

PRESS RELEASE

Biovitrum initiates clinical Phase IIb study of anti-obesity treatment

- second Biovitrum product to enter phase II clinical trials in 2003-

Stockholm, Sweden, 7 April 2003 — Biovitrum today announced the start of a clinical Phase IIb study of the anti-obesity compound BVT.933 (GW876167), a 5-HT_{2C} receptor agonist for the suppression of appetite. Three hundred obese patients will be treated with BVT.933 at different doses for three months in a placebo-controlled, double blind trial conducted at six centers in Sweden. The primary objective of the study is to assess effects on body weight. Safety, tolerability and selected efficacy variables in obese patients will also be monitored. A clinical phase IIa study with 154 obese but otherwise healthy patients was concluded in 2002.

The study represents the first phase of the collaboration entered into last year with GlaxoSmithKline (GSK) to develop therapies for obesity and other medical disorders. Under the terms of this agreement, GSK has the exclusive rights to develop, register, manufacture and commercialize Biovitrum's existing collection of proprietary 5-HT_{2C} receptor agonist compounds.

The successful development and market launch of an anti-obesity drug could result in \$150 million in potential payments to Biovitrum over the term of the agreement. Additional milestone payments are payable for development of products for other indications, in addition to royalties on future sales of all products arising from the collaboration.

“We are very pleased that Biovitrum continues to be an active partner in its collaboration with GSK”, says Paul de Potocki, Senior Vice President Commercial Operations at Biovitrum. “We look forward to supporting the development and market launches of new products that have potential for improving health and quality of life.”

Dr Lawson Macartney, Cardiovascular, Metabolic & Urogenital Therapy Area Strategy Team Head, GlaxoSmithKline said: "Obesity is a troubling disease with epidemic prevalence rates in both developed and developing countries that will require further scientific advances to combat effectively. We are excited about this series of compounds and look forward to working with Biovitrum to bring these innovative treatments to people who struggle with obesity and other disorders."

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Notes to Editors:

Biovitrum is a biotech company active in the discovery and development of drugs to treat metabolic diseases, such as type 2 diabetes and obesity, and in the development of protein therapeutics, with metabolic diseases and oncology as targeted therapy areas. The company has a strong intellectual property and technology platform, with a number of compounds in pre-clinical and clinical development. Biovitrum is one of the largest biotech companies in Europe with more than 550 employees. Annual revenues, including royalties and contract service fees, finance the major part of the annual research budget.

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 IIb 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.