Gilead Announces Data From Phase 2 Study of Simtuzumab for Previously Untreated Pancreatic Cancer

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-- Data to be Presented at European Society for Medical Oncology Congress in Madrid --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Sep. 17, 2014-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced results from a Phase 2 study evaluating simtuzumab, an investigational inhibitor of lysyl oxidase-like-2 (LOXL2), in combination with gemcitabine for patients with previously untreated advanced pancreatic cancer. In the study, the addition of simtuzumab (200 mg or 700 mg) to gemcitabine did not significantly increase progression-free survival (PFS) compared to placebo plus gemcitabine. PFS was the primary endpoint of the study. Detailed results will be presented during a poster session at the European Society for Medical Oncology Congress (ESMO 2014) in Madrid, Spain, September 26-30 (Abstract #5072).

In this randomized, double-blind, placebo-controlled Phase 2 trial, 236 patients with advanced pancreatic cancer received intravenous gemcitabine plus either intravenous simtuzumab (200 mg, n=76; 700 mg, n=79) or placebo (n=81) in cycles of 28 days. Median PFS for the simtuzumab 200 mg, simtuzumab 700 mg and placebo groups was 3.5 months, 3.7 months and 3.7 months, respectively. The difference in PFS between the simtuzumab and placebo arms was not statistically significant. Expected gemcitabine-related toxicities included anemia, thrombocytopenia, neutropenia and nausea. There was no difference in adverse events between patients taking simtuzumab versus placebo.

“Although simtuzumab did not provide clinical benefit in difficult-to-treat advanced pancreatic cancer patients in this study, we continue to explore simtuzumab in other areas of unmet medical need, with ongoing clinical trials in colorectal cancer, myelofibrosis and serious fibrotic lung and liver diseases,” said Norbert Bischofberger, PhD, Gilead’s Executive Vice President of Research and Development and Chief Scientific Officer.

Simtuzumab is an investigational monoclonal antibody that is highly selective for LOXL2, an enzyme that modifies the extracellular matrix by promoting the cross-linking of collagen fibers. LOXL2 is thought to play an important role in tumor progression and metastasis and in the development of fibrotic diseases. Simtuzumab is being evaluated in several ongoing Phase 2 trials, including in combination with FOLFIRI for advanced colorectal cancer, in combination with ruxolitinib for myelofibrosis, as monotherapy for idiopathic pulmonary fibrosis, a rare lung disease, and for liver fibrosis caused by non-alcoholic steatohepatitis (NASH) and primary sclerosing cholangitis (PSC).

Other agents in Gilead’s oncology pipeline, including momelotinib and GS-5745, are currently being evaluated in clinical trials for the treatment of pancreatic cancer.

Additional information about clinical studies of simtuzumab and Gilead’s other investigational cancer agents can be found at www.clinicaltrials.gov. Simtuzumab, momelotinib and GS-5745 are investigational products and their safety and efficacy have not 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 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 simtuzumab in other therapeutic areas. Gilead may also experience challenges in enrolling patients

in clinical studies, requiring those studies to be modified or delayed. Further, Gilead may make a strategic decision to discontinue development of simtuzumab if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, simtuzumab 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 June 30, 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, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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