5th Congress of the European Society for Sexual and Impotence Research (ESSIR:

Bayer and GlaxoSmithKline: Two New Studies on Erectile Dysfunction Presented

Vardenafil improved erectile function in 92 percent of patients

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Hamburg, Germany – Findings from two new studies assessing the safety and efficacy of the oral investigational drug Vardenafil were presented at the 5th Congress of the European Society for Sexual and Impotence Research (ESSIR) in Hamburg. These findings support the growing body of evidence that shows Vardenafil may significantly improve erectile function (EF) in men with erectile dysfunction (ED).

In a new 10-week study of Vardenafil, overall, 92 percent of men with symptoms of ED reported improvement in EF based on the global assessment question (GAQ). This open-label, uncontrolled study was designed to reflect the actual clinical practice of flexible dosing.

In this multicenter study of 398 men with ED, investigators evaluated the efficacy, safety and tolerability of flexible doses of Vardenafil – starting treatment with 10 mg and either staying at that dosage or adjusting to 5 mg or 20 mg at two and six weeks. After 10 weeks in the study, 70 percent of men reported that their EF returned to the range regarded as normal (as defined by the International Index of Erectile Function [IIEF], EF domain score of $\geq$26) on any dose.

“This study is important because physicians were allowed to adjust the dose of treatment based on clinical response, thereby simulating ‘real world’ conditions,” said Dr. Axel-Jürg Potempa, urology specialist at Munich University and lead study investigator. “We were also very encouraged to find that seven in 10 men taking the drug indicated that their erectile function returned to the range regarded as normal at 10 weeks.”

Adverse events were generally mild to moderate in intensity. The most commonly reported adverse events were headache and flushing.

In a second study designed to assess the safety and efficacy of Vardenafil, men with ED were nearly five and a half times more likely, on average, to report success in maintaining erections after taking Vardenafil than before they took the drug. An important indicator of efficacy for a treatment to improve erectile function (EF) is a patient's average success rate in maintaining erections. In this multicentre, randomised study in which patients and physicians were blinded to the dose, 1,020 men with impaired EF resulting from a broad range of causes took the drug 10 or 20 mg as needed for up to 52 weeks. Treatment followed a four-week baseline period. After one year of treatment:

- among men taking Vardenafil 20 mg, the average success rate in maintaining erections improved from 16 percent at baseline to 86 percent (i.e., 5.4 times).
- among men taking Vardenafil 10 mg, the average success rate in maintaining erections improved from 14 percent at baseline to 82 percent (i.e., 5.9 times).

These findings are consistent with observations from previous placebo-controlled trials of Vardenafil. With both doses of the drug, adverse events were generally mild to moderate in intensity. The most commonly reported treatment-emergent adverse events were headache, flushing, rhinitis, accidental injury, flu syndrome and dyspepsia. "Treatment-emergent" does not necessarily connote relatedness to the study drug.

"This is an important study for two reasons. First, patients reported sustained, improved erectile function with Vardenafil over a one-year period," said Dr. Iñigo Sáenz de Tejada president of the Fundación para la Investigación y el Desarrollo en Andrologia in Madrid, Spain and lead study investigator. "Secondly, on average, men were successful more than eight out of 10 times in maintaining an erection sufficient for sexual intercourse with Vardenafil. It's interesting to note that men also reported high overall sexual satisfaction with Vardenafil."

Vardenafil is an active ingredient that has been researched and developed by Bayer. Bayer and GlaxoSmithKline will jointly market the product and pursue its further development. The European Committee for Proprietary Medicinal Products (CPMP) recently concluded its investigation into the registration documentation for Vardenafil with a positive opinion. This means that a European Marketing

Authorization should be granted within the next few months followed by a launch in Europe in the first half of 2003.

Leverkusen, December 2, 2002

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.