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Gilead expands Hepatitis C alliance with Indian partners

Likely to bring in sofosbuvir by mid-2015

PT JYOTHI DATTA
Mumbai, January 27

American drug-maker Gilead Sciences Inc has included investigational drug GS-5816 into an existing licensing agreement with Indian partners.

The investigational drug is a single tablet regimen that combines the compound (GS-5816) and Hepatitis C drug sofosbuvir for the treatment of all six genotypes of hepatitis C, Gilead said. It is at present being evaluated in late-stage or Phase III clinical trials.

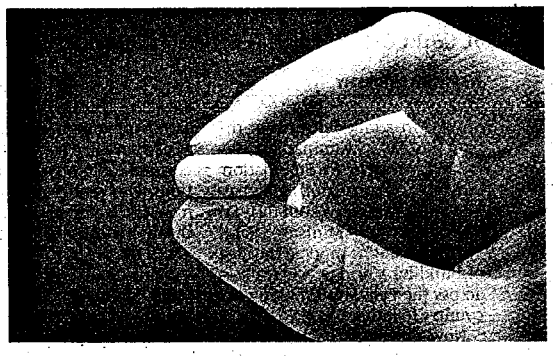
Last September, Gilead had inked agreements with eight Indian companies allowing them to make less expensive versions of sofosbuvir for certain markets. (See infobox).

Gilead expects to bring its sofosbuvir into India by "mid-2015", a spokesperson told *Business Line*. On the latest expanded agreement, the company said its India-based partners would be able to manufacture GS-5816 and the single tablet regimen of sofosbuvir/GS- 5816, once approved, for distribution in 91 developing countries. These countries account for 54 percent of the total worldwide population of individuals infected with the hepatitis C virus (HCV), it said.

The California-headquartered company's announcement came even as US President Barack Obama was in India participating in Republic Day ceremonies and interacting with Indian and American business leaders.

January developments

In fact, January has been significant for Gilead as it received regulatory approval to market sofosbuvir in India. Regulatory submissions have been completed in additional countries, including Pakistan, Thailand, Brazil, Uganda, South Africa and Nigeria, Gilead added.



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Local regulatory approvals, however, came even as the Indian Patent Office rejected a Gilead patent application that covered sofosbuvir. The company has since appealed the Patent Office decision, even as it maintained that the main patent application was still pending on the drug. Gilead's patent applications in India have been opposed by a clutch of pro-health groups and some industry representatives as well. The drug-maker has attracted criticism in some global quarters over the pricing of sofosbuvir, one of the first of several oral Hepatitis C drugs. It costs $84,000 for 12 weeks in the US and is expected to be pegged at less than $1,000 for the same period in India.

One pill

Outlining benefits of the investigational drug, Gilead said, the sofosbuvir/GS-5816 regimen would become the first pan-genotypic, all-oral single tablet regimen for HCV. And such an option is important for developing countries, where genotype testing is often unreliable or not readily available, the company said.

"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," Gregg H Alton, Gilead's Executive Vice-President, Corporate and Medical Affairs, said in a statement. The single tablet regimen of sofosbuvir/GS-5816 is an investigational agent and its safety and efficacy have not been established, the company said. Late stage Phase III studies are currently under way, with data anticipated in the second half of 2015, it added.

India focus

- Gilead's generic licensing agreement allows partners to produce less expensive versions of sofosbuvir and the single tablet regimen of ledipasvir/sofosbuvir
- Its India-based generic partners are Biocon, Cadila Healthcare, Cipla, Hetero Labs, Mylan Laboratories, Ranbaxy Laboratories, Sequent Scientific and Strides Arcolab

International Cooperation.