

10th World Congress of the International Society for Sexual and Impotence Research (ISSIR):

Men Treated with Vardenafil Report Reliable Improvement in Erectile Function over Time and Improvements in Erection Quality Following Prostate Cancer Surgery

Leverkusen – Findings from a clinical trial investigating the efficacy of Vardenafil will be presented at the 10th World Congress of the International Society for Sexual and Impotence Research (ISSIR) in Montreal. Men with erectile dysfunction (ED) who were taking the oral investigational drug Vardenafil reported consistently improved erectile function (EF) the first time they took the drug and subsequently thereafter. For the three months of the study involving over 800 ED patients, Vardenafil was reported to consistently improve rates of successful penetration, intercourse success and overall satisfaction during the first and subsequent attempts.

Investigators evaluated the ability of Vardenafil to provide reliable efficacy over time in a broad population of men with ED. They analysed data from a phase III, randomised, double-blind study in which 805 men with ED received Vardenafil 5, 10 or 20 mg or placebo for up to 26 weeks. The analysis showed that at a 20 mg dose:

- On average men were successful in 74 percent of their first attempts in penetrating their partner compared with 46 percent of men taking placebo.
- Of those men taking Vardenafil who were successful the first time, they continued to achieve successful penetration in 91 percent of subsequent attempts.

“Men want to be confident that the ED drug they are taking works the first time and time after time,” said Luc Valiquette, M.D., Professor of Urology at the Hospital Saint-Luc du CHUM in Montreal. “I’ve seen frustration in some of my patients because some of the current treatments do not consistently work,

and their efficacy may diminish over time. This reinforces the need for new ED therapies that are effective, consistent and safe."

Data from two other clinical trials presented at the ISSIR meeting also showed that over time men taking Vardenafil consistently report improvement in EF.

- In a year-long study of Vardenafil, a broad population of men with ED reported improvement in their EF.
- A six-month open label study of Vardenafil reported return to normal EF, with 81 percent of men reporting improved erections.

In another study, the first of its kind to assess the effect of a phosphodiesterase (PDE-5) inhibitor on EF and depressive symptoms among men with ED resulting from prostate cancer surgery, men taking Vardenafil were more likely to report improved erections and fewer depressive symptoms than men taking placebo.

In this phase III clinical trial, 440 men aged 44 to 77 years with ED following prostatectomy and who experienced ED for six months before entering the study, were randomly assigned to placebo or Vardenafil (at a dose of 10 or 20 mg) for 12 weeks. After 12 weeks:

- Up to 71 percent of patients who had undergone a specific type of prostatectomy, known as bilateral nerve-sparing, reported statistically significant improvement in erections with Vardenafil 20 mg versus 12 percent of men taking placebo.
- A significant decrease in depressive symptoms was observed among a small subset of depressive prostatectomy patients taking Vardenafil 20 mg.

"Men who suffer from ED following prostatectomy are among the most difficult to treat because their ED is typically severe. The finding that Vardenafil significantly improved erectile function in our study patients is important because more than two thirds of these men had severe ED," said Gerald Brock, M.D., lead study investigator and Associate Professor, Department of Surgery, Division of Urology at St. Joseph's Health Centre in London, Ontario, Canada. He also added: "The finding that Vardenafil eased depressive symptoms in these men is very good news, because it means that Vardenafil helps improve quality of life in men who are often suffering both emotionally and physically from this condition."

In all these studies, drug-related adverse events were reported as generally mild to moderate in intensity with the most frequent adverse events being headache, flushing and rhinitis.

ED – the persistent inability to attain and maintain an erection adequate to permit satisfactory sexual intercourse – is a common health condition among men that is largely untreated. It is estimated that some degree of ED affects more than one half of all men over the age of 40 and that worldwide an estimated 152 million men suffer from ED.

Vardenafil, researched and discovered by Bayer AG, will be marketed by Bayer and GlaxoSmithKline (GSK) through a worldwide co-promotion and co-development agreement that the two companies signed in November 2001. Marketing Authorisation Applications have been approved by regulatory authorities in several Latin American countries and have been submitted for regulatory review in all major regions worldwide, including the United States, Europe and Japan.

Bayer is an international, research-based group with major businesses in healthcare, agriculture, polymers and specialty chemicals.

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

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Forward-Looking Statements

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