In USA alone, the health care cost associated with diabetes in 2007 according to CDC was estimated at \$ 174 billion. Despite that several different treatment modalities exist for Type 2 diabetes, many diabetics exhibit inadequate

glycemic control. Thus, there is a great need for novel, efficacious and safe medications to fight this debilitating disease.

**About 7TM Pharma**

7TM Pharma is a biotech company focusing on the clinical development of drugs with a primary therapeutic focus on obesity, gastrointestinal diseases and with its partner Ortho-McNeil-Janssen Pharmaceuticals (a Johnson and Johnson company) inflammation. 7TM Pharma's approach is to actively seek licensing partners during early clinical development.

7TM's investors include Novo A/S, Alta Partners, LD Pensions, Scottish Widows Investment Partnership, Index Ventures, Sofinnova Capital, SR One, Global Life Science Ventures and GIMV.

For more information on 7TM Pharma, please visit [www.7tm.com](http://www.7tm.com)

**About CHDR**

The Centre for Human Drug Research, CHDR, is a full-service clinical pharmacology research unit located in the Netherlands. It has 20+ years of experience in designing and performing early Phase (Phase I-IIa) clinical studies. CHDR also has a wide-ranging self-funded research program in which biomarkers related to pharmacological responses are developed. By specializing in data-intensive clinical studies, time and cost efficient translational drug development is improved.

For more information on CHDR, please visit [www.chdr.nl](http://www.chdr.nl)