Experimental Drug Could Reduce Risks For Stroke, Blood Clots

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Developers of an experimental drug that's part of a new generation of anti-clotting medicines stated that in a key patient study, Apixaban significantly cut the risks of stroke, major bleeding and death. Drugmakers Pfizer Inc. and Bristol-Myers Squibb Co. said the 18,201-patient, late-stage study of Apixaban found that compared with the popular blood thinner Warfarin, Apixaban reduced risk of stroke and dangerous blood clots by 21 percent, reduced major internal bleeding by 31 percent and risk of death by 11 percent.

The companies jointly tested and developed the drug. They plan later this year to apply for U.S. approval to sell it. The highly anticipated study, known by the acronym ARISTOTLE, will be a key part of the research data supporting that application. If it's approved, Apixaban would be sold under the brand name Eloquis.

Roughly five million Americans and six million European Union residents have atrial fibrillation. It can strike one in four people at some point after age 40, raising their risk of stroke to five times that of people without the condition, according to the companies.

Because of its prevalence, and the need for repeated blood tests to ensure patients on warfarin are getting a dose that won't inadverently trigger internal bleeding, a better blood thinner has long been an important goal. Among the new blood thinners in testing or recently on the market are two others that work like Eloquis. Warfarin, a mainstay treatment for more than 50 years, works by preventing platelets from clumping together in the blood.

European regulators approved Eliquis in May for preventing blood clots in patients having hip or knee replacement surgery, a smaller pool of patients than those with atrial fibrillation. A second drug, Xarelto, was approved in the U.S. two months ago, also just for knee and hip replacement patients. Known chemically as rivaroxaban, it was developed by German drugmaker Bayer Healthcare, which already markets it in 110 countries. Johnson & Johnson will market Xarelto in the U.S.

The drug that won the race for the first U.S. approval for general use in atrial fibrillation patients was Pradaxa, from German drugmaker Boehringer Ingelheim, which the Food and Drug Administration approved last October. Pradaxa also is approved in Japan and Canada. On Friday, Boehringer said in a statement that Pradaxa, known chemically as Dabigatran, already has been prescribed to more than 350,000 patients in the U.S., Japan and Canada.