



Neurotune announces regulatory approval for Phase II Clinical Trial to treat neuropathic pain in HIV patients

Schlieren (Zurich), Switzerland, 17th August 2009. Neurotune AG, a Swiss biopharmaceutical company, has received MCC 's (the South African National Regulatory Agency) approval for a Phase II clinical study of neurotune's lead compound NT-11624 for neuropathic pain caused by treatment with anti-retroviral medication.

Approximately 500.000 HIV-patients in the United States and Europe receive anti-retroviral medication. Neurotune's Phase II trial (8-week, randomized, double-blind, placebo-controlled, parallel group study) will evaluate the safety and efficacy of NT-11624 (dimiracetam) in the treatment of neuropathic pain, a common side effect of antiretroviral medications. The primary objective of the Phase II study is to assess the drug's safety in patients under polytherapy for HIV. A secondary objective is to estimate the beneficial effect of dimiracetam on the reduction of pain compared to placebo. The Visual Analogue Scale (VAS) and the Total Symptom Score (TSS) will be primarily used to assess the improvement in symptoms after treatment from baseline through to week eight. The study will enroll at least 100 patients with a planned completion of the study in the middle of 2010.

"We have reached an important step in the development of our Company" says Bruno Oesch PhD, neurotune's CEO "as we are preparing for the recruitment of the first patients in South Africa". "The approval obtained" - adds Ruggero G. Fariello MD, Neurotune's CMO - "allows us to swiftly move on to confirm the phase I safety data and obtain a preliminary evidence of efficacy of our product in a wide range of doses. Although the study is not designed to prove efficacy any hint of clinical improvement will be useful for planning doses to be used in future studies. Our previous phase I study has also given us the confidence that NT-11624 will be devoid of any cognitive side effects, a major drawback of today's pain medication".

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ABOUT NEUROTUNE AG

Neurotune was incorporated in January 2005 and has its domicile in Schlieren, Switzerland. Neurotune develops small-molecular drugs to treat disorders of the human nervous system, i.e. neuropathic pain and sarcopenia.

ABOUT NEUROPATHIC PAIN

Neuropathic pain is a type of chronic pain. It is a result of damage to the nervous system following infection, disease, injury, and certain medications. Neuropathic pain serves no protective function. Instead of functioning properly to warn of tissue injury, the nervous system malfunctions and becomes the cause of the pain. Neuropathic pain can continue for months or years and is often described as "burning," "electric," "tingling," or "shooting."

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