

## **Gilead Announces Data From New Preclinical Study Evaluating an Investigational TLR7 Agonist in SIV-Infected Monkeys**

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### ***– Data Support Continued Investigation of GS-9620 as Part of an HIV Eradication Strategy –***

BOSTON--(BUSINESS WIRE)--Feb. 24, 2016-- 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, GS-9620, and a related molecular analogue, GS-986, as part of an HIV eradication strategy. Data from the study conducted in simian immunodeficiency virus (SIV)-infected virally suppressed rhesus macaques on antiretroviral therapy (ART) demonstrate that TLR7 agonist treatment induced transient plasma SIV RNA blips and reduced SIV DNA. In addition, TLR7 agonist treatment resulted in subsequent prolonged virus suppression in some of the macaques after stopping ART. These data were presented in an oral session (Session O-7) at the 2016 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston.

“Our ultimate goal with TLR7 agonist therapy is to stimulate the body to drive latent HIV out of viral reservoirs in infected cells and to enhance virus-specific immune responses in HIV-infected individuals,” said James Whitney, PhD, Assistant Professor of Medicine, Harvard Medical School, and 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. “This study demonstrates the approach has promise, and that lower, longer-term TLR7 agonist dosing may be a potentially useful approach to inducing long-term HIV-remission.”

Earlier research presented at CROI 2015 showed that GS-986 treatment, in combination with ART, reduced SIV DNA levels by 30 to 90 percent in some tissues. This follow-up study was designed to assess whether GS-9620 produced results similar to GS-986, and whether lower doses of the compounds would induce transient plasma viremia and/or perturb SIV viral reservoirs. A lower dose was chosen with the intent to minimize induction of peripheral interferon-alpha (IFN-alpha), an anti-viral protein that can cause adverse events.

In this placebo-controlled study, SIV-infected rhesus macaques received ART beginning day 65 post-infection. All animals achieved and maintained viral suppression (plasma RNA less than 50 copies/mL) through week 67 when they received 10 to 19 doses of either GS-9620 or GS-986 every other week.

TLR7 agonist dosing induced transient and variable increases in plasma SIV RNA levels across all treatment groups. After completing all doses of TLR7 agonist and prior to stopping ART, peripheral lymphocytes and lymph node biopsies from the animals had less inducible virus. Two of the TLR7 agonist-treated rhesus macaques maintained undetectable plasma viral load for more than 90 days after stopping ART.

“Today’s preliminary results give us deeper insight into how we might use GS-9620 effectively as we continue to focus on the potential role of TLR7 agonists in HIV eradication strategies,” said Norbert W. Bischofberger, PhD, Gilead’s Executive Vice President, Research and Development and Chief Scientific Officer. “We have advanced research on GS-9620 to a Phase 1b safety study in HIV-infected individuals taking ART and other GS-9620 studies are also underway, including one in patients with chronic hepatitis B for its potential to reduce HBsAg.”

The proprietary TLR7 agonist compounds GS-9620 and GS-986 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 proprietary investigational TLR7 agonists, including GS-9620 and GS-986, as part of an HIV eradication strategy. In addition, Gilead may make a strategic decision to discontinue development of GS-9620 and other proprietary investigational TLR7 agonists if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, GS-9620 and other proprietary investigational TLR7 agonists 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, 2015, 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](http://www.gilead.com), follow Gilead on Twitter ([@GileadSciences](https://twitter.com/GileadSciences)) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.*

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