

Janssen seeks FDA approval for Xarelto

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Singapore: Janssen submitted complete response to the US FDA for the use of XARELTO (rivaroxaban) to reduce the risk of secondary cardiovascular events in patients with acute coronary syndrome (ACS). The response includes specific information requested by the FDA in their letter issued to Janssen on June 21, 2012.

Janssen has also resubmitted the supplemental new drug application (sNDA) for XARELTO to reduce the risk of stent thrombosis in patients with ACS, which the company withdrew on July 9, 2012 based on its connection to the above mentioned sNDA for XARELTO. Data from the ATLAS ACS 2 TIMI 51 trial support both sNDAs.

"We are confident about the results of the ATLAS ACS 2 TIMI 51 trial and have relied on the data from that study to develop our comprehensive responses to questions raised by the FDA in their review of our application," said Dr Paul Burton, VP, Janssen R&D. "We look forward to working with the agency to make XARELTO available to patients who experience a heart attack and need treatment to reduce the risk of another heart attack, a blocked coronary stent or death."

XARELTO is approved for three clinical uses in the US. It is used to reduce the risk of blood clots in the legs and lungs of people who have just had knee replacement surgery. It is used to reduce this risk in people who have just had hip replacement surgery and it is used to reduce the risk of both hemorrhagic and thrombotic strokes as well as other blood clots in people with atrial fibrillation not caused by a heart valve problem.