

Gilead Files Investigational New Drug Application for Its Novel Protease Inhibitor; Anti-HIV Drug Developed Using Gilead's Proprietary Prodrug Technology

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Jan. 12, 2004--Gilead Sciences, Inc. (Nasdaq:GILD) today announced that it has submitted an investigational new drug (IND) application to the U.S. Food & Drug Administration (FDA) to evaluate GS 9005 (formerly known as GS 4338) as a potential new therapy for HIV. Under this IND, Gilead plans to assess the oral bioavailability, pharmacokinetics, safety and efficacy of GS 9005 in healthy volunteers and HIV positive patients. GS 9005 is a novel HIV protease inhibitor (PI) discovered at Gilead. Based on data from preclinical and in vitro studies, GS 9005 has the potential to be dosed as a single pill once daily and may have a clinical resistance profile that is distinct from commercially-available drugs in the PI class.

GS 9005 utilizes the company's novel prodrug technology, which allows a drug to preferentially target lymphocytes, the primary site of HIV replication. This technology has been evaluated through the development of GS 7340, an investigational anti-HIV compound in Phase I/II development. GS 7340 is a prodrug of tenofovir, the active agent in the company's HIV drug Viread(R) (tenofovir disoproxil fumarate). Positive results from early clinical studies of GS 7340 provided the validation of this technology, which Gilead plans to apply to other HIV product candidates and drugs in other therapeutic categories that involve the lymphatic system.

"Although great progress has been made in the treatment of HIV, there is still a marked need for new therapeutics with the combined attributes of once-daily dosing, significant potency, improved long-term safety and activity against drug-resistant virus," said John C. Martin, PhD, President and Chief Executive Officer of Gilead Sciences, Inc. "We look forward to initiating clinical studies of GS 9005 and further advancing this important technology."

As an investigational compound, GS 9005 has not yet been determined safe or efficacious in humans for its ultimate intended use.

About Gilead

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes therapeutics to advance the care of patients suffering from life-threatening diseases worldwide. The company has seven marketed products and focuses its research and clinical programs on anti-infectives. Headquartered in Foster City, CA, Gilead has operations in the United States, Europe and Australia.

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors. These risks include the risk that the IND for GS 9005 may not be accepted by the FDA and the risk that the safety, efficacy, resistance and dosing potential of GS 9005 that was observed in preclinical studies may not be observed in human clinical trials. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in the Gilead Annual Report on Form 10-K for the year ended December 31, 2002 and in Gilead's Quarterly Reports on Form 10-Q, all of which are on file with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead and Gilead assumes no obligation to update any such forward-looking statements.

Viread is a registered trademark of Gilead Sciences, Inc.

For more information on Gilead Sciences, please visit www.gilead.com or call the Gilead Public Affairs Department at 1-800-GILEAD-5 (1-800-445-3235).

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