Gilead Announces Latest Data in Ongoing HIV Cure Research Program

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– New Studies Evaluate Agents with Potential Role in Eliminating HIV Viral Reservoir –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 23, 2019-- Gilead Sciences, Inc. (NASDAQ: GILD) today presented results from two studies of investigational toll-like receptor 7 (TLR7) agonists as part of an HIV cure research program. The Phase 1 and preclinical study results demonstrate that the TLR7 agonists vesatolimod (GS-9620) and GS-986 can induce immune activation and follow earlier preclinical research suggesting that TLR7 agonists can potentially lead to viral remission, as part of combination regimens. The HIV viral reservoir is present even in virologically suppressed individuals and its elimination is regarded as a main obstacle to achieving a cure. The data were presented at the 10th International AIDS Society Conference on HIV Science (IAS 2019) being held in Mexico City.

“While treatments have improved dramatically, people living with HIV still face a lifetime of therapy and potential complications. That reality drives our ongoing pursuit of a cure for HIV,” said Diana Brainard, MD, Senior Vice President, HIV and Emerging Viruses, Gilead Sciences. “These findings demonstrate that TLR7 agonists have a potential role to play in scalable strategies for achieving sustained viral remission in humans, and we will continue to evaluate these agents as part of investigational curative regimens.”

Studies on TLR7 agonists presented at IAS include:

Oral presentation WEAA0304: Vesatolimod (GS-9620) is safe and pharmacodynamically active in HIV-infected individuals

This double-blind, placebo-controlled Phase 1 clinical study enrolled 48 people living with HIV on antiretroviral therapy. The median age of the participants in this study was 47 years (43 were male), with a median of 8.1 years of therapy. In the study, 36 participants received escalating doses of vesatolimod (1-12 mg) and 12 received placebo every other week. Vesatolimod at higher doses stimulated a range of immune responses. Vesatolimod was well-tolerated at all doses, with no drug-related Grade 3 or 4 adverse events, no related serious adverse events and no adverse events leading to study drug discontinuation. Study drug-related adverse events including mild, transient flu-like symptoms were observed in 9 of 36 participants at doses of 2 mg and higher, consistent with previous trials. These symptoms resolved within one day and did not occur with each dose.

“This study demonstrates that vesatolimod can be administered to people living with HIV at doses that may have immune effect and are well-tolerated. The results support studies into the potential role of vesatolimod as part of combination regimens aimed at achieving ART-free control of HIV,” said Sharon A. Riddler, MD, Director of Clinical Research in the Infectious Diseases Division, University of Pittsburgh School of Medicine, one of the study principal investigators.

Oral presentation WEAA0105: Oral TLR7 agonist administration induces an immunostimulatory response in SIV-infected ART-suppressed infant rhesus macaques

This preclinical study evaluated the oral administration of GS-986 in two simian immunodeficiency virus (SIV)-infected, virologically suppressed rhesus macaques. At seven months of age, both macaques were administered 0.1 mg of GS-986 orally. Four weeks later, a second 0.3 mg dose was administered, and in both instances blood count, viral loads, cytokine concentrations and immune response were monitored. At both the 0.1 mg and 0.3 mg dose levels, GS-986 induced immune system activation with observed increases in peripheral plasma cytokines/chemokines and activation of immune cells. GS-986 was well-tolerated with normal complete blood count and maintenance of viral suppression.

These results add new information to the existing preclinical data on GS-986 for the potential future application of an oral TLR7 agonist in people living with HIV.

Vesatolimod and GS-986 are investigational compounds and are not approved by the U.S. Food and Drug Administration or any other regulatory authority. Their safety and efficacy have not been established.

There is no cure for HIV infection or AIDS.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. 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 is estimated that more than 12 million people living with HIV globally receive antiretroviral therapy provided by Gilead or one of the company’s manufacturing partners.

For more information on Gilead Sciences, please visit the company’s website at www.gilead.com.

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 ongoing and additional clinical trials involving GS-9620 and GS-986. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. 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 March 31, 2019, 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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