For Immediate Release

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## Daiichi Sankyo Initiates ELDERCARE-AF Study of Anticoagulant Edoxaban

Tokyo, Japan (August 24, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has initiated the ELDERCARE-AF ( $\underline{e}$ doxaban  $\underline{l}$ ow- $\underline{d}$ ose for  $\underline{e}$ lde $\underline{r}$  <u>care</u> <u>AF</u> patients) study aimed at additional dosage and formulation for patients with non-valvular atrial fibrillation for the anticoagulant edoxaban developed by Daiichi Sankyo (JAN: Edoxaban Tosilate Hydrate).

This study is a phase 3 clinical trial in Japan to verify the safety and efficacy (prevention of stroke and systemic embolism) of 15 mg once-daily oral administration of edoxaban to non-valvular atrial fibrillation patients who are not eligible for current available oral anticoagulation therapy with an approved dose regimen of VKA (vitamin K antagonist) or DOACs (direct oral anticoagulants) and are aged 80 years and older.

## <u>About Edoxaban</u>

Edoxaban selectively, reversibly and directly inhibits FXa (activated blood coagulation factor X) which is involved in blood clotting within blood vessels.

In Japan, LIXIANA<sup>®</sup> was launched for the prevention of venous thromboembolism after major orthopedic surgery of 15 mg and 30 mg tablets in July 2011, and was approved for the treatment and prevention of venous thromboembolism (deep vein thrombosis and pulmonary thromboembolism) as well as for the prevention of ischemic stroke and systemic embolism in non-valvular AF patients with 30 mg tablets in September 2014, with additional dosage approval for 60 mg tablets in December 2014.

## **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.<sup>\*1</sup> Cerebral vascular disease including stroke is the fourth most common cause of death in Japan.<sup>\*2</sup> 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, with a 50% increased risk of a poorer prognosis.

- \*1 Health Japan 21 Forum (in Japanese only) <u>http://www.kenko-nippon21forum.gr.jp/free/prerelease/contents041.pdf</u>
- \*2 Demographic statistics, 2014 in Japan (in Japanese only) http://www.mhlw.go.jp/toukei/saikin/hw/jinkou/geppo/nengai14/