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## **Biovitrum's unique neuropathic pain compound is very safe and shows positive effect**

**Biovitrum has completed a first phase 2 study in patients with neuropathic pain. The candidate drug, BVT.115959, is a pH-selective A<sub>2A</sub>-receptor agonist for the treatment of pain. The results of this first patient study is promising as it shows a high level of safety and tolerability, as well as a positive treatment effect that increased over time.**

The most important finding in this first phase 2 study is that the unique candidate drug BVT.115959 is very safe and tolerable. Moreover, a positive treatment effect that increased over time was observed although the analysis of the primary variable was not statistically significant. Further analysis of the efficacy data showed statistical significance. The conclusion of these observations is that BVT.115959 has a clear opportunity to show good efficacy and few side-effects in further studies.

192 patients with chronic neuropathic pain secondary to diabetes were included in this exploratory phase 2 study. The study is the first of its kind with a compound which is steered to its target protein (A<sub>2A</sub>-receptor) depending upon pH in the injury area.

BVT.115959 decreases inflammation by activating the adenosine receptor 2A in injured tissue. As a consequence of this, BVT.115959 has a potential to fulfil a great medical need to treat chronic pain without giving rise to central nervous system derived side effects.

"Patients with chronic neuropathic pain are in great need of improved treatment options. Also, there is a great commercial potential in this area. Consequently, the promising observations in this first phase 2 study with a new and safe treatment option for pain is good news. Our plan is to out-license the project in line with our business strategy", says Biovitrum's CEO Martin Nicklasson.

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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, trauma and inflammatory injuries. Even though inflammation is the body's main defence 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 anti-depressants and anti-epileptics, 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 2 study**

In this randomized<sup>1</sup> and placebo-controlled<sup>2</sup> study, the compound was administered three times daily for four weeks. Patients with concomitant medication, including analgesics, were included in the study. The primary objective was to assess the efficacy of BVT.115959 using pain estimation scales. Among the secondary objectives were safety assessments, the perceived sleep disturbance, quality of life and mood stability. The study was conducted at 22 clinics in Germany, the Czech Republic and South Africa. BVT.115959 has previously completed initial clinical studies (phase 1) in a total of 67 healthy volunteers. In these studies the compound was found to be safe and tolerable.

<sup>1</sup> Patients are divided between experimental and control groups at random

<sup>2</sup> Results will be compared with patients treated with an agent without any actual medicinal effect; the control group

### **About Biovitrum**

Biovitrum is a pharmaceutical company with operations in Sweden and in the UK. Biovitrum has currently a research 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 and eye 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 [www.biovitrum.com/](http://www.biovitrum.com/).