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FDA Questions Safety of Xarelto

Xarelto, a drug used to prevent strokes in patients with a common irregular heart rhythm, has had its efficacy and safety called into question by Food and Drug Administration staff.

A report by the advisory panel has recommended against approving Xarelto for preventing strokes in patients, saying a new study is needed, Reuters reports.

Johnson & Johnson, which developed the anti-clotting drug with Germany-based Bayer Healthcare, countered that it has lots of evidence Xarelto is effective.

It remains to be seen if the committee also requests additional information, but a Bayer spokesman said the company is still "positive" about receiving approval, the WSJ reports.

The staff review recommended that the agency issue a "complete response" for Xarelto, which is also known by its generic name, rivaroxaban.

Typically, complete response letters ask companies to submit additional information before products can be approved, the WSJ reports.

However, the staff review also suggested "it might not be unreasonable to approve rivaroxaban as a second- or third-line treatment."

Xarelto is currently approved in the U.S. as a short-term treatment to prevent certain blood clots, known as venous thromboembolism, or VTE, in people undergoing knee- and hip-replacement surgery.

A panel of outside FDA advisers is to review the data and a presentation by J&J on Thursday before recommending whether the agency should approve Xarelto, the WSJ reports.

The negative review sent Bayer shares sharply lower, with the shares closing down 7.5 percent on Tuesday, recovering from deeper losses earlier in the session.

Shares of Johnson & Johnson moved up 0.4 percent in afternoon trading, reports the WSJ.

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