

XVIth Congress of the European Association of Urology (EAU):

New compound proves to be effective regardless of severity of erectile function difficulties, cause or age

Performance of new product for improvement of erectile function established in 'real sex life' setting

Leverkusen – Results from the first large-scale patient trial of Bayer's new, selective phosphodiesterase 5 (PDE-5) inhibitor show this oral treatment not only improved erections in up to 80 percent of patients, but also increased their ability to complete sexual intercourse with ejaculation.

In this large-scale study, the rate for successfully completing sexual intercourse (defined as attempting, penetrating, and completing intercourse with ejaculation) by the end of the three-month trial period was 75 percent among patients taking the 20 mg dose of the compound. This increased from a 24 percent success rate before treatment with vardenafil, and compared to a 39 percent success rate for patients on placebo.

New analyses

Results from three separate new sub-analyses of these data were presented for the first time today at the XVIth annual European Association of Urology (EAU) meeting in Geneva, Switzerland. The data show that Bayer's new, selective phosphodiesterase 5 (PDE-5) inhibitor improved erectile function regardless of the following: whether the cause of the problem was organic, psychogenic or mixed; what age group the patient belonged to; and whether a patient's condition was mild, moderate or severe.

Prof. Hartmut Porst, member of the international Vardenafil Study Group and lead investigator for the study, told congress delegates, "The ability to achieve complete sexual intercourse with ejaculation requires a treatment that significantly improves erectile function over the complete time of sexual intimacy and without troublesome side effects. The fact that the compound is effective regardless of age and severity of erectile function difficulties is good news for the diverse population of men who suffer from this common condition."

“Our study also demonstrated that the new product was safe and well tolerated, with few patients reporting any adverse events. There was no evidence of cardiovascular or other serious drug-related problems; so what we have is convincing evidence that vardenafil’s clinical effects in this study are consistent with its high PDE-5 selectivity, making it potentially highly suitable for the treatment of erectile function difficulties in a wide range of patients,” he added.

The new analyses reviewed data from a group of 580 patients between 21 and 70 years old, who were in stable heterosexual relationships but had experienced erectile function difficulties of organic, psychogenic or mixed etiology for a mean duration of 2.8 years. Patients were split into four groups receiving either the compound in 5 mg, 10 mg or 20 mg doses or placebo on demand, but not more than once a day. Those randomized to receive the active substance reported a successful treatment effect. Efficacy was determined by their responses to the questions forming the International Index of Erectile Function (IIEF), in particular to the key questions determining the ability to penetrate and maintain an erection during sexual intercourse. The study involved 39 treatment centers in Belgium, France, Germany, the Netherlands, Poland, South Africa, and the United States.

The new substance, which in preclinical studies showed a higher potency in comparison to sildenafil and greater selectivity for the inhibition of the PDE-5 enzyme, is now being evaluated in Phase III trials. Results are expected for publication later this year, with initial approvals anticipated in the second half of 2002. Bayer expects to generate as much as EUR 900 million in annual worldwide sales. The research and development in the field of erectile function leverages the strong foundation of Bayer’s expertise in urology — a 14-year history of marketing an antibiotic widely used to treat urinary tract infections.

“Difficulty with erectile function is a common medical condition that can greatly impact the health and daily life of men and their partners. Currently, only a small percentage of men are adequately treated. Physicians need more options for treatment, and we hope to assist in meeting this need with the new compound,” said David R. Ebsworth, Ph.D., Head of Bayer’s Pharmaceuticals Business Group worldwide.

Currently it is estimated that approximately 52 percent of men over age 40 suffer from mild to severe difficulty with erectile function. With only one oral therapy on the market, there is an increasing need for oral therapy options as more men reach out to find solutions to this medical condition.

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