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J&J wins US approval for new blood thinner

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(AP) -- Johnson & Johnson said Friday that U.S. regulators have approved its new type of blood thinner shown to reduce deadly blood clots in patients who have undergone knee and hip replacements.

The Food and Drug Administration decision makes rivaroxaban the first U.S.-approved drug that works by blocking a clotting protein called factor Xa. That's in contrast to older blood thinners that work by preventing platelets from sticking together.

The once-a-day pill will serve as an alternative to the popular injection Lovenox, which is the standard treatment for patients who have undergone orthopedic surgery. Rivaroxaban had greater efficacy than Lovenox in head-to-head trials, and similar rates of side effects such as major internal bleeding. J&J said its new drug would be priced similarly to Lovenox, which is marketed by French drugmaker Sanofi-Aventis SA.

More than 800,000 knee and hip replacement surgeries are performed in the U.S. each year, causing inflammation in the leg tissue and preventing patients from walking for extended periods of time.

"The combination of tissue damage and immobility can lead to large blood clots in the legs, which can break off and travel to the lungs," said Dr. Paul Chang, vice president of J&J's Janssen Pharmaceuticals unit.

J&J first filed its application for rivaroxaban in July 2008, but in May 2009 the FDA delayed making a decision on the drug after raising

concerns about internal bleeding risk. The drug's label will carry a warning about that side effect as well as itching, muscle pain, blisters and fainting.

Rivaroxaban was discovered by German drugmaker Bayer Healthcare, which already markets the drug in 110 countries around the world. New Brunswick, N.J.-based J&J will market the drug in the U.S. under the brand name Xarelto.

While Friday's decision is an important step for J&J, the larger market opportunity for the drug is in treating patients with irregular heartbeats caused by a condition called atrial fibrillation. The FDA is due to rule on that use in November.

For more than half a century, atrial fibrillation patients have relied on the tough-to-use blood thinner warfarin, sold as Coumadin and other brands. Doctors have trouble gauging the right dose of the drug for each patient, and too much of the medicine can lead to dangerous bleeding. Patients must get frequent blood tests to make sure they're getting the proper dose, and even eating foods like leafy green vegetables can throw readings off.

In October, the FDA approved the first alternative to warfarin for atrial fibrillation - Pradaxa, made by the German firm Boehringer Ingelheim. But it costs about $7 a day wholesale compared with less than 50 cents for warfarin.