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Gilead expands Hepatitis C drug licensing pacts with Indian firms

New Delhi, Jan 26: US-based drug firm Gilead Sciences has expanded its Hepatitis C generic licensing agreements with India-based firms to include investigational pan-genotypic medicine GS-5816 as part of a single tablet regimen that combines it and sofosbuvir.

The investigational NS5A inhibitor GS-5816 is being evaluated in Phase III 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, Gilead Sciences Inc said in a statement.

"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...," it added.

These countries together account for 54% of the total worldwide population of individuals infected with the hepatitis C virus, it added.

Commenting on the development, Gilead Sciences Corporate and Medical Affairs Executive Vice President Gregg H Alton said: "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."

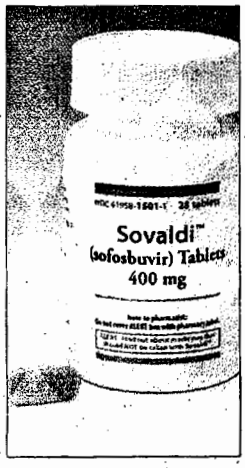
Developing countries are home to a diverse mix of hepatitis C genotypes, and the development of a medicine that has the potential to cure any patient, regardless of genotype, could help accelerate access to treatment, he added.

Currently, Gilead Sciences Inc has licensing agreements for hepatitis C drugs with eight India-based firms, Cipla, Ranbaxy, Cadila, Mylan Laboratories, Sequent Scientific, Strides Arcolab, Biocon and Hetero Labs to manufacture generic versions of sofosbuvir and investigational single tablet regimen of ledipasvir/sofosbuvir for distribution.

Sofosbuvir had recently received regulatory approval in India in January and regulatory submissions have been completed in additional countries, including Pakistan, Thailand, Brazil, Uganda, South Africa and Nigeria, Gilead Sciences said.

Gilead Sciences said Sofosbuvir has been approved under the trade name Sovaldi by the US Food and Drug Administration (USFDA) in December 2013 and by the European Commission in January 2014.

Phase III studies evaluating combination of GS-5816 and sofosbuvir are currently underway and data is anticipated in second half of 2015, Gilead Sciences said. *PTI*



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