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

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FOSTER CITY, Calif.--(BUSINESS WIRE)--Jan. 13, 2014-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) for idelalisib, a targeted, oral inhibitor of PI3K delta, for the treatment of refractory indolent non-Hodgkin's lymphoma (iNHL). FDA has granted a standard review for the iNHL NDA and has set a target review date under the Prescription Drug User Fee Act (PDUFA) of September 11, 2014.

The NDA for iNHL, submitted on September 11, 2013, was supported by a single arm Phase 2 study (Study 101-09) evaluating idelalisib in patients with iNHL that is refractory (non-responsive) to rituximab and to alkylating-agent-containing chemotherapy. Following Gilead's NDA submission for iNHL, FDA granted idelalisib a Breakthrough Therapy designation for relapsed chronic lymphocytic leukemia (CLL). The FDA grants Breakthrough Therapy designation to drug candidates that may offer major advances in treatment over existing options. Gilead submitted an NDA for idelalisib for the treatment of CLL on December 6, 2013.

About Idelalisib

Idelalisib is an investigational, highly selective 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.

Gilead's clinical development program for idelalisib in iNHL includes Study 101-09 in highly refractory patients and two Phase 3 studies of idelalisib in previously treated patients. The development program in CLL includes three Phase 3 studies of idelalisib in previously treated patients. 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 been established.

About Indolent Non-Hodgkin's Lymphoma

Indolent non-Hodgkin's lymphoma refers to a group of largely incurable slow-growing lymphomas that run a relapsing course after therapy and can 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.

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 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 risk that FDA and other regulatory agencies may not approve idelalisib for iNHL or CLL and that any marketing approvals, if granted, may have significant limitations on its use. Further, additional studies of idelalisib, including in combination with other products such as GS-9973, may produce unfavorable results. In addition, even if approved, Gilead may not be able to successfully commercialize idelalisib and may make a strategic decision to discontinue its development 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 September 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.

Source: Gilead Sciences, Inc.

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