PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Hindu, Delhi
Wednesday 21st January 2015, Page: 15
Width: 16.80 cms, Height: 16.23 cms, a4, Ref: pmin.2015-01-21.60.127

Gilead licenses Strides to make, distribute AIDS drug in 112 countries

Strides will be able to launch its product by mid-2016

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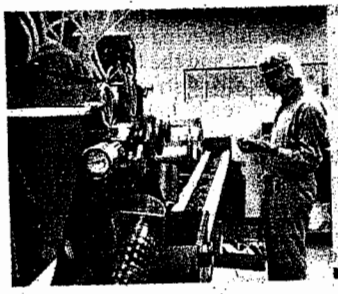
MUMBAI: U.S. pharmaceutical major Gilead Sciences has signed a licensing agreement with Bengaluru-based Strides Arcolab, under which Gilead has extended non-exclusive rights to Strides to make and distribute Tenofovir Alafenamide (TAF), both as a single agent product and in combination with other drugs.

This is seen as a goodwill creation exercise by sections of the Indian pharmaceutical industry as multinationals have been increasingly viewed with scepticism in developing markets.

TAF is a novel nucleotide reverse transcriptase inhibitor used in human immunodeficiency virus (HIV) patients in the treatment of acquired immunodeficiency syndrome (AIDS). TAF is awaiting U.S. Food and Drug Administration (FDA) approval, and is expected to go to market by year-end.

A statement from Strides said the licence extends to 112 countries, which together account for more than 30 million people living with HIV. Strides will receive a technology transfer from Gilead, enabling it to make low-cost versions of TAF for developing countries.



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Strides will be able to launch its product by mid-2016. TAF has demonstrated high antiviral efficacy at a dose 10 times lower than Gilead's Viread (tenofovir disoproxil fumarate), as well as an improved renal and bone safety profile, the statement said.

Different model for developing markets

Gilead pursuing different model for developing markets

Today's announcement follows last week's rejection of Gilead's patent application for its blockbuster drug sofosbuvir by the Indian patent office. Sofosbuvir is considered a breakthrough drug in the treatment of Hepatitis C and Gilead's application covered the metabolites of sofosbuvir. The main patent application for the product is still pending and Gilead is to appeal against the decision.

In September, 2014, Gilead signed agreements with seven Indian generic drug manufacturers licensing them to make sofosbuvir to supply it to 90 countries. Sofosbuvir is priced at $84,000 per patient in the U.S., and the effective price for generic version is around $900 and a 10 per cent royalty.

"Gilead's chosen voluntary licensing model is refreshing, and will certainly earn it goodwill. It ensures protection of intellectual property (IP) and simultaneously ensures access to medicines," D. G. Shah, Secretary-General, Indian Pharmaceutical Alliance (IPA), told *The Hindu*. "Today, its TAF licensing announcement is just an extension of its existing model for developing markets."

Other multinational pharmaceutical giants such as GSK opt for a price differentiated model for developing markets mainly for their older products, which Merck uses the discounted model, pricing its drugs at 75 per cent of U.S. prices.

"Pharmaceutical multinational prefer Indian manufacturers over other generic manufacturing destinations like South Africa and Brazil because India is already supplying generics to 200 countries and has proven capability, cost-effectiveness and quality," Mr. Shah said.

International cooperation.