FDA clears Eli Lilly's blood thinner Effient

July 10 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- The Food and Drug Administration on Friday approved a highly anticipated blood thinner from Eli Lilly, though the drug must carry the agency's sternest warning because of its bleeding risks.

The approval makes Lilly's Effient the first real competition to the blood thinner Plavix, the world's second-best selling medication made by Sanofi-Aventis and Bristol-Myers Squibb.

The FDA delayed its decision on Effient multiple times during an 18-month review, as agency staffers weighed the drug's benefits versus its risks.

A study of over 13,000 patients conducted by Lilly found that Effient prevents more heart attacks than Plavix, but also causes more internal bleeding.

The FDA said Effient will carry a boxed warning to alert physicians to the risks of "significant, sometimes fatal, bleeding." The boxed warning is reserved for issues that can cause serious injury or death.

The drug should not be taken by patients with a history of bleeding, stroke or who are undergoing surgery, the FDA said.

"Physicians must carefully weigh the potential benefits and risks of Effient as they decide which patients should receive the drug," said Dr. John Jenkins, FDA's director of new drugs.

The drug offers an alternative treatment for preventing dangerous blood clots that can lead to heart attack or stroke, Jenkins said.

The boxed safety warning could curb sales, but not to a large extent, according to Miller Tabak & Co. analyst Les Funtleyder.

"The FDA has been a lot more liberal with black box warnings than it was in the past, and in a way the black box has lost some of the meaning it had when it was rare," said Funtleyder. "But it still has the ability to somewhat limit sales."

Company studies showed 7 percent of patients taking Effient experienced nonfatal heart attacks, compared with 9.1 percent of patients taking Plavix. Despite lower rates of certain heart attacks, the actual rates of death were similar for both drugs.

Indianapolis-based Lilly developed Effient, known chemically as prasugrel, with Japanese drugmaker Daiichi Sankyo Co. The two companies will share revenue.

"After more than a decade of research and testing, we are proud to provide this new treatment option to patients with acute coronary syndrome," Daiichi President Takashi Shoda said in a statement.

Wall Street analysts say Effient sales could reach an estimated $1 billion annually, compared with the $4.9 billion racked up by Plavix last year.

Like Plavix, Effient prevents blood platelets from sticking together and forming potentially dangerous clots. But where Plavix is approved for use in a wide range of patients, Effient is only approved for those undergoing angioplasty, a procedure in which an inflatable balloon is used to clear arteries clogged with plaque, which are often propped open with a stent.

Approval of Effient was considered crucial for Lilly because patents protecting its four best-selling drugs expire by 2013.

But even if the drug reaches the $1 billion mark, it will have trouble replacing the revenue of Lilly's best-selling product, the anti-psychotic Zyprexa, which garnered $4.7 billion in sales last year.