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Biovitrum Initiates Phase II Clinical Trial of Novel Pain Treatment

Biovitrum examines a novel method for treating pain in a phase II clinical trial. The treatment aims at neuropathic pain, which is a chronic form of pain resulting from nerve injuries. Contrary to current treatments that act in the brain, Biovitrum´s substance is expected to act peripherally, directly in the injured nerve. There is a very large unmet medical need in this area. The market is estimated to approximately SEK 18 billion. The study is expected to include up to 300 patients and results are expected during the first half of 2008.

The drug candidate presently tested is a substance that activates a protein (adenosine receptor 2A) that, among other things, is responsible for reducing inflammations. The substance is expected to have a pain-alleviating effect by reducing inflammation directly in the damaged nerve whereas available treatments mainly are represented by drugs acting in the brain. The efficacy of these drugs is limited and the risk is high for side effects such as dizziness, nausea and somnolence. As Biovitrum´s substance acts at the site of injury peripherally in the body, the risk is reduced for this type of side effects related to the central nervous system. This therefore represents a novel treatment with both reduced risk of side effects and the potential for analgesic as well as anti-inflammatory effects.

”Yet another project in our portfolio with a new and safer treatment is now advancing into clinical phase II trials. Neuropathic pain is an indication for which there is a large unmet need and huge market potential, where we will seek a partnership for late-stage development and marketing. We hope our efforts will lead to a safe and effective drug that will improve the situation for many patients who suffer from chronic pain,” says Biovitrum's CEO Mats Pettersson.

Biovitrum currently has seven projects in clinical trials and an option of an eight; three in phase II and four in phase I within mainly the areas of inflammation and hematological and metabolic disorders. Results from ongoing clinical trials are expected according to previously communicated time plan. However, due to a delay in patient recruitment the results from phase II in the glaucoma project 5-HT2A are expected during second half of 2007, instead of mid 2007 as previously announced.

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Facts to the editor

About neuropathic pain
Neuropathic pain is a form of chronic pain that stems from injuries to the sensory nerves, often associated with diabetes and inflammatory injuries. Even though inflammation is the body's main defense against infection, irritation and injury, inflammation can also be linked to development of chronic pain. In inflammations the pH-value decreases in the injured tissue. Biovitrum´s drug candidate makes use of this condition and acts only at the lower pH. Consequently, the action of the substance is directed to the site of injury, thereby reducing the risk of side effects. The number of people who suffer from neuropathic pain worldwide is estimated at almost 38 million. Currently available drugs, represented mainly by antiepileptics, have limited efficacy and entail significant risks for side effects related to the central nervous system such as dizziness, nausea and somnolence. Nevertheless, the total pharmaceuticals market for neuropathic pain is to day estimated to approximately SEK 18 billion

About the Phase II-study
The now initiated phase II clinical trial concerns the drug candidate BVT.115959, a A2A-agonist. The study will include up to 300 diabetics with neuropathic pain evoked by injured sensory nerves. Results from the study are expected during the first half of 2008. In the study, which is randomized (patients are divided between experimental and control groups at random) and placebo-controlled (results will be compared with patients treated with an agent without any actual medicinal effect; the control group), the compound is administered three times daily for four weeks. The primary objective is to assess the efficacy of BVT.115959 using pain estimation scales. Among the secondary objectives are additional assessments of pain and perceived sleep disturbances, quality of life and mood stability. The study is being conducted at several clinics in the UK, Germany, the Czech Republic and South Africa. BVT.115959 has previously completed initial clinical trials (phase I) in a total of 67 healthy volunteers. In these studies the compound was found to be safe and tolerable.

About Biovitrum
Biovitrum is one of the largest biopharma companies in Europe. With operations in Sweden and in the UK Biovitrum conducts research and develops pharmaceuticals for unmet medical needs both for common diseases and conditions that affect small patient populations. Biovitrum has a broad and balanced R&D portfolio with several projects in clinical and preclinical phases for the treatment of obesity, diabetes, inflammation and eye and blood diseases as well as a number of well defined niche indications. Biovitrum also develops and produces protein-based drugs on a contractual basis and markets a range of specialist pharmaceuticals primarily in the Nordic countries. Biovitrum has revenues of approximately SEK 1.2 billion and 550 employees. Biovitrum has been listed on the Stockholm Stock Exchange since September 15, 2006. More information is available at www.biovitrum.com .