**Gilead Announces Response Data from Phase 2 Study of Idelalisib for Previously Untreated Chronic Lymphocytic Leukemia**

May 15, 2013 6:31 PM ET

***-- Regimen Achieves 97 Percent Overall Response Rate with Estimated Progression-Free Survival at 24 Months of 93 Percent --***

***-- Results from Study 101-08 and Other Idelalisib Clinical Studies to Be Presented at American Society of Clinical Oncology Annual Meeting --***

FOSTER CITY, Calif.--(BUSINESS WIRE)--May. 15, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced results from a Phase 2 study (Study 101-08) evaluating idelalisib (formerly GS-1101), an investigational, targeted, oral inhibitor of PI3K delta, in combination with rituximab for older patients with treatment-naïve chronic lymphocytic leukemia (CLL). This regimen achieved a complete response (CR) rate of 19 percent and an overall response rate (ORR) of 97 percent, with estimated progression-free survival (PFS) at 24 months of 93 percent. Detailed results will be presented during an oral session at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago (Abstract #7005).

CLL is a slow-growing cancer that induces the production of too many mature white blood cells. It is the second most common type of leukemia in the United States and can lead to life-threatening complications, including serious infection. Currently, patients with CLL are usually treated first with rituximab in combination with one or more chemotherapy agents.

“New therapies that can drive CLL into remission while potentially avoiding or delaying the need for chemotherapy would represent a much needed clinical advance,” said Susan M. O’Brien, MD, Ashbel Smith Professor of Medicine in the Department of Leukemia at the University of Texas MD Anderson Cancer Center in Houston and a principal investigator of the study. “The high overall response rate and durable disease control observed in this Phase 2 study suggest that idelalisib in combination with rituximab could become an important therapeutic option for CLL patients new to treatment.”

Among the 64 patients in the study, Kaplan-Meier estimated PFS at 24 months was 93 percent. The median time on treatment was 14 months, with 33 patients remaining on treatment. The median time to response was two months. No relapses on study have been reported. The nine patients with chromosome 17p deletion (del 17p) (n=6) or mutation in the TP53 gene (n=3), which have been linked to poor prognosis, all responded to therapy including three with a complete response. Ninety-four percent of patients with thrombocytopenia at baseline responded to treatment (16/17), as did all patients with anemia at baseline (17/17). Of patients with systemic symptoms such as extreme fatigue, fever, night sweats or weight loss (known as “B symptoms”) at baseline, 77 percent (20/26) were asymptomatic by eight weeks.

Patients completing 48 weeks of therapy without progression could continue to receive idelalisib in an extension study. Forty-three patients completed 48 weeks of treatment (21 discontinued – 17 due to adverse events, three due to death and one due to other reasons); 40 patients entered the extension study and 33 remain on treatment.

During the primary and extension study, Grade 3 diarrhea and/or colitis was reported in 33 percent of patients, Grade ≥3 pneumonia in 17 percent and Grade ≥3 transaminase elevations (measure of liver function) in 23 percent of patients.

“These results demonstrate for the first time idelalisib’s potential benefit for patients with a previously untreated hematological malignancy,” said Roy D. Baynes, MD, PhD, Senior Vice President of Oncology and Inflammation Therapeutics at Gilead Sciences. “Based on these promising data, we are now evaluating Phase 3 study designs for idelalisib as part of a frontline treatment regimen for CLL patients.”

Idelalisib’s clinical and safety profile for a number of blood cancers will be characterized in six additional oral or poster presentations at ASCO 2013:

**Chronic Lymphocytic Leukemia (CLL)**

- Final results of a Phase 1 study of idelalisib in patients with relapsed or refractory CLL (Abstract #7003; oral session).
- Update on a Phase 1 study of idelalisib in combination with rituximab and/or bendamustine in patients with relapsed or

refractory CLL (Abstract #7017; poster session).

**Indolent Non-Hodgkin's Lymphoma (iNHL)**

- Combinations of the PI3K delta inhibitor idelalisib with rituximab and/or bendamustine are tolerable and highly active in patients with previously treated, indolent non-Hodgkin lymphoma: Updated results from a Phase 1 study (Abstract #8500; oral session).
- Final results of a Phase 1 study of idelalisib, a selective inhibitor of PI3K delta, in patients with relapsed or refractory indolent non-Hodgkin lymphoma (Abstract #8526; poster session).

**Mantle Cell Lymphoma (MCL)**

- Final results of a Phase 1 study of idelalisib, a selective inhibitor of PI3K delta in patients with relapsed or refractory mantle cell lymphoma (Abstract #8519; clinical science symposium).

- Preliminary results of PI3K delta inhibitor idelalisib treatment in combination with everolimus, bortezomib, or bendamustine/rituximab in patients with previously treated mantle cell lymphoma (Abstract #8501; oral session).

**About Study 101-08**

Study 101-08 is an open-label, single-arm Phase 2 trial that enrolled 64 treatment-naïve patients ≥65 years old with CLL or small lymphocytic lymphoma (SLL), a less common form of the disease. Patients received intravenous rituximab 375 mg/m$^2$ weekly for eight weeks and oral idelalisib 150 mg twice daily for 48 weeks. The primary endpoint of the study is overall response rate, defined as the proportion of patients achieving a complete or partial response with this regimen (response definitions based on standard criteria). Patients completing 48 weeks of therapy without progression could continue to receive idelalisib in an extension study.

**About Idelalisib**

Idelalisib is an investigational, targeted, highly selective oral inhibitor of phosphoinositide 3-kinase (PI3K) delta, a molecular target that is critical for the activation, proliferation and survival of B lymphocytes. PI3K delta signaling is hyperactive in many B-cell leukemias and lymphomas and drives proliferation, survival and trafficking to lymphoid tissue. Idelalisib is being developed both as a single agent and in combination with approved and investigational therapies.

Gilead's clinical development program for idelalisib includes three Phase 3 studies evaluating the drug in combination with approved therapies for patients with previously treated CLL, and two Phase 3 studies of idelalisib in combination with approved therapies for patients with previously treated indolent non-Hodgkin's lymphoma (iNHL). In addition, combination therapy with idelalisib and GS-9973, Gilead's novel spleen tyrosine kinase (Syk) inhibitor, is being studied in a Phase 2 trial of patients with relapsed or refractory CLL, iNHL and other lymphoid and hematological malignancies.

Additional information about clinical studies of idelalisib and Gilead's other investigational cancer agents can be found at www.clinicaltrials.gov. Idelalisib and GS-9973 are investigational products and their safety and efficacy have not yet been established.

**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 risks related to the possibility of unfavorable results from clinical trials involving idelalisib, including in combination with GS-9973 or other product candidates. Gilead also faces risks related to its ability to enroll patients in a Phase 3 clinical study in treatment-naïve CLL patients or other studies and may need to modify or

delay this study or other studies. As a result, idelalisib may never be successfully commercialized. Further, Gilead may make a strategic decision to discontinue development of idelalisib 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, 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, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.*

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