Gilead Expands Hepatitis C Generic Licensing Agreements to Include Investigational Pan-Genotypic Agent

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–Sofosbuvir/GS-5816 Single Tablet Regimen May Provide Important New Option for Patients in Developing Countries –

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jan. 26, 2015-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the company has expanded its hepatitis C generic licensing agreements to include the investigational NS5A inhibitor GS-5816, which is being evaluated in Phase 3 clinical studies as part of a single tablet regimen that combines the compound and sofosbuvir for the treatment of all six genotypes of hepatitis C. The expanded agreements will allow Gilead's India-based partners to manufacture GS-5816 and the single tablet regimen of sofosbuvir/GS-5816, once approved, for distribution in 91 developing countries, which together account for 54 percent of the total worldwide population of individuals infected with the hepatitis C virus (HCV).

If approved by regulatory authorities, the sofosbuvir/GS-5816 regimen would become the first pan-genotypic, all-oral single tablet regimen for HCV. A pan-genotypic therapeutic option is particularly important for developing countries, where genotype testing is often unreliable or not readily available.

"Today's announcement marks an important milestone in Gilead's effort to make effective hepatitis C treatment accessible to as many patients, in as many places, as quickly as possible," said Gregg H. Alton, Executive Vice President, Corporate and Medical Affairs, Gilead Sciences. "Developing countries are home to a diverse mix of hepatitis C genotypes, and the development of a medicine that has the potential to cure any patient, regardless of genotype, could help accelerate access to treatment."

Professor Abhijit Chowdhury, Head of Hepatology, Institute of Post Graduate Medical Education and Research, Kolkata, commented: "Pan-genotypic hepatitis C treatments have the potential to radically change the treatment landscape in developing countries, removing the need for patients to undergo burdensome laboratory tests. Even if testing facilities are available, their cost is a barrier to treatment access, so a regimen that can be used for any genotype is going to be a real attribute in tackling this disease on a global level."

The amended agreements expand on Gilead's existing generic licensing partnerships for hepatitis C, announced in September 2014, under which partners may produce sofosbuvir and the single tablet regimen of ledipasvir/sofosbuvir. Eight Indian-based generic manufacturers now hold licenses to manufacture Gilead's HCV medicines – Biocon Ltd., Cadila Healthcare Ltd., Cipla Ltd., Hetero Labs Ltd., Mylan Laboratories Ltd., Ranbaxy Laboratories Ltd., Sequent Scientific Ltd. and Strides Arcolab Ltd.

Sofosbuvir recently received regulatory approval in India (January 2015), and regulatory submissions have been completed in additional countries, including Pakistan, Thailand, Brazil, Uganda, South Africa and Nigeria.

About GS-5816

The single tablet regimen of sofosbuvir/GS-5816 is an investigational agent and its safety and efficacy have not been established. Phase 3 studies evaluating the combination of GS-5816 and sofosbuvir are currently underway, with data anticipated in the second half of 2015.

Gilead's Approach to Treatment Access in Developing Countries

Gilead makes it a priority to increase access to its medicines for people who can benefit from them, regardless of where they live or their economic means. In developing countries, Gilead's treatment access strategies include tiered pricing, voluntary generic licensing (often in advance of U.S./EU regulatory approval), negotiation with national governments, regional business partnerships, product registration, medical education and partnerships with non-profit organizations.

This approach has been successfully applied to Gilead's humanitarian program in HIV over the past 10 years, where seven million patients are now receiving Gilead-based HIV medicines in developing countries.

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, including the possibility of unfavorable clinical results on the single tablet regimen of sofosbuvir/GS-5816. Further, sofosbuvir/GS-5816 may not receive marketing approval by regulatory authorities. As a result, the generic licensing partners may not be able to produce and distribute generic versions of sofosbuvir/GS-5816. 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.

Source: Gilead Sciences, Inc.

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