

For Immediate Release

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**Daiichi Sankyo Announces Large-scale Registry of Venous Thromboembolism (VTE)  
in Cancer Patients**

**Tokyo, Japan (March 13, 2017)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has commenced a company-initiated large-scale clinical registry for cancer patients (hereafter, Cancer-VTE Registry).

The Cancer-VTE Registry is an observational study that will enroll and follow up to 10,000 cancer patients for one year for the following purposes:

- Identify the frequency of concurrent VTE in registered patients and clarify the background factors of patients with VTE complications.
- Identify treatment status of VTE in registered patients.
- Investigate the incidence of VTE events, hemorrhagic events, ischemic stroke and systemic embolisms at the time of observation in a registered patient for one year, and clarify background factors related to the events to understand the optimal group to be treated for Direct Oral Anticoagulant (DOAC) and clarify appropriate use of DOAC including LIXIANA<sup>®</sup> (Edoxaban Tosilate Hydrate, hereafter Edoxaban) for that group.

Daiichi Sankyo will continue to contribute to the treatment and recurrence prevention of VTE through this observational study.

### **About VTE in Cancer Patients**

VTE is a generic term for deep vein thrombosis and pulmonary thromboembolism. Deep vein thrombosis is a disease in which blood clots are formed in deep veins such as those in legs, pelvis and arms. Pulmonary thromboembolism is a disease in which a part of a thrombus formed in a deep vein is liberated and flows to the lungs, occluding the pulmonary artery, resulting in a lethal situation. It is known that the incidence of VTE is significantly higher in cancer patients than in those without cancer due to various factors such as the release of a procoagulant protein from tumor tissue. In addition, treatment with chemotherapeutic agents, immunomodulators, and angiogenesis inhibitors is also known to increase the risk of developing VTE. In cancer patients who developed VTE, the risk of death from acute thrombotic events is said to be higher than in patients without cancer. In addition, cancer patients who developed VTE have a lower survival rate than cancer patients who do not develop VTE.

### **About VTE Anticoagulation Therapy and DOACs**

Warfarin or unfractionated heparin has traditionally been used for VTE anticoagulation therapy. However since 2007, injectable preparations, such as low molecular weight heparin, have been used, and since 2014, three products, including Edoxaban, have been available in Japan as DOAC for the treatment and recurrence prevention of VTE.

### **About Edoxaban Clinical Research Program (ECRP)**

Daiichi Sankyo is committed to expanding scientific knowledge about edoxaban, as demonstrated through our research programs evaluating its use in a broad range of cardiovascular conditions, patient types and clinical settings in atrial fibrillation (AF) and venous thromboembolism (VTE). The edoxaban clinical research program includes multiple RCTs (randomized, controlled trials), registries and non-interventional studies, with the goal of generating new clinical and real-world-data regarding its use in AF and VTE populations. Daiichi Sankyo expects that more than 100,000 patients will participate in the edoxaban clinical research program, including completed, ongoing and future research.

The RCTs include:

- ENSURE-AF (Edoxaban vs. warfarin in subjects Undergoing cardioversion of Atrial Fibrillation), in AF patients undergoing electrical cardioversion
- ENTRUST-AF PCI (Edoxaban Treatment versus VKA in patients with AF undergoing PCI), in AF patients undergoing percutaneous coronary intervention
- Hokusai-VTE Cancer (Edoxaban in Venous Thromboembolism Associated with Cancer), in patients with cancer and an acute VTE event
- ELDERCARE-AF (Edoxaban Low-Dose for Elderly CARE AF patients), in elderly AF patients in Japan
- ELIMINATE-AF (Evaluation of edoxaban compared with VKA in subjects undergoing catheter ablation of non-valvular Atrial Fibrillation)

- ENVISAGE-TAVI AF (Edoxaban Versus standard of care and their effects on clinical outcomes in patients having undergone Transcatheter Aortic Valve Implantation (TAVI) – Atrial Fibrillation)

In addition, global and regional registry studies will provide important real-world data about the use of edoxaban and other oral anticoagulants in everyday practice, and include:

- ETNA-AF (Edoxaban Treatment in routine clinical practice in patients with non valvular Atrial Fibrillation)
- ETNA-VTE (Edoxaban Treatment in routine clinical practice in patients with Venous Thromboembolism)
- EMIT-AF/VTE (Edoxaban Management In diagnostic and Therapeutic procedures-AF/VTE)
- Prolongation PREFER in AF (PREvention of thromboembolic events – European Registry) in patients with AF
- ANAFIE (All Nippon AF In Elderly) Registry in Japan
- Cancer-VTE Registry in Japan

We are committed to adding to the scientific body of knowledge around edoxaban in a variety of AF and VTE patients, including those who are vulnerable.