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ASIA EDITION

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June 19, 2015 | News | By BioSpectrum Bureau

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Daiichi Sankyo Company Limited has initiated its Hokusai-VTE Cancer, a multinational study which will investigate the efficacy and safety of edoxaban, an oral, once-daily selective factor Xa inhibitor, versus dalteparin for the treatment of VTE associated with cancer (other than basal-cell or squamous-cell carcinoma of the skin) for whom long-term treatment with a low molecular weight heparin (LMWH) is intended.

The purpose of the study is to evaluate edoxaban in comparison with dalteparin in preventing the combined outcome of VTE recurrence or major bleeding following an acute deep vein thrombosis (DVT) or pulmonary embolism (PE) event in patients with cancer. The recruitment has started, and approximately 1,000 patients are expected to be enrolled in the study at clinical sites across 13 countries.

Edoxaban is currently marketed in Japan, US and Switzerland, and has also been recommended for approval in the EU by the European Committee for Medicinal Products for Human Use (CHMP). In other countries, regulatory review is ongoing.

VTE is an umbrella term for two conditions, DVT and PE. DVT is a disease caused by a blood clot found in deep veins, usually within the leg, thigh or pelvis, although they can occur in other parts of the body as well. PE occurs when part of a clot detaches and lodges in the pulmonary arteries, causing a potentially fatal condition. VTE is a major cause of morbidity and mortality worldwide.

VTE is a major cause of morbidity and mortality in patients with cancer, with an annual incidence that can be as high as 20 percent depending on the cancer type, background risk and time since diagnosis. Patients with cancer have multiple risk factors for VTE and the risk of VTE events increases in patients with cancer receiving chemotherapy. In addition, patients with cancer and VTE have a lower survival rate than those without VTE.