First Study of its Kind of Erectile Dysfunction Treatment in Prostatectomy Patients:

Patients Reported Vardenafil Significantly Improved Erectile Function Following Radical Prostatectomy

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Birmingham/ UK – In the first clinical study of its kind examining the use of drug therapy to improve erectile function in men who had undergone nerve-sparing radical prostatectomy (removal of the prostate gland), patients taking vardenafil reported statistically significant improvement in erectile function. Among men who had undergone bilateral nerve-sparing surgery, 71 percent of those taking vardenafil 20 mg experienced improved erections.

Vardenafil is an investigational treatment for erectile dysfunction (ED) discovered by Bayer AG and will be co-promoted and co-developed with GlaxoSmithKline plc (GSK). Vardenafil is being evaluated in a broad range of patient populations, including difficult-to-treat patients.

The new data, presented at the 17th Annual Congress of the European Association of Urology (EAU), are important because at least one third of men with prostate cancer who undergo nerve-sparing radical prostatectomy experience ED. The International Association of Cancer Registries (IARC) estimated in 2000 that globally there were 550,000 new cases of prostate cancer.

“Men who have had a radical prostatectomy generally experience very severe ED, as was seen in this study population,” said Gerald Brock, MD, Associate Professor, Department of Surgery, Division of Urology at St. Joseph´s Health Care in London, Ontario, Canada. “The response rates seen in this study are impressive considering the severe level of ED.”

First Study of its Kind Evaluating ED Drug Following Prostatectomy

The multi-center, randomized, double-blind, placebo-controlled, fixed-dose prospective study was designed to evaluate the effect of vardenafil (a phosphodiesterase-5 [PDE-5] inhibitor) on erectile function as compared to placebo in men who had undergone either unilateral or bilateral nerve-sparing radical retropubic prostatectomy six months to five years prior to screening. The majority of men (70 percent) enrolled in the study presented with severe ED.

Following a four-week baseline period, 444 men were randomized to treatment with vardenafil 10 mg, vardenafil 20 mg or placebo for 12 weeks. Participants were evaluated using the erectile function (EF) domain of the International Index of Erectile Function (IIEF), a standard sexual function questionnaire used by urologists that includes questions about the ability to achieve and maintain erections to the completion of sexual intercourse. Participants were also asked to track success in partner penetration and ability to maintain an erection in a patient diary. In addition, the global assessment question (GAQ) was used for those men completing the 12-week study to evaluate if patients experienced improved erections.

Positive Results Seen in Study Population

Patients at all ED severity levels – mild, moderate, severe – taking vardenafil 10 or 20 mg reported statistically significant improvement in erectile function. Results included:

- Nearly half of men reported successful penetration compared to only 22 percent in the placebo group ($p<0.0001$).
- An almost four-fold increase in the ability to maintain an erection was reported compared with the placebo group ($p<0.0001$).
- Both doses of vardenafil were significantly superior to placebo for the EF domain score.

For the 20mg group:

- 65 percent reported improved erections compared to 13 percent in the placebo group ($p<0.0001$).
- Among the men with severe ED, a seven-fold improvement in successful intercourse was reported.

The most commonly reported drug related adverse events were headache, flushing and nasal congestion.

Two Additional Safety and Efficacy Studies Presented

Other clinical studies presented at EAU – one study in men with hypertension (high blood pressure) and one study in men with coronary artery disease (CAD) – were conducted to further evaluate the safety and efficacy profile of vardenafil. The former found that men taking vardenafil reported a statistically significant improvement in EF domain score compared to placebo regardless of whether they were taking an antihypertensive medication. In the latter study, men with CAD reported that they were able to exercise at a level considered equivalent to sexual intercourse after taking one dose of vardenafil 10 mg.

ED and Vardenafil

It is estimated that ED – the reduced ability to attain and, or maintain an erection sufficient for sexual intercourse – affects more than half of all men over 40 years of age.[1] While it is estimated that 140 million men worldwide are affected by ED, only one in 20 receives medical treatment, demonstrating the clear need for additional therapies in this area.

Vardenafil is a PDE-5 inhibitor being researched and developed by Bayer. Its clinical development programme to date has involved approximately 4,000 patients and included eight phase III trials. In a published phase III study in a broad population, up to 85 percent of patients taking vardenafil reported statistically significant improvements in erectile function versus placebo.[2]

In November 2001, Bayer and GSK signed a worldwide co-promotion and co-development agreement for vardenafil. Vardenafil has been submitted for regulatory review for marketing approval in all major regions worldwide, including the United States, Europe and Japan.

About Bayer

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

About GSK

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.

Reference:

1: Feldman HA *et al* Impotence and its medical correlates: results of the Massachussets Male Aging Study. J Urol 1994; 151: 54-61.

2: W.J.G. Hellstrom, et al., Int. J. Imp. Res. 2001: 13 Suppl 5: S65.

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Forward-Looking Statements
This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F).The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.