

Pfizer's blockbuster drug Lipitor goes generic

30 November 2011, by Veronique Dupont

Pfizer's patent on the best-selling drug of all-time, the cholesterol-lowering medication Lipitor, expired on Wednesday, opening the path to generic competitors for America's most popular medication.

Lipitor came on the market in 1997, and has raked in some \$100 billion for Pfizer even in a crowded market that includes various other cholesterol-lowering statins, many of which have already gone generic.

In the United States, anti-cholesterol drugs account for 255 million prescriptions a year, and about nine million people are taking Lipitor.

India's pharmaceutical giant Ranbaxy won US approval to make the first generic version of Lipitor, known as atorvastatin, from its New Jersey lab, after the company had faced delays from US authorities due to problems with quality control at some of its Indian factories.

US-based Watson Pharmaceuticals also announced a deal to distribute a generic version made by Pfizer, whereby Pfizer manufactures the drug and Watson sells it, sharing net sales with Pfizer until 2016.

"There should be a price war in that first six months," as more companies elbow for market share of the cheaper generic version of Lipitor, said Morningstar analyst Damien Conover.

Meanwhile, Pfizer is left hunting for new sources of revenue to replace the cash flow from its longtime star, which made up 15 percent of annual sales.

Pfizer has not released its projected losses due to the patent expiration, but its company forecasts call for sales in 2012 of \$63-63.5 billion, versus \$67.8 billion in 2010.

Lipitor global sales were over \$10 billion last year,

according to earnings reports. Conover estimated a sales figure of \$3.8 billion in 2012.

Pfizer already lost exclusive rights on the product in Canada, Spain, Mexico and Brazil last year, but it continues to earn revenue in developing countries.

In the United States, Pfizer is aiming to defend its territory and undercut its competitors in the generic market.

By forming alliances with pharmacies and health insurance companies, Pfizer will continue to offer Lipitor "at or below generic cost" during the next 180 days, company spokesman MacKay Jameson told AFP in an email.

"In this 180-day period, typically payers do not receive a significant cost-savings by utilizing a generic," he added.

Lipitor currently costs about \$120 per month, a price that should drop 30 percent in December, slightly more than the typical 10-20 percent that a drug price typically falls after a patent expires.

Pfizer has made a deal with Diplomat Specialty Pharmacy in the northern state of Michigan to create the program "Lipitor For You," so customers can sign up online to continue to get the drug in their pharmacy or home-delivered.

It is too early to know if this approach will continue beyond six months. Pfizer could decide to continue to compete with other generic makers but it would have to lower prices even more, which may not prove profitable.

Pfizer is counting on licensing deals that will continue to generate revenue from Lipitor, such as one signed with the French pharmaceutical giant Sanofi-Aventis which will make and market its generic version in France starting in May 2012.

"I don't think they'll be able, in the short term, to compensate, but they have a lot of products in pipeline," said Conover, referring to Pfizer.

Among them are an anti-clotting drug known as Eliquis, and another against rheumatoid arthritis known as tofacitinib, which together could make up a billion dollars in annual sales.

Ratings agency Standard and Poor's said it views the New York-based drug giant as well-placed to survive the expiration of the patent on Lipitor.

"Over the next two years, the company will be able to weather the upcoming storm of patent expirations and associated revenue loss while maintaining its excellent business risk profile and a solidly minimal financial risk profile."

A two-year study released earlier this month showed that maximum doses of Lipitor and its competitor Crestor, made by AstraZeneca, were similarly effective and safe in cutting down plaque in the arteries. Side effects may include liver and muscle problems.

With Lipitor now generic, Crestor will be left as the sole major brand-name statin on the market.

"The market for Crestor will go close to zero," said Cam Patterson, chief of cardiology at the University of North Carolina-Chapel Hill.

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