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Biovitrum has Completed an Exploratory Clinical Phase II Study in Glaucoma

Biovitrum has completed a first explorative clinical Phase II study with the candidate drug BVT.28949, a 5-HT_{2A} antagonist intended for the treatment of glaucoma. The preliminary results show a dose dependent reduction of the intraocular pressure; a reduction that amounted to 10 % as compared to the pressure before treatment after four weeks at the highest dose.

The objective of the present explorative phase II study was to validate a novel mechanism (mediated via the 5-HT_{2A} receptor) for the treatment of glaucoma, for the first time using a selective antagonist (BVT.28949). The study included 129 patients with an elevated intraocular pressure, with or without developed glaucoma. The study was double-blind[1], randomized[2], placebo-controlled[3] and was carried out at several clinics in both Sweden and Ukraine.

The results show that 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 treatment, after 4 weeks, the reduction in pressure in that dose group was 10 % from starting pressure. However, the reduction was no longer statistically significantly different from placebo ($p<0.067$). The treatment was tolerable and safe.

- It is with satisfaction we have completed this explorative study and thus successfully validated a novel target for the treatment of glaucoma. The results from the study will now be further analyzed. Our ambition is to approach other companies to discuss an out-licensing of the project, which is fully in line with our strategy," says Martin Nicklasson, CEO of Biovitrum.

Glaucoma is a disease characterized by damage to the optic nerve and it is in most cases accompanied by an increased pressure within the eye. The current hypothesis is that BVT.28949 reduces intraocular pressure by stimulating the outflow of aqueous humor through a mechanism different from that of presently available products. It is estimated that nearly 70 million people worldwide suffer from glaucoma. The total market value for this type of medicines amounts to approximately $3.9 billion.

[1]Neither patients nor researchers know who belongs to the control group and the experimental group during the active phase of the trial.
[2]Patients are divided between experimental and control groups at random.
[3]Results will be compared with results from individuals treated with an agent without any actual medicinal effect; the control group.

For further information please contact:

Biovitrum AB (publ)
Martin Nicklasson, CEO
Phone. +46 8 697 20 00
martin.nicklasson@biovitrum.com

Göran Arvidson, CFO
Phone: +46 8 697 2368, Mobile: +46 70 633 30 42
goran.arvidson@biovitrum.com

Erik Walum, Director Science Communication
Phone. +46 8 697 32 40, Mobile: +46 70 312 90 75
erik.walum@biovitrum.com

Facts to the editor

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 www.biovitrum.com.

About BVT.28949

While several effective treatments exist for decreasing intraocular pressure, they do not successfully control glaucoma in a significant number of patients. According to Biovitrum´s opinion there is a need for glaucoma treatments acting through novel mechanisms, with the potential to be used as a second-line monotherapy or in combination with current therapies.

BVT.28949 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. BVT.28949 lowers the intraocular pressure by increasing the outflow of aqueous humor and Biovitrums current hypothesis is that BVT.28949 acts through stimulation of outflow via the trabecular meshwork, unlike prostaglandins (e.g. Xalatan®) which reduce intraocular pressure through another outflow mechanism.