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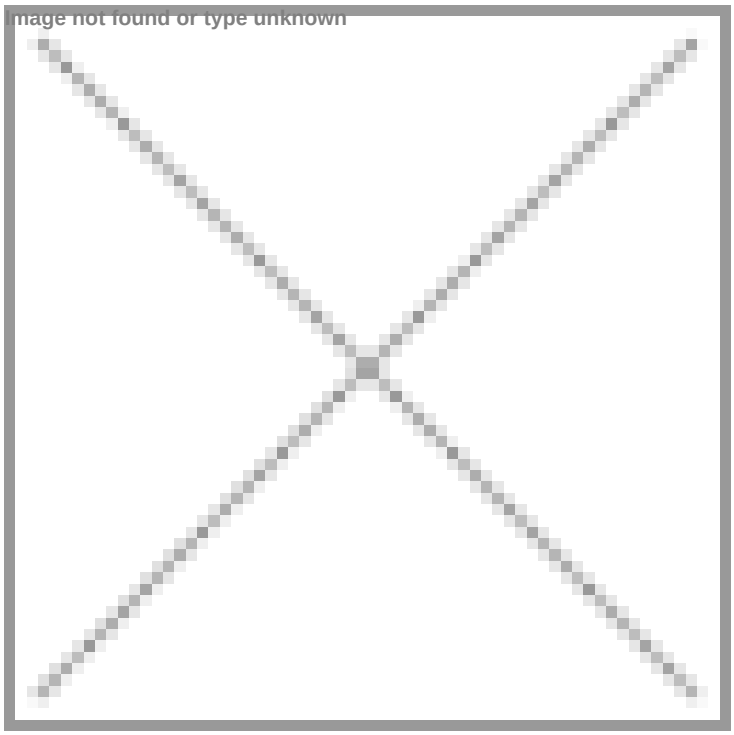

Singapore: US Food and Drug Administration (FDA) have issued a complete response letter regarding a supplemental New Drug Application (sNDA) for XARELTO (rivaroxaban) for the reduction of the risk of secondary cardiovascular events in patients with acute coronary syndrome (ACS) to Janssen Research & Development. Janssen is evaluating the complete response letter and will respond to the agency's questions.

"We are confident in the robust study results of the ATLAS ACS 2 TIMI 51 trial and the positive benefit-risk profile of rivaroxaban in patients with ACS. We will continue to work with the FDA to fully address their questions as quickly as possible," said Dr Paul Burton, vice president, Cardiovascular Franchise Medical Leader at Janssen R&D.

XARELTO is approved for three clinical uses in the US: to reduce the risk of blood clots in the legs and lungs of people who have just had knee replacement surgery, to reduce this risk in people who have just had hip replacement surgery, and 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.