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Daiichi Sankyo enrolls patients for edoxaban trial

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Daiichi Sankyo completes patient enrollment for Hokusai-VTE phase III study of edoxaban

Singapore: Japan-headquartered Daiichi Sankyo has completed patient enrollment in the global Hokusai-VTE phase III study investigating the once-daily oral factor Xa inhibitor edoxaban for the treatment and prevention of recurrence of venous thromboembolism (VTE) in patients who have had an acute symptomatic deep vein thrombosis, pulmonary embolism, or both.

Hokusai-VTE is the largest single phase III clinical study in the treatment and prevention of recurrence of venous thromboembolism. More than 8,250 patients have been enrolled in the trial from more than 400 clinical sites across 38 countries.

The clinical study has been designed to reflect clinical practice, using a standard heparin lead-in, and providing a flexible treatment duration of three, six or 12 months. Edoxaban 60mg once-daily will be compared to warfarin control therapy. This study design is allowing investigators to evaluate patients with a broad range of risks, including patients with moderate or severe conditions of pulmonary embolism and deep vein thrombosis.

"With its rigorous design and large patient population, Hokusai-VTE marks an important step in the development of the new class of oral anticoagulants, direct factor Xa inhibitors," said Dr Harry BÃ¼ller, professor of Internal Medicine, chairman of the Department of Vascular Medicine at the Academic Medical Center in Amsterdam, The Netherlands and Chairman of the Hokusai-VTE steering committee. "What sets the study apart from other studies of its kind is that it aims to reflect clinical practice through the flexible treatment duration."

Edoxaban is an investigational once-daily, novel oral anticoagulant that specifically, reversibly and directly inhibits factor Xa, which is an important factor in the coagulation system that leads to blood clotting. It is licensed only in Japan for the prevention of venous thromboembolism after major orthopaedic surgery under the brand name Lixiana. Elsewhere, including Europe and the US, edoxaban is currently in phase III of clinical development and has not been approved yet.

"We are very pleased to announce that we have completed patient recruitment for the Hokusai-VTE clinical study, the largest global study of its kind and we expect to see first results during FY 2013," said Dr Glenn Gormley, global head of research

and development and senior executive officer, Daiichi Sankyo.