

For Immediate Release

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**Daiichi Sankyo Announces Large-Scale Registry of
Nonvalvular Atrial Fibrillation in the Elderly**

Tokyo, Japan (October 3, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has commenced a company-initiated, large-scale registry, called ANAFIE (All Nippon AF In Elderly) Registry in Japan to study nonvalvular atrial fibrillation (hereafter, NVAf) in elderly patients aged 75 years and older.

The ANAFIE Registry is the NVAf registry to date in Japan, with a planned enrollment of 30,000 elderly NVAf patients and a planned follow-up of 2 years. The objectives of the ANAFIE Registry are to 1) investigate the current status of the use of anticoagulants and their impact on outcomes, and thus identify issues that are barriers to optimal treatment in this population, and 2) identify risk factors for thrombotic and bleeding events, including intracranial hemorrhage, and thus determine the population in which direct oral anticoagulants (DOACs) could provide benefits, as well as the optimal DOAC treatment regimen, including LIXIANA (JAN: Edoxaban Tosilate Hydrate), in elderly patients with NVAf.

As the only Japanese pharmaceutical company who has developed and launched a DOAC product globally, Daiichi Sankyo is committed to contributing to the health of Japanese elderly NVAf patients.

About Atrial Fibrillation

Atrial fibrillation (AF) is a condition in which the heartbeat is rapid and irregular, and can potentially lead to a stroke. There is an analysis that AF can potentially affect 10% of men aged 65 years and older while it is generally said that one in 20-30 people aged 65 years and older is an AF affected patient in Japan.^{*1} Cerebral vascular disease including stroke is the fourth most common cause of death in Japan.^{*2} Compared to patients without AF, affected patients have 3-5 times higher risk of stroke. The mortality rate among stroke patients with AF is about twice that of patients without AF.

*1 Health Japan 21 Forum (in Japanese only)

<http://www.kenko-nippon21forum.gr.jp/free/prerelease/contents041.pdf>

*2 Demographic statistics, 2014 in Japan (in Japanese only)

<http://www.mhlw.go.jp/toukei/saikin/hw/jinkou/geppo/nengai14/>

About Anticoagulant therapy and DOACs

Warfarin has been the standard of care for NVAF treatment for the past 50 years. Since 2011, four DOACs have been approved in Japan for prevention of ischemic stroke and systemic embolism in NVAF, including LIXIANA from Daiichi Sankyo.

About Extensive Clinical Research Program for Edoxaban

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 extensive edoxaban research program include 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.

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 ThromboEmbolicism) ;
- 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.

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.