

## **Gilead Announces Updated Phase 2 Results for Investigational GS-9973 in Relapsed Chronic Lymphocytic Leukemia**

June 3, 2014 8:31 AM ET

***-- Syk Inhibitor Demonstrates 49 Percent Overall Response Rate with an Estimated Progression-Free Survival Rate at 24 Weeks of 70 Percent in Previously Treated CLL Patients --***

***-- Data Presented at American Society of Clinical Oncology Annual Meeting --***

CHICAGO--(BUSINESS WIRE)--Jun. 3, 2014-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced updated interim results of a Phase 2 study (Study 102) evaluating GS-9973, its investigational oral inhibitor of spleen tyrosine kinase (Syk), for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). In this study, single-agent treatment with GS-9973 achieved an overall response rate of 49 percent, with an estimated progression-free survival (PFS) rate at 24 weeks of 70 percent. Detailed results will be presented today during an oral session at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago (Abstract #7007).

“Most CLL patients eventually relapse following treatment, underscoring the need for novel therapies targeting survival pathways that may enable patients to obtain control of their disease without requiring chemotherapy,” said Jeff Sharman, MD, lead study author and Medical Director of Hematology Research for the US Oncology Network. “The strong response rates and acceptable safety profile seen in this study suggest that GS-9973 has the potential to provide therapeutic benefit for relapsed CLL patients.”

The efficacy analysis focuses on a cohort of 41 CLL patients with a median exposure of 32 weeks (range 1-53) in Study 102. Among this cohort, the Kaplan-Meier estimated PFS rate at 24 weeks was 70 percent (95 percent CI: 51-83 percent). Median PFS and median duration of response were not reached. At the time of data snapshot, 46 percent of patients (n=19) continued GS-9973 treatment. There was a 49 percent (n=20) overall response rate, of which all were partial responses. Ninety-five percent of evaluable patients (n=37/39) experienced tumor shrinkage, including all 25 patients with a chromosome 17p deletion and/or a mutation in the TP53 gene or other genetic abnormalities that have been linked to poor prognosis. Sixty-two percent of evaluable patients (n=24) achieved at least a 50 percent tumor reduction.

The safety of GS-9973 was also assessed in a larger population of 145 CLL or non-Hodgkin lymphoma (NHL) patients with an overall median exposure of 13 weeks at the time of data snapshot. Non-hematologic Grade  $\geq 3$  adverse events included fatigue (6.9 percent); dyspnea (6.2 percent); pneumonia (4.1 percent); nausea (3.4 percent); atrial fibrillation, chest pain, dehydration, febrile neutropenia and hypoxia (2.8 percent each); and back pain, hypotension, pyrexia and sepsis (2.1 percent each). Reversible Grade  $\geq 3$  transaminase elevations (a measure of liver function) were reported in 14 percent of patients.

Based on these data, Gilead plans to initiate new CLL study cohorts to include patients who have relapsed following treatment with other inhibitors of the b-cell receptor (BCR) pathway.

### **About Study 102**

This Phase 2, open-label, single-arm safety and efficacy study is evaluating GS-9973 (800 mg twice daily) in patients with relapsed or refractory CLL and NHL (indolent NHL, diffuse large B-cell lymphoma and mantle cell lymphoma). The median age of the CLL patients included in the analysis was 73 years. These patients had received a median of two prior treatment regimens (e.g., anti-CD20 antibodies, alkylating agents, fludarabine) before study entry (range: 1-8). The primary endpoint of the study is progression-free survival at week 24 for the CLL cohort. Patients are allowed to continue daily dosing as long as they benefit from therapy. The study is ongoing. Initial results were presented at the American Society of Hematology Annual Meeting in December 2013.

### **About GS-9973**

GS-9973 is an investigational, targeted, reversible oral inhibitor of spleen tyrosine kinase (Syk), a protein that is critical for the activation, proliferation and survival of B lymphocytes. Additional information about clinical studies of GS-9973 can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). GS-9973 is an investigational product and its safety and efficacy have not been established.

### **About Chronic Lymphocytic Leukemia**

CLL is a slow-growing cancer in which the bone marrow overproduces white blood cells, leaving less room in the bone marrow and blood for other types of blood cells. It is the most common leukemia in adults in the United States, occurring typically in older individuals, and it can lead to life-threatening complications, including anemia and serious infections. The National Cancer Institute estimates that in 2013, there were approximately 16,000 new CLL diagnoses in the United States and 4,500 deaths related to this cancer.

## **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 transform and simplify care for people with life-threatening illnesses around the world. Headquartered in Foster City, California, Gilead has operations in North and South 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 possibility of unfavorable results from clinical trials involving GS-9973. Gilead may also experience challenges in initiating new CLL study cohorts in the currently anticipated timelines and such studies may be modified or delayed. Further, Gilead may make a strategic decision to discontinue development of GS-9973 if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, GS-9973 may never be successfully commercialized. 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, 2014, 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](http://www.gilead.com), follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000*

Source: Gilead Sciences

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