Gilead Submits New Drug Application to U.S. FDA for Idelalisib for the Treatment of Indolent Non-Hodgkin's Lymphoma

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-- Idelalisib Would Be First PI3K Delta Targeted Therapy Approved for a Hematological Cancer and First New Class of Therapy Approved for iNHL in More Than a Decade --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Sep. 11, 2013-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for approval of idelalisib, an investigational, targeted, oral inhibitor of PI3K delta, for the treatment of indolent non-Hodgkin's lymphoma (iNHL). The data submitted in this NDA support the use of idelalisib for patients with iNHL that is refractory (non-responsive) to rituximab and to alkylating-agent-containing chemotherapy.

Indolent non-Hodgkin's lymphoma refers to a group of largely incurable slow-growing lymphomas that run a relapsing course after therapy and lead ultimately to life-threatening complications such as serious infections and marrow failure. Most iNHL patients are diagnosed at an advanced stage of disease, and median survival from time of initial diagnosis for patients with the most common form of iNHL, follicular lymphoma, is 8 to 10 years. The outlook for refractory iNHL patients is significantly poorer.

"Gilead is committed to advancing a pipeline of novel cancer therapies that have the potential to improve the lives of patients," said John C. Martin, PhD, Chairman and Chief Executive Officer of Gilead Sciences. "Based on the rate and duration of response observed to date in this highly refractory iNHL patient population, we believe idelalisib could become an important new therapy for patients who have limited treatment options."

Gilead's NDA for idelalisib is supported by data from a single-arm, open-label Phase 2 study (Study 101-09) of 125 patients with iNHL refractory to rituximab and to alkylating-agent-containing chemotherapy. In an interim data analysis presented in June at the International Conference on Malignant Lymphoma in Lugano, Switzerland, single-agent idelalisib achieved an overall response rate of 53.6 percent, with a median duration of response of 11.9 months. Median progression-free survival for all patients was 11.4 months. 89 percent of patients experienced lymph node shrinkage. The most common Grade ≥3 adverse events or laboratory abnormalities were diarrhea (10 percent), transaminase elevations (measure of liver function, 13 percent) and neutropenia (26 percent).

Updated results from this study were included in the NDA filing and have also been submitted for presentation at an upcoming scientific conference. Gilead plans to file for regulatory approval of idelalisib in the European Union in the fourth quarter of this year.

About Idelalisib

Idelalisib is an investigational, targeted, highly selective oral inhibitor of phosphoinositide 3-kinase (PI3K) delta, a protein 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.

In addition to the Phase 2 iNHL study, Gilead's clinical development program for idelalisib includes two Phase 3 studies of idelalisib in combination with approved therapies for patients with previously treated iNHL and three Phase 3 studies evaluating the drug in combination with approved therapies for patients with previously treated chronic lymphocytic leukemia (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 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 the risk that Gilead will be unable to file for regulatory approval in the European Union in the anticipated timeline. In addition, the FDA and other regulatory agencies may not approve idelalisib, and any marketing approvals, if granted, may have significant limitations on their use. Additionally, clinical trials involving idelalisib, including in combination with GS-9973 or other product candidates, may produce unfavorable results. 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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