



Press Release

Hetero receives the first approval from Drug Controller General of India (DCGI) for the fixed-dose combination therapy 'Ledipasvir-Sofosbuvir'

~The product will be available under the brand name 'Ledifos' in India~

India, Hyderabad, December 8th, 2015: Hetero, one of India's leading generic pharmaceutical companies and one of the world's largest producer of anti-retroviral drugs, today announced that it is the first company in India to receive the approval for the fixed-dose combination Ledipasvir-Sofosbuvir (90mg/400mg) from Drug Controller General of India (DCGI). Following the non-exclusive licensing agreement signed with Gilead Sciences in September last year, to manufacture and market chronic hepatitis C medicines, Hetero is all set to launch the fixed-dose combination therapy 'Ledipasvir-Sofosbuvir' for the Indian patients. The product will be available under the brand name 'Ledifos' in India.

This fixed-dose combination is the generic version of Gilead's brand Harvoni, approved by US FDA for the treatment of chronic hepatitis genotype 1 in both treatment –naïve and treatment-experienced patients. Sofosbuvir in combination with Ledipasvir has shown to have high cure rates of around 90%.¹

Hepatitis C is a growing public health concern, particularly in developing countries. In India alone, it is estimated that 12-18 million patients are infected with Hepatitis C which is several fold greater than those with HIV/AIDS. Untreated chronic hepatitis C increases the risk of cirrhosis of liver, liver failure and hepatocellular carcinoma.

Dr BPS Reddy, CMD, Hetero group of companies commented: "We have been the front-runners in launching the generic Sofosbuvir in several countries. We are now happy to extend the fixed-dose combination therapy 'Ledipasvir-Sofosbuvir (Ledifos) to Indian patients, which is much more effective than Sofosbuvir. With the launch of Ledisof, we look forward in bringing a paradigm shift in Hepatitis C management in the country."

About Hetero

Hetero is one of India's leading generic pharmaceutical companies and is one of the world's largest producer of anti-retroviral drugs for the treatment of HIV/AIDS. With more than 20 years of expertise in the pharmaceutical industry, Hetero's strategic business areas include APIs, generics and biosimilars. Hetero also offers custom pharmaceutical services to its partners around the world. The company is recognized for its strengths in Research & Development, manufacturing and commercialization of a wide range of products.

Hetero has more than 25 state-of-the-art manufacturing facilities strategically located worldwide. Majority of our facilities have been successfully audited and approved by various regulatory authorities like US-FDA, EU, TGA – Australia, MCC – South Africa and others. Our portfolio includes more than 200 products, encompassing major therapeutic categories such as HIV/AIDS, Oncology, Cardiovascular, Neurology, Hepatitis, etc.

Hetero has a strong global presence in over 120 countries and focusses on making affordable medicines accessible to patients worldwide. For more information on Hetero, please visit www.heteroworld.com

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