Gilead to Stop Phase 3 Study 116 of Idelalisib in Chronic Lymphocytic Leukemia Early Because of Positive Risk-Benefit

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 9, 2013-- Following a recommendation by an independent Data Monitoring Committee (DMC), Gilead Sciences, Inc. (Nasdaq:GILD) today announced that its Phase 3 study (Study 116) evaluating idelalisib in previously-treated chronic lymphocytic leukemia (CLL) patients who are not fit for chemotherapy will be stopped early. This DMC recommendation is based on a predefined interim analysis showing highly statistically significant efficacy for the primary endpoint of progression-free survival in patients receiving idelalisib plus rituximab compared to those receiving rituximab alone. The safety profile of idelalisib was acceptable and consistent with prior experience in combination with rituximab in previously treated CLL. Gilead has informed the U.S. Food and Drug Administration (FDA) of the plan to end the study and will engage in a dialogue with the FDA regarding a regulatory filing in CLL. Data from Study 116 will be submitted for presentation at an upcoming scientific conference.

“Given the significant unmet medical need in CLL, particularly in this population of patients who are not fit for chemotherapy, we are pleased that idelalisib has shown a clinically meaningful benefit for patients,” said Norbert W. Bischofberger, PhD, Gilead’s Executive Vice President, Research and Development and Chief Scientific Officer. “This is the first Phase 3 study to report positive results for a new class of targeted therapies that inhibit B-cell receptor signaling as a major component of their mechanism of action, an important area of focus in the development of chemotherapy-free regimens in CLL and other B-cell malignancies. We extend thanks to the investigative sites and to the other research collaborators participating in this study, as well as to the patients who volunteered, and we look forward to sharing these data with the hematology community.”

Patients from Study 116 randomized to idelalisib will continue receiving idelalisib and patients in the control arm (placebo plus rituximab) will become eligible to receive open-label idelalisib therapy in an extension study. Gilead is also planning an expanded access program (EAP) for patients with recurrent CLL who are not fit for chemotherapy and require treatment.

A new drug application (NDA) for idelalisib was submitted for refractory indolent non-Hodgkin’s lymphoma (iNHL) on September 11, 2013. Gilead plans to file for regulatory approval of idelalisib in the European Union later this year.

About Study 116

Study 116 was a randomized, double-blind, placebo-controlled, Phase 3 study evaluating the efficacy and safety of idelalisib in combination with rituximab. The study enrolled 220 adult patients with previously treated recurrent CLL who had measureable lymphadenopathy with disease progression less than 24 months following completion of prior therapy, and who required treatment but were not fit to receive cytotoxic therapy. Eligible patients were randomized to receive eight infusions of rituximab over 24 weeks plus either idelalisib (150 mg) or placebo taken orally twice daily continuously until disease progression or unacceptable toxicity. Patients who progressed on Study 116 were eligible to receive active idelalisib therapy in a double-blind extension study (Study 117).

About Idelalisib

Idelalisib is an investigational, highly selective and potent oral inhibitor of phosphoinositide 3-kinase (PI3K) delta. PI3K delta signaling is critical for the activation, proliferation, survival and trafficking of B lymphocytes and is hyperactive in many B-cell malignancies. Idelalisib is being developed both as a single agent and in combination with approved and investigational therapies.

In addition to a Phase 2 study in double-refractory iNHL, Gilead’s clinical development program for idelalisib includes two Phase 3 studies of idelalisib in patients with previously treated iNHL and three Phase 3 studies of idelalisib in patients with previously treated CLL. Combination therapy with idelalisib and GS-9973, Gilead’s novel spleen tyrosine kinase (Syk) inhibitor, also is being evaluated in a Phase 2 trial of patients with relapsed or refractory CLL, iNHL and other lymphoid 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 the possibility of unfavorable results from clinical trials involving idelalisib, including in combination with GS-9973 or other product candidates. Gilead may also be unable to file for regulatory approval for idelalisib for CLL with the FDA or for CLL and iNHL in the European Union in the currently anticipated timelines. In addition, the pending new drug application for idelalisib for iNHL may not be approved by the FDA, and if marketing approval is granted, there may be significant limitations on its use. 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 June 30, 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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