Gilead Begins Phase II Study of NX 211, Investigational Compound for the Treatment of Patients with Topotecan Resistant Ovarian Cancer

November 2, 2000 5:50 PM ET

Phase I Data Scheduled for Presentation at Upcoming Oncology Conferences

Foster City, CA -- November 2, 2000

Gilead Sciences, Inc. (Nasdaq: GILD) announced today that it has initiated the first Phase II clinical trial of NX 211 in patients with relapsed ovarian cancer resistant to treatment with topotecan. NX 211 is a liposomal formulation of a novel topoisomerase I inhibitor for the potential treatment of various solid tumors. This trial is designed to evaluate the safety and efficacy of NX 211 in up to 58 patients at five sites in the United States.

"This trial is an important step in the advancement of our emerging oncology portfolio," said John C. Martin, Ph.D., President and Chief Executive Officer, Gilead Sciences. "The rapid movement of NX 211 into Phase II trials is a direct result of our commitment to oncology and the benefits of our proprietary liposomal technology."

Study Design

This Phase II trial (Study 110-07) is an open-label, multicenter trial that will evaluate the efficacy and safety of NX 211 as determined by response rate, time to disease progression and patient tolerance. The pharmacokinetic profile of the compound will also be evaluated. This study will enroll patients with ovarian cancer that have progressed or relapsed within six months of treatment with a regimen including topotecan. Patients will be treated with NX 211 on days 1 and 8, repeated every 21 days.

Phase I Results

Gilead initiated Phase II trials based on results from three Phase I trials that evaluated different doses and schedules of NX 211 in patients with a variety of advanced malignancies. Results from 89 patients enrolled in these Phase I dose escalation trials will be described in a presentation on November 10 at the Chemotherapy Foundation Symposium XVIII in New York. Additional data on the safety and pharmacokinetic profiles of NX 211 will be presented next week at the 11th NCI-EORTC-AACR Symposium on New Drugs in Cancer Therapy in Amsterdam, The Netherlands. In the three Phase I studies, a maximum tolerated dose was determined for NX 211, with hematological toxicity as the dose-limiting toxicity. Non-hematological toxicity was mild. Although these Phase I studies were not designed to evaluate efficacy, there was indication of clinical and biological anti-tumor activity in seven patients.

"Currently, there is a clear need for new treatments for relapsed and refractory ovarian cancer," said Nicole Onetto, M.D., Vice President, Medical Affairs, Gilead Sciences. "Based on the encouraging results we've seen in Phase I studies, we will initiate additional clinical trials in ovarian, small cell lung and other tumor types to help gain a better understanding of the potential role of NX 211 in the treatment of cancer."

NX 211

NX 211 is a liposomal formulation of the anti-cancer agent lurtotecan. Gilead licensed worldwide rights to lurtotecan in 1998 from Glaxo Wellcome. Lurtotecan functions by inhibiting topoisomerase I, an enzyme in the cell nucleus involved in cell maintenance and growth. Topoisomerase I inhibitors are used for the treatment of certain cancers because the topoisomerase I enzyme is involved in the unwinding of DNA segments. By inhibiting topoisomerase I, DNA will not unwind, thereby preventing cell replication.

Ovarian Cancer

Ovarian cancer is the fifth leading cause of cancer death among women in Canada, Europe and the United States and causes more deaths than any other reproductive cancer. In the United States, according to American Cancer Society statistics, an estimated 23,000 women will be diagnosed with ovarian cancer in the year 2000, and nearly 14,000 will die from the disease. The standard of care for advanced ovarian cancer includes surgery followed by chemotherapy. Many patients – nearly 80 percent

– relapse after initial treatment, and improved therapies for these patients are still needed.

Patients and physicians who would like more information about enrollment in this study may contact Gilead Sciences Medical Information at 1-800-GILEAD-5 (1-800-445-3235) or 1-650-574-3000 from outside the United States.

Gilead Sciences

Gilead Sciences, Inc., headquartered in Foster City, CA, is an independent biopharmaceutical company that seeks to provide accelerated solutions for patients and the people who care for them. Gilead discovers, develops, manufactures and commercializes proprietary therapeutics for challenging infectious diseases (viral, fungal and bacterial infections) and cancer. Gilead maintains research, development or manufacturing facilities in Foster City, CA; Boulder, CO; San Dimas, CA; Cambridge, UK and Dublin, Ireland and sales and marketing organizations 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, including statements relating to the safety profile of NX 211 and the anti-tumor activity observed in Phase I studies. These statements are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements. Such risks and uncertainties include: the risk that the safety data observed in Gilead's Phase I trials may not be observed in its more reliable Phase II trials; uncertainties associated with observations of anti-tumor activity in Phase I trials that were not designed to evaluate efficacy, and the risk that this activity may not be observed in Phase II trials that are designed to evaluate efficacy; the risk that Phase II trials may demonstrate that NX 211 does not have sufficient anti-tumor activity at tolerable doses; and other risks related to clinical trials and regulatory approval of NX 211. 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, 1999 and on Gilead's Quarterly Reports on Form 10-Q, all of which are on file with the U.S. Securities and Exchange Commission.

# # #