Bristol-Myers, Pfizer's Eliquis approved in Japan

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Regulators in Japan have approved sales of an anticlotting drug called Eliquis, developed by Bristol-Myers Squibb Co. and Pfizer Inc., that's a potential blockbuster in a new category of medicines to prevent strokes and heart attacks. But that's only if it can win U.S. approval, as two rival drugs have done.

Pfizer and Bristol-Myers said Wednesday that Japan approved use of Eliquis for treating the most common type of irregular heartbeat, atrial fibrillation, in patients at risk for strokes or dangerous clots called systemic embolisms. Already approved for sale in Canada and the European Union, Eliquis has twice been rejected by the U.S. Food and Drug Administration.

About a quarter of all people aged 40 and older develop atrial fibrillation, a condition in which the heart's two upper chambers contract irregularly and don't pump blood efficiently. This can persist for years or only happen occasionally. It increases the risk of a stroke fivefold, and strokes caused by atrial fibrillation are more severe than other strokes, with half of patients who suffer them dying within a year if not treated.

For decades, atrial fibrillation patients were treated with the blood thinner warfarin, sold under brands including Coumadin. While warfarin is very cheap, users must get frequent blood tests to ensure they're getting enough to prevent strokes but not too high a dose, which can cause dangerous internal bleeding.

In the last two years, drug regulators in the U.S. and other countries have approved two new anticlotting drugs for patients with atrial fibrillation and other conditions: Pradaxa, from German drugmaker Boehringer Ingelheim, and Xarelto, from partners Johnson & Johnson and Bayer Healthcare.

Some analysts have said Eliquis, known chemically as apixaban, is the best of the three new drugs, but Pradaxa and Xarelto got a big head start in building U.S. market share. That means that if Eliquis is approved by the FDA, Pfizer and Bristol-Myers will have a tough job persuading doctors and patients who already have switched from warfarin to Pradaxa or Xarelto to again switch medication.

The FDA originally was to decide whether to approve Eliquis last March, but said it needed more time to review new data. In June, the FDA said it couldn't approve the drug until the companies provided more information on "data management and verification" from a huge international study called ARISTOTLE. That was submitted in September. The FDA is scheduled to rule by March 17.

Approval in Japan, the world's second-biggest market for prescription drugs after the U.S., will boost sales of Eliquis, but U.S. sales are needed to reach blockbuster status—annual sales of more than $1 billion.

The makers of all three drugs must persuade doctors and consumers that their pill is the most effective and safest, and that it's worth the extra cost. Xarelto and Pradaxa both cost roughly $250 per month. Pfizer and Bristol-Myers have not disclosed a price for Eliquis. Warfarin typically costs less than $10 per month, plus at least $1,600 a year for frequent tests of its level in the blood.

Johnson & Johnson has not has not yet reported sales figures for Xarelto. However, partner Bayer reported Xarelto sales totaling about $235

million in the first nine months of this year. Boehringer Ingelheim reported Pradaxa sales of about $615 million worldwide in the first half of 2012.

In afternoon trading, shares of Bristol-Myers were down 12 cents at $32.34, and Pfizer shares were up 11 cents at $25.19.