Gilead Announces Data from New Preclinical Study Evaluating a Combination of an Investigational TLR7 Agonist and an Investigational HIV Envelope Targeting Antibody in SHIV-Infected, Virally Suppressed Monkeys

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– Data Support Continued Clinical Investigation of GS-9620 and GS-9722 as Part of an HIV Eradication Strategy –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Mar. 4, 2018-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced results from a preclinical study conducted in collaboration with researchers at Beth Israel Deaconess Medical Center evaluating the combination of a proprietary investigational oral toll-like receptor 7 (TLR7) agonist, GS-9620, and a proprietary investigational broadly neutralizing antibody (bNAb), PGT121, as part of an HIV eradication strategy. Data from the study conducted in simian-human immunodeficiency virus (SHIV)-infected rhesus monkeys on suppressive antiretroviral therapy (ART) demonstrated that a combination treatment of GS-9620 and PGT121 resulted in a subset of animals maintaining viral suppression after ART discontinuation. These data, discussed during a press conference at the 2018 Conference on Retroviruses and Opportunistic Infection (CROI) in Boston, support further clinical investigation of combination strategies involving bNAbs and a TLR7 agonist which may have the potential to achieve long-term viral suppression without the need for daily ART.

“HIV has the ability to hide in certain immune cells, which is called the latent viral reservoir and which represents a key barrier to curing HIV. New HIV therapies that aim to wake up and target the viral reservoir have the potential to play an important role in long-term viral suppression without ART,” said Dan H. Barouch, MD, PhD, Professor of Medicine, Harvard Medical School, and Director, Center for Virology and Vaccine Research, Beth Israel Deaconess Medical Center. Dr. Barouch, who led the study, is also a member of the Ragon Institute of MGH, MIT and Harvard. “In this proof-of-concept preclinical study, 45 percent of the animals that received both GS-9620 and PGT121 did not demonstrate viral rebound after stopping ART, suggesting that this combination may be able to target the viral reservoir in virally suppressed monkeys.”

In the study, 44 SHIV-infected rhesus monkeys started ART on day 7 post-infection. After 96 weeks of continuous ART, the animals were divided into four equal groups that received either 5 doses of PGT121 (10 mg/kg infusion every two weeks for 10 weeks) (n=11), 10 doses of GS-9620 (0.15 mg/kg by oral gavage every two weeks for 20 weeks) (n=11), both PGT121 and GS-9620 (n=11), or neither (placebo) (n=11). Animals continued to receive ART throughout this period and for 16 weeks afterwards. ART was discontinued at week 130 and viral rebound was monitored in plasma.

After ART discontinuation, 11 of 11 animals in the placebo arm experienced viral rebound with a median rebound time of 21 days, nine of 11 animals that received only PGT121 demonstrated viral rebound and 10 of 11 animals that received only GS-9620 showed viral rebound. In contrast, five of 11 animals that received the combination of PGT121 and GS-9620 demonstrated no viral rebound for at least 168 days, and the other six animals in the combination group rebounded but then began re-suppressing the virus without ART.

“We remain committed to researching and developing HIV eradication strategies, and we are encouraged by these data presented at CROI from a preclinical animal model of HIV infection showing that the combination of GS-9620 and PGT121 may potentially induce viral remission in the absence of ART,” said Norbert W. Bishofberger, PhD, Gilead’s Executive Vice President, Research and Development and Chief Scientific Officer. “GS-9620 is currently in a Phase 1b dose-escalation study in ART-suppressed people living with HIV and we have advanced GS-9722, a derivative of PGT121, into Phase 1 testing.”

The proprietary bNAbs PGT121 and GS-9722, as well as the TLR7 agonist GS-9620, are investigational agents and their safety and efficacy have not been established. There is no cure for HIV or AIDS.

This research was supported by the Bill & Melinda Gates Foundation and the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health.

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 35 countries worldwide, with headquarters in Foster City, California.

For nearly 30 years, Gilead has been a leading innovator in the field of HIV, driving advances in treatment, prevention, testing and linkage to care, and cure research. Today, it's estimated that more than 10 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company's manufacturing partners.

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 proprietary investigational TLR7 agonist, GS-9620, and proprietary investigational broadly neutralizing antibody (bNAb), GS-9722, as part of an HIV eradication strategy. In addition, Gilead may make a strategic decision to discontinue development of GS-9620, GS-9722 and other proprietary investigational TLR7 agonists and bNAbs if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, GS-9620, GS-9722 and other proprietary investigational TLR7 agonists and bNAbs 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 Annual Report on Form 10-K for the year ended December 31, 2017, 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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