

Bayer HealthCare and GlaxoSmithKline:

Vardenafil Receives Positive Opinion from European Committee for Proprietary Medicinal Products

European Marketing Authorisation should be Granted Within the Next Few Months

Leverkusen/London – Bayer HealthCare and GlaxoSmithKline plc (GSK) announced today that they have received a positive opinion from the European Committee for Proprietary Medicinal Products (CPMP) for Vardenafil, a new oral drug under regulatory assessment for the treatment of erectile dysfunction (ED). This means that a European Marketing Authorisation should be granted within the next few months followed by a launch in Europe in the first half of 2003.

Vardenafil was researched and developed by Bayer was selected for clinical development because of its in-vitro potency and high selectivity for the PDE-5 enzyme. The substance will be co-promoted with GlaxoSmithKline plc. As leading European-based companies, Bayer and GSK are poised to bring the drug to market using their extensive network of local operating companies throughout the continent.

Wolfgang Plischke, PhD, President of the Pharmaceuticals Division of Bayer Health Care, Bayer AG, said: "This positive opinion from the CPMP – received earlier than anticipated – marks another important milestone, bringing us one step closer to the global launch of Vardenafil. The plans are in place to ensure an expedited launch at approval". "We are very pleased with the Committee's decision following their assessment of our extensive clinical trial data package that showed excellent efficacy following treatment with Vardenafil in men with ED", added Robert A. Ingram, Chief Operating Officer and President Pharmaceutical Operations, GlaxoSmithKline.

The clinical data presented to the CPMP for Vardenafil included results from pivotal phase III studies of almost 4,000 men, including men of varying ages and severity of ED, and those considered challenging to treat, such as men

with diabetes and those who have undergone prostatectomy. In one large-scale trial including a broad range of patients, 80 percent and 85 percent of men taking Vardenafil 10 and 20 mg respectively reported an improvement in erectile function compared with 28 percent on placebo. In clinical trials, the most common adverse events reported for the substance were headache, flushing, rhinitis and dyspepsia, events typical of PDE inhibition.

Erectile dysfunction – the inability to sustain an erection sufficient for sexual intercourse – is a major medical condition among men that is largely untreated. Although an estimated 152 million men are affected worldwide, research shows that only ten percent of men are being treated for the condition, suggesting the need for additional therapies in this area.

Leverkusen, November 22, 2002

Forward-Looking Statements

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