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Biovitrum Presents Detailed Results from Clinical Neuropathic Pain and Glaucoma Projects

Biovitrum invites press and analysts to a meeting on May 7th from 3 - 5 p.m. (CET) at SwedenBio, Wallingatan 24, Stockholm, Sweden.

We have recently completed two patient studies with new unique treatments. One study involved the treatment of glaucoma (5-HT_{2A} receptor antagonist) and the other neuropathic pain in diabetes patients (pH selective A_{2A} receptor agonist). We would now like to give journalists and analysts the opportunity to learn more about the details of the design of the studies and the results. New information not previously presented about the studies and the results are already available on our homepage www.biovitrum.com.

At the meeting our Project Leaders will give the background to the projects, explain the design of the studies and discuss the results. The presentations will be given in layman Swedish. Together with the project leaders, our experts from the Department of Clinical Development will be present to answer questions together with the Project Leaders.

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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.

About the glaucoma study

Glaucoma is an eye disease characterized by gradual degeneration of the optic nerve, resulting in vision impairment and if left untreated will ultimately lead to blindness. The largest disease risk factor is believed to be elevated ocular pressure due to overproduction or impaired drainage of aqueous humor. Whilst several effective treatments exist for decreasing intraocular pressure, they do not successfully control glaucoma in a significant number of patients. It is Biovitrum's belief that there is a need for glaucoma treatments acting through novel mechanisms, with the potential of being used as a second-line monotherapy or in combination with current therapies.

The results show that our drug candidate (BVT.28949) reduces the intraocular pressure and that the reduction is dose dependent. After 2 weeks of treatment a statistically significant reduction of the pressure as compared to placebo ($p < 0.003$) was obtained at the highest dose, 7 mg/ml. At the end of the 4 week treatment, the reduction in pressure in that dose group was 10 % compared to starting pressure. However, this reduction was no longer statistically significant compared to placebo ($p < 0.067$). The treatment was tolerable and safe.

The objective of this explorative phase II study was to validate a novel mechanism (mediated via the 5-HT_{2A} receptor) for the treatment of glaucoma, using this selective antagonist for the first time. The study included 129 patients with an elevated intraocular pressure, with or without developed glaucoma. The study was double-blind, randomized and placebo-controlled and was carried out at several clinics in Sweden and Ukraine.

The drug candidate is a selective 5-HT_{2A} antagonist (serotonin receptor 2A antagonist), suitable for topical administration in the form of eye drops. 5-HT_{2A}-receptors control the outflow of aqueous humor from the eye globe. The drug candidate lowers the intraocular pressure by increasing the outflow of aqueous humor and Biovitrum's current hypothesis is that the substance acts through stimulation of outflow through the trabecular meshwork, unlike prostaglandins (e.g. Xalatan®) which reduce intraocular pressure through another outflow mechanism.

About the neuropathic pain study

Peripheral neuropathic pain is a chronic form of pain which stems from injuries to sensory nerves. These injuries are often associated with diabetes, trauma and inflammatory injuries. 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.

The most important finding in the phase II study is that our unique candidate drug (BVT.115959) is very safe and tolerable. Moreover, a positive treatment effect that increased over time was observed, although the planned analysis of the primary variable generated a difference that was not statistically significant. Further analysis of the primary efficacy data showed statistical significance. The conclusion of these

observations is that our new drug candidate has a clear opportunity to show good efficacy and few side-effects in further studies.

In this randomized and placebo-controlled 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 the substance 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. The substance has previously completed initial clinical studies (phase I) in a total of 67 healthy volunteers. In these studies the compound was found to be safe and tolerable.

Whilst Inflammation is the body's main defense against infection, irritation and injury, inflammation it can also be linked to the development of chronic pain. At the site of inflammation the pH-value decreases in the injured tissue. Biovitrum's drug candidate makes use of this pH change 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.