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ASIA EDITION

Daiichi's thrombosis drug meets primary endpoint

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Singapore: Global phase III clinical trial of once-daily edoxaban for the treatment of acute symptomatic deep vein thrombosis (DVT) and pulmonary embolism (PE) by Japanese firm Daiichi Sankyo has met its primary efficacy endpoint.

The study was designed for the evaluation of the drug Hokusai-VTE. It found that the investigational, oral, once-daily direct factor Xa-inhibitor edoxaban met the primary efficacy endpoint of non-inferiority compared to warfarin, following initial use of heparin in both arms, for the treatment and prevention of recurrent symptomatic venous thromboembolism (VTE).

Once-daily edoxaban also demonstrated superiority as compared to warfarin for the principal safety outcome of clinically relevant bleeding (the composite of major or clinically relevant non-major bleeding).

"Hokusai-VTE was designed to include a broad range of VTE patients, including those with severe pulmonary embolism, and we are therefore pleased that the study found that edoxaban administered once-daily is as efficacious as warfarin for the prevention of recurrent symptomatic VTE while significantly reducing the risk of bleeding," said Dr Harry Buller, professor, internal medicine and chairman, Department of Vascular Medicine at the Academic Medical Center in Amsterdam, The Netherlands.

Dr Buller, who is also the chairman of the Hokusai-VTE steering committee, said that, "A promising finding was the sizeable reduction in recurrent symptomatic VTE among patients with severe pulmonary embolism who were treated with edoxaban."

"We are excited about the results from the Hokusai-VTE study demonstrating that once-daily edoxaban may provide a new treatment option for a broad range of VTE patients. Daiichi Sankyo plans to submit New Drug Applications for edoxaban for VTE by the first quarter of 2014 in the U.S., Japan and Europe," said Mr Glenn Gormley, global head, R&D, and senior executive officer, Daiichi Sankyo.