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ZYDUS AND GILEAD ENTER INTO A GENERIC LICENSING AGREEMENT TO MANUFACTURE BREAKTHROUGH TREATMENT FOR HEPATITIS C

Zydus granted license to produce generic sofosbuvir and a single tablet regimen of ledipasvir/sofosbuvir for treatment of chronic hepatitis C

Ahmedabad, India, September 15, 2014

Zydus and Gilead Sciences, Inc. today announced that they signed a non-exclusive licensing agreement which will allow the generic manufacture of sofosbuvir and the investigational single tablet regimen of ledipasvir/sofosbuvir for distribution in 90 developing countries, including India.

There are nearly 10 million patients suffering from hepatitis C in India. The problem is further compounded by the fact that patients remain undiagnosed till the late stage and can ill afford the treatment.

Speaking on the development, Chairman and Managing Director of the Zydus group, Mr. Pankaj R. Patel said. "By joining hands and providing access to affordable therapy, we are taking a far reaching step towards fighting the scourge of hepatitis C. This is a laudable initiative on the part of Gilead to make this breakthrough therapy accessible. It is through such joint initiatives and combined efforts that we serve the cause of healthcare. Bridging healthcare gaps and serving critical patient needs with access to new therapies have always been our mission and we stand committed to this."

Zydus Heptiza, the specialty division of the Zydus group which will be marketing the therapy has been solely focused on improving treatment access in Chronic Viral Hepatitis. Over the last four years since launch, Heptiza is the only division present with an entire range of antivirals approved for hepatitis B & C management in India. It has been reaching out to high risk population with free screening for hepatitis B & C patients and has made available hepatitis B vaccination to patients, free of cost.

Under the licensing agreement, Zydus will receive a complete technology transfer of the Gilead manufacturing process to enabling production to be scaled up as quickly as possible. Zydus will set its own prices for the generic product, paying a royalty on sales to Gilead to support product registrations, medical education and training, safety monitoring and other business essential 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® 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.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs over 16,000 people worldwide and is dedicated to creating healthier communities globally. Zydus Cadila is the only Indian pharma company to launch its own patented NCE – Lipaglyn™, the world's first drug to be approved for the treatment of diabetic dyslipidemia. It aims to be a leading global healthcare provider with a robust product pipeline, achieve sales of over Rs. 10000 crore by 2015 and be a research-based pharmaceutical company by 2020.

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