Gilead Announces Preclinical Data for an Investigational TLR7 Agonist in SIV-Infected, Virally Suppressed Monkeys

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– Data Support Plans for Phase 2 Clinical Trial in Humans –

SEATTLE--(BUSINESS WIRE)--Feb. 25, 2015-- Gilead Sciences, Inc. (NASDAQ:GILD) today announced results from a preclinical study conducted in collaboration with researchers at Beth Israel Deaconess Medical Center evaluating a proprietary investigational oral toll-like receptor 7 (TLR7) agonist and analogue of GS-9620 as part of an HIV eradication strategy. Data demonstrate that treatment with the TLR7 agonist induced transient plasma Simian Immunodeficiency Virus (SIV) RNA, as well as reduced SIV DNA in virally suppressed rhesus macaques given antiretroviral therapy (ART). In addition, the study found that after discontinuation of ART, SIV viral loads were lower among macaques that received the proprietary TLR7 agonist compared to the placebo group. These data were presented in an oral session (Session O-9) at the 22nd Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle.

“One reason current therapies can’t cure HIV is that latent reservoirs of the virus persist even among individuals who are virally suppressed on ART,” said James Whitney, PhD, Assistant Professor of Medicine, Harvard Medical School, and study Principal Investigator in the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center in Boston. Dr. Whitney is also an Associate Member of The Ragon Institute of MGH, MIT and Harvard, which was founded in 2009 to contribute to the accelerated discovery of an HIV/AIDS vaccine and to establish itself as a world leader in the collaborative study of immunology. “These data demonstrate that, given alongside ART, the TLR7 agonist may have the potential to both stimulate virus production and eliminate latently infected cells – an eradication strategy being explored today.”

In this placebo-controlled study, 10 SIV-infected rhesus macaques received ART for 38 weeks, at which point they were virally suppressed (plasma RNA less than 50 copies/mL). At week 38, six macaques were given placebo and four macaques were given seven bi-weekly doses of the TLR7 agonist, while maintaining ART. Total viral DNA levels were measured at baseline and two weeks after completion of the TLR7 agonist dosing in peripheral blood mononuclear cells (PBMC), colon and inguinal lymph nodes – where latent SIV reservoirs are common. ART was discontinued two weeks after the final dose of the TLR7 agonist to assess plasma viral rebound.

The four macaques receiving bi-weekly doses of the TLR7 agonist were given 0.1 mg/kg for the first dose, 0.2 mg/kg for the second dose and 0.3 mg/kg for each of the last five doses. Doses 1-3 had no effect on plasma viremia, whereas doses 4-7 led to transient and consistent increases in plasma virus (500-1,000 SIV RNA copies/mL) in all four macaques with a return to less than 50 copies/mL within four to seven days after receiving the TLR7 agonist. In addition, SIV DNA levels of the four treated macaques were reduced by 30 to 90 percent compared to the placebo group, which remained unchanged. Following discontinuation of ART in the macaques that received the TLR7 agonist, plasma SIV RNA was ~0.5 $\log_{10}$ lower compared to the placebo group.

“These preliminary results suggest that TLR7 agonists may have a role to play in HIV eradication strategies,” said Norbert W. Bischofberger, PhD, Gilead’s Executive Vice President, Research and Development and Chief Scientific Officer. “GS-9620 is a potent TLR7 agonist currently being evaluated in a Phase 2 study in patients with chronic hepatitis B for its potential to reduce HbSAg. Based on today’s results, we are now also looking forward to moving GS-9620 into proof-of-concept studies in HIV-infected individuals taking ART.”

The proprietary TLR7 agonist compound and GS-9620 are investigational agents 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. 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. In addition, we may observe unfavorable results from clinical trials involving the proprietary investigational TLR7 agonist or other TLR7 agonists, including GS-9620. In addition, Gilead may make a strategic decision to discontinue development of the proprietary TLR7 agonist or GS-9620 if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, the proprietary TLR7 agonist and GS-9620 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 September 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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