Gilead Initiates Phase 3 Clinical Trial Evaluating GS-1101 for the Treatment of Chronic Lymphocytic Leukemia

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FOSTER CITY, Calif., May 01, 2012 (BUSINESS WIRE) --Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the first patient has been dosed in a Phase 3 clinical trial evaluating the efficacy and safety of GS-1101 (formerly CAL-101). GS-1101 is an investigational, first-in-class specific inhibitor of the phosphoinositide-3 kinase (PI3K) delta isoform and is being evaluated in combination with rituximab in previously treated chronic lymphocytic leukemia (CLL) patients. The Phase 3 trial (Study 116) will enroll 160 patients at approximately 70 sites in the United States and Europe.

"Initiation of our first Phase 3 study in oncology is an important step as we seek to develop therapies across a broad range of cancers," said Roy D. Baynes, MD, PhD, Senior Vice President, Oncology and Inflammation Therapeutics at Gilead. "Based on the promising clinical data we've seen thus far, we believe GS-1101 could represent a much needed advance in the treatment of CLL and we look forward to working with study investigators to further our understanding of this potentially important new therapy."

CLL is a type of cancer in which the bone marrow overproduces lymphocytes, leaving less room in the blood and bone marrow for other blood cells. CLL is the second most common form of leukemia, according to the National Cancer Institute, which estimates there will be 16,000 new diagnoses and approximately 4,500 deaths in the United States from the disease in 2012.

Study 116 is the first of several planned Phase 3 studies exploring the utility of GS-1101 in combination with various chemoimmunotherapies in previously treated CLL patients. A Phase 3 study examining GS-1101 in combination with bendamustine and rituximab is anticipated to begin enrolling patients later this quarter. A third study evaluating GS-1101 in combination with ofatumumab is anticipated to begin enrollment in the second half of this year.

GS-1101 is also in Phase 2 evaluation as a potential treatment for indolent non-Hodgkin's lymphoma (iNHL).

About Study 116

Study 116 is a randomized, double-blind, placebo-controlled, Phase 3 study evaluating the efficacy and safety of GS-1101 in combination with rituximab. The study will enroll 160 adult patients with previously treated recurrent CLL who have measureable lymphadenopathy, have experienced CLL disease progression less than 24 months following completion of prior therapy, and are currently not sufficiently fit to receive cytotoxic therapy because of comorbidities. Eligible patients will be randomized in a 1:1 ratio to receive eight infusions of rituximab over 24 weeks plus either GS-1101 (150 mg) or placebo taken orally twice daily on a continuous basis. The primary efficacy endpoint is progression-free survival (PFS).

Patients who are tolerating primary study therapy (GS-1101 or placebo) will be eligible to receive active GS-1101 therapy in a double-blind extension study (Study 117).

Additional study details can be found at www.clinicaltrials.gov.

About GS-1101

GS-1101 is a first-in-class specific inhibitor of the PI3K delta isoform. PI3K delta is preferentially expressed in leukocytes (white blood cells) involved in a variety of inflammatory and autoimmune diseases and hematological cancers. GS-1101 is currently being developed as a potential therapy for treatment of CLL and iNHL.

GS-1101 is an investigational product and has not yet been determined safe or efficacious in humans.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Asia Pacific.

Forward-Looking Statement

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, including the risks related to Gilead's ability to enroll patients in the Phase 3 clinical trials of GS-1101 for the treatment of CLL as planned, the possibility of unfavorable results of the clinical trials, the need to modify or delay the clinical trials or to perform additional trials and the risk of failing to obtain approvals from regulatory authorities. As a result, GS-1101 may never be successfully commercialized for any treatment area. Further, Gilead may make a strategic decision to discontinue development of GS-1101 if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. 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 Gilead's Annual Report on Form 10-K for the year ended December 31, 2011, as filed 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.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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