

Gilead Terminates Phase 2/3 Study of GS-5745 in Patients With Ulcerative Colitis

September 21, 2016 5:01 PM ET

FOSTER CITY, Calif.--(BUSINESS WIRE)--Sep. 21, 2016-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the company is stopping its combined Phase 2/3 clinical study of GS-5745, an investigational anti-MMP9 antibody, among patients with moderately to severely active ulcerative colitis. This decision follows a planned interim analysis of unblinded efficacy and safety data by the Data Monitoring Committee (DMC) after the first 150 patients of a planned 1600-patient trial were treated for an 8-week induction duration. The DMC recommended that the study be terminated early due to meeting the pre-specified futility and efficacy criteria. No safety concerns were noted in this interim analysis. Gilead has also reviewed the data and determined that there is insufficient evidence of a treatment benefit in the group of patients randomized to receive either one of two doses of GS-5745.

Separately, a Phase 3 study of GS-5745 is ongoing in patients with gastric cancer, as well as a Phase 2 study in patients with gastric cancer in combination with nivolumab and additional Phase 2 studies in moderately to severely active Crohn's disease, rheumatoid arthritis and cystic fibrosis. These studies will continue as planned.

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. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

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 other clinical trials for GS-5745. In addition, it is possible that Gilead may make a strategic decision to discontinue development of GS-5745 if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, GS-5745 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, 2016, 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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