

FDA OKs first generic for Gleevec leukemia pill

4 December 2015, by Linda A. Johnson

U.S. regulators have approved the first generic version of one of the first very effective—and expensive—cancer drugs, Gleevec, which costs about \$10,000 a month.

The Food and Drug Administration granted a subsidiary of Indian drugmaker Sun Pharmaceutical Industries Ltd. approval to sell generic Gleevec, known as imatinib mesylate, in 100-milligram and 400-milligram pills for chronic myeloid leukemia.

Mumbai-based Sun Pharmaceutical, a top maker of [generic medicines](#), said Friday that it will begin selling the once-a-day pill in the U.S. on Feb. 1, 2016.

Gleevec, developed and sold by Swiss drugmaker Novartis AG, was approved in 2003. It was quickly hailed as a near-cure, transforming [chronic myeloid leukemia](#) from an almost universally fatal disease to one manageable with long-term medication. It's also approved to treat [acute lymphoblastic leukemia](#) and several other cancer types, in adults and children.

Gleevec, known as Glivec in some other countries, is the top-selling drug for Novartis, with 2014 global sales of \$4.75 billion, about \$2.5 billion of that from U.S. sales.

It currently has a U.S. list price of about \$10,000 per month for the more-common 400-milligram daily dosage.

Novartis, the world's biggest drug maker by revenue and a leader in cancer medicines, is aiming to limit the number of U.S. patients who immediately defect to generic Gleevec.

Employing a common strategy of brand-name drugmakers whose blockbusters are going off patent, Novartis is offering patients with private insurance discount cards that set their monthly

copayment at \$10, with Novartis covering up to \$30,000 a year of the pharmacy bill. Insurers would be on the hook for the remainder. The program isn't available to patients paying cash or insured under government health programs.

Sun has exclusive rights to sell generic Gleevec for six months. After that, if FDA approves other drugmakers' generic versions, their prices should start dropping sharply.

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