

## **Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries**

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*-- Indian companies granted license to produce generic sofosbuvir and investigational single tablet regimen of ledipasvir/sofosbuvir for treatment of chronic hepatitis C --*

NEW DELHI--(BUSINESS WIRE)--Sep. 15, 2014-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced that the company has signed non-exclusive licensing agreements with seven India-based generic pharmaceutical manufacturers to expand access to its chronic hepatitis C medicines in developing countries. The agreements allow the companies – Cadila Healthcare Ltd., Cipla Ltd., Hetero Labs Ltd., Mylan Laboratories Ltd., Ranbaxy Laboratories Ltd., Sequent Scientific Ltd. and Strides Arcolab Ltd. – to manufacture sofosbuvir and the investigational single tablet regimen of ledipasvir/sofosbuvir for distribution in 91 developing countries.

The countries within the agreement account for more than 100 million people living with hepatitis C, representing 54% of the total global infected population.

“Hepatitis C is a significant public health issue worldwide, and Gilead is working to make its chronic hepatitis C medicines accessible to as many patients, in as many places, as quickly as possible. In developing countries, large-volume generic manufacturing and distribution is widely regarded as a key component in expanding access to medicines. These agreements are essential to advancing the goals of our humanitarian program in these countries,” commented Gregg H. Alton, Executive Vice President, Corporate and Medical Affairs, Gilead Sciences.

Under the licensing agreements, the Indian companies receive a complete technology transfer of the Gilead manufacturing process to enable them to scale up production as quickly as possible. The licensees also set their own prices for the generic product they produce, paying a royalty on sales to Gilead to support product registrations, medical education and training, safety monitoring and other essential business activities. The licenses also permit the manufacture of sofosbuvir or ledipasvir in combination with other chronic hepatitis C medicines.

Sofosbuvir was approved under the trade name Sovaldi<sup>®</sup> by the U.S. Food and Drug Administration (FDA) in December 2013 and by the European Commission in January 2014. The FDA and the European Medicines Agency are currently reviewing the company’s applications for a single tablet regimen of ledipasvir/sofosbuvir; it is an investigational agent and its safety and efficacy have not been established.

For a fact sheet on the agreement, visit [www.gilead.com](http://www.gilead.com).

### **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 ten years, with six million patients 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 worldwide. Headquartered in Foster City, California, Gilead has operations in North and South America, Europe and Asia Pacific.

## 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 that licensees will not be able to produce and distribute generic versions of Gilead medicines, that licensing terms will be modified or that ledipasvir/sofosbuvir does not receive regulatory approval. 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 June 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.

*U.S. full prescribing information for Sovaldi is available at [www.gilead.com](http://www.gilead.com).*

*Sovaldi is a registered trademark of Gilead Sciences, Inc.*

*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) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.*

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