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Results from Biovitrum's Phase II Clinical Trial of Novel Pain Treatment is expected to be presented in beginning of second quarter 2008

Biovitrum evaluates a novel method for treating pain in a phase II clinical trial. The recruitment of patients to the study has now been completed and the results are expected to be presented already early second quarter 2008.

Comments Biovitrum's CEO Martin Nicklasson:

The study has been completed in an excellent manner without any delays, which is very positive for such a large 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 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.

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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

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 23 clinics in 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 conditions that affect smaller patient populations and for common diseases. Biovitrum has currently a broad and balanced R&D portfolio with several projects in clinical and preclinical phases for a number of well defined specialist indications as well as for common diseases within obesity, diabetes, inflammation, eye and blood diseases. Biovitrum 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 around 500 employees. Biovitrum's share is listed on the OMX Nordic Exchange in Stockholm since September 15, 2006. For more information see http://www.biovitrum.com.