

Anti-clot drug recommended for new approval in EU

September 21 2012, by Linda A. Johnson

(AP)—Advisers to European Union regulators have recommended approval of a new anti-clotting drug for use by adults with a common irregular heart rhythm that boosts risk of strokes or blood clots, drugmakers Bristol-Myers Squibb Co. and Pfizer Inc. said.

The drug, Eliquis, is a crucial one for the two companies, which have been slammed by new generic competition slashing sales of their top-selling drugs. Meanwhile, the partners are trailing competitors in a three-way race for global market share in a new class of anti-clotting drugs expected to be blockbusters, with sales well over \$1 billion a year.

Pfizer and Bristol-Myers, both based in New York, said Friday advisers to the European Medicines Agency have issued a positive opinion on Eliquis for use in patients with the irregular rhythm called atrial fibrillation if it's not caused by a heart valve problem. If the European Medicines Agency approves it, that would allow sales in all 27 European Union member states, as well as Iceland and Norway.

The drug got its first approval in May 2011, also in the EU, for treating a much smaller group of patients, adults who have had hip or knee replacement surgery.

However, the U.S. Food and Drug Administration has rejected the drug twice, most recently in June. The agency said it needed more information on "data management and verification" from a huge international study called ARISTOTLE, but the FDA did not require

new studies. That would have delayed any potential approval for a couple of years.

Known chemically as apixaban, Eliquis is one of three new medicines heavily touted for preventing blood clots and the strokes and heart attacks they can trigger.

Boehringer Ingelheim's Pradaxa was approved for U.S. sales in late 2010. Xarelto, sold by Johnson & Johnson and Bayer Healthcare, was approved in November 2011.

The companies say this new generation of blood thinners works better than the long-time standard, warfarin.

Millions of patients and their doctors have long wanted a better alternative to warfarin, an inexpensive generic drug also sold under brand names such as Coumadin. Getting the dose of warfarin correct is so tricky that patients need frequent blood tests to ensure they're getting enough to prevent clots but not enough to cause internal bleeding. Some foods interact with warfarin, adding to the difficulty.

The newer drugs also carry risks of serious internal bleeding. They cost nearly twice the price for warfarin, including the cost of the blood tests that drug requires.

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