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Biovitrum completes successful phase IIa trial for anti-obesity treatment

Stockholm, Sweden, 27 February 2002 – Biovitrum today announced the positive results of a phase IIa trial for its anti-obesity treatment BVT.933.

"We are delighted to have achieved Proof of Concept in our appetite suppressing compound BVT.933 in patients. We now look forward to the continued development of a product that has the significant potential for improving health and quality of life", commented Dr. Johan Kördel, Head of Research at Biovitrum.

BVT.933 is a *selective 5-HT$_{2C}$ receptor agonist* designed to suppress appetite. In a double-blind placebo-controlled phase IIa study, 154 obese but otherwise healthy patients were treated with either placebo or BVT.933 in two dose groups over four weeks. Patients in both dose groups receiving BVT.933 achieved a statistically significant and clinically relevant weight reduction compared to placebo. The study was performed without any diet restrictions or instructions regarding exercise or other lifestyle parameters.

In line with Biovitrum's overall strategy, the company seeks to establish co-development and license agreements with major pharmaceutical companies for the final development and commercialization of its drug candidates.

Biovitrum is a private Swedish biopharmaceutical company active within research and development of small molecule therapeutics and recombinant proteins. The research is focused on metabolic disorders, such as diabetes and obesity, but also covers other selected therapeutic areas. *ReFacto* (a recombinant factor VIII treatment for hemophilia), acquired by American Home Products provides the company with substantial revenues from royalty, co-promotion and supply arrangements. A separate division of the company develops, produces and markets human-derived plasma products.

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Note to Editors:

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Biovitrum has two products in clinical trials; BVT.933 to treat obesity and BVT.3498 for the treatment of diabetes. Biovitrum has several projects in pre-clinical development from early stage target discovery through to later stage pre-clinical development. The company is based in Stockholm and Uppsala and currently employs over 900 people; 450 are involved in R&D, half of whom are PhDs.

Biovitrum was spun-out of Pharmacia in August 2001 after its merger with Monsanto, to build an international biopharmaceutical company that would combine the experience and resources of an established pharmaceutical company with the innovation and growth potential of an entrepreneurial start-up. Biovitrum is financed by a group of outside investors led by MPM Capital LP and Nordic Capital. Pharmacia holds a 19% stake and Biovitrum's management and staff own 15% on a fully diluted basis.

In the near term, Biovitrum plans to divest the human plasma business and will continue to focus on its core business of research and development of small molecules and recombinant protein therapeutics, to treat metabolic disorders (and other selected indications) that are currently poorly treated and which have a significant and expanding market. The company will complement its considerable in-house expertise, experience and capabilities through in-licensing, partnering with biotech and academia worldwide and acquiring complementary businesses, products and technologies.

Obesity
Obesity is a rapidly increasing global health problem that causes complications such as hypertension, type 2 diabetes, dyslipidemia and atherosclerosis, which in turn cause coronary heart disease, stroke and premature death. In addition, obesity is associated with sleep apnea, osteoarthritis and increased risk for cancers of the breast, prostate and colon. Obesity now affects 100 million people, from an overweight population of 1 billion individuals, and the prevalence has increased by 30% in the last decade alone. Obesity is estimated to be responsible for 6.8 % of all health care expenditures in the United States and place a massive financial burden on health care providers worldwide. Efforts to change the intake of high fat food and combat an increasingly sedentary lifestyle have been insufficient. So far, only two pharmacological treatment alternatives for obesity are available and the need for more effective therapy alternatives is enormous.

Selective 5-HT_{2C} receptor agonist that suppresses appetite:
5-HT is also known as *serotonin*, a neurotransmitter (a chemical that carries messages between nerve cells). Neurotransmitters are released by nerve cells and stimulate receptors on other nerve cells to transmit nerve messages. There is a range of different receptors that are sensitive to *serotonin*; one of these is the *5-HT_{2C} receptor,* which is linked to the regulation of appetite. An *agonist* is a drug that stimulates receptors (conversely *antagonists* block receptors). *BVT.933* selectively stimulates the *5-HT_{2C}* receptor. This has been shown experimentally to result in the suppression of appetite. *5-HT_{2C} receptors* have been shown through many studies to play a major role in appetite control.

Double-blind placebo-controlled phase IIa study: In a *double-blind controlled study* neither the patients nor the clinicians involved in the study know if the patient belongs to the drug group or the placebo group. The clinician administers the trial and returns the results to the drug's innovator who then decodes which patients received the placebo and which received the drug. The majority of the placebo-controlled clinical trials are now conducted as double-blind. This procedure enables the separation of 'placebo' effects, caused for instance by patient expectations and subsequent changes in lifestyle and behavior, from the true pharmacological effects of a drug candidate.

Phase I clinical trials establish safety in a drug candidate, and are usually performed in healthy volunteers.

Phase IIa clinical trials establish if a drug candidate has the desired initial efficacy in patients suffering from a specific disease or condition. If such efficacy can be demonstrated, *Proof of Concept* has been achieved for the drug candidate.

Phase IIb clinical trials are typically performed on a larger patient population and during a longer time period compared to Phase IIa. The main objective is to establish a correct dosing of the drug candidate in order to achieve desired efficacy without undesired side effects.

Phase III clinical trials establish the long-term efficacy and safety of the drug candidate in its final dose and formulation. These studies may involve thousands of patients who are treated during one to two years.

Upon completion of the Phase III studies the drug candidate is filed with appropriate authorities for review and approval for launch.