
Bayer AG Ad-hoc Message

July 24, 2002

Bayer AG: FDA approvable letter for Vardenafil

Bayer AG [DAX and NYSE: BAY] and GlaxoSmithKline plc [LSE and NYSE: GSK], announced today that they have received an approvable letter from the U.S. Food and Drug Administration (FDA) for vardenafil, an oral investigational drug under review for the treatment of erectile dysfunction (ED). The drug has been approved by regulatory authorities in several Latin American countries and has been submitted for approval to regulatory agencies in all major markets.

The companies said that the FDA has asked for additional clinical pharmacology studies before granting final approval for vardenafil. A U.S. launch for the product is now projected for 2003.

Wolfgang Plischke, Ph.D., president, Pharmaceutical Division of Bayer HealthCare, Bayer AG, said, "Bayer and GSK are committed to bringing vardenafil to market as quickly as possible, and believe that the compound can provide a new alternative for millions of men."