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Indoco Remedies receives US FDA final approval for rivaroxaban tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg

Our Bureau, Mumbai

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Indoco Remedies Ltd., a fully integrated, research-oriented pharmaceutical company, announced final approval of the company's Abbreviated New Drug Application (ANDA) for rivaroxaban tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg, to market a generic equivalent to the reference listed drug (RLD), Xarelto tablets, 2.5 mg, 10 mg, 15 mg and 20 mg, of Janssen Pharmaceuticals, Inc. (Janssen), from US FDA.

Rivaroxaban tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg are bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xarelto tablets, 2.5 mg, 10 mg, 15 mg and 20 mg, of Janssen Pharmaceuticals, Inc. (Janssen).

Rivaroxaban tablets USP, will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India.

Rivaroxaban is used for the treatment of venous thromboembolism (VTE).

Commenting on the achievement, Aditi Panandikar, managing director said, "Besides reflecting the capability of Indoco Remedies to deliver products of high-quality standards, this development also provides impetus to our growth aspirations in an important market such as the US."

Indoco is a fully integrated, research-oriented pharmaceutical company with a strong global presence. The company's turnover is US$ 180 million with a human capital of over 6,000 employees, including over 400 skilled scientists and field staff who are the strength of the organization.