



## **ELIMINATE-AF Study Investigating Once-Daily LIXIANA® (edoxaban) in Patients Undergoing Catheter Ablation of Non-valvular Atrial Fibrillation was initiated.**

**Laval, QC (March 31<sup>st</sup>, 2017)** – Servier Canada Inc. announced today that the first patient has been enrolled into the **E**valuation of Edoxaban **co**Mpared with VKA **I**N subjects undergoing **c**ATHeter ablation of non-valvular **A**trial **F**ibrillation (ELIMINATE-AF) study in March 2017. The ELIMINATE-AF is a prospective, multinational, randomized, open-label, blinded endpoint evaluation, parallel-group phase 3b study to evaluate the efficacy and safety of uninterrupted anticoagulation with once-daily edoxaban against a vitamin K antagonist in AF patients undergoing catheter ablation of atrial fibrillation (AF.).<sup>1</sup> The study is being performed by Daiichi Sankyo with whom Servier Canada has a strategic agreement to commercialize Lixiana® (edoxaban) in Canada. The study will investigate the incidence of the composite of all-cause death, stroke and major bleeding (International Society on Thrombosis and Hemostasis [ISTH] definition) in the edoxaban group against the VKA group in the period from date of first intake of study medication to Day 90/EOT.<sup>1</sup> The primary safety objective is to descriptively compare the incidence of major bleeding (ISTH definition). Edoxaban will be used with the approved dosage regimen for stroke prevention in atrial fibrillation. Approximately 560 patients will be enrolled in ELIMINATE-AF from 75 clinical sites across Canada, Europe and Asia.<sup>1</sup> For more information, please visit: <https://clinicaltrials.gov/ct2/show/NCT02942576> .

“The number of patients undergoing catheter ablation is increasing in Canada and the risk of thromboembolic events associated with this procedure remains high. The ELIMINATE-AF study will provide further knowledge on the use of edoxaban throughout the procedure for the prevention of clinically important events.” said Dr Carlos Morillo, Chief Cardiology Division, Department of Cardiac Sciences, Libin Cardiovascular Institute, University of Calgary.

### **About Atrial Fibrillation**

AF is a condition where the heart beats irregularly and rapidly. When this happens, blood can pool and thicken in the chambers of the heart causing an increased risk of blood clots. These blood clots can break off and travel through the blood stream to the brain (or sometimes to another part of the body), where they have the potential to cause a stroke.<sup>2</sup> AF is the most common type of heart rhythm disorder, and is associated with substantial morbidity and mortality.<sup>3</sup> AF affects approximately 350 000 people in Canada.<sup>4</sup> Compared to those without AF, people with the arrhythmia have a 3-5 times higher risk of stroke.<sup>5</sup> One in five of all strokes are as a result of AF.<sup>6</sup>

### **About LIXIANA® (edoxaban)**

Lixiana® is an oral once daily, direct factor Xa inhibitor. Factor Xa is one of the key components responsible for blood clotting. AF, a heart rhythm disorder causing irregular rapid contractions of the upper chambers of the heart can lead to the formation of a clot. Venous thromboembolism (VTE), another condition in which blood clots form in deep veins of the leg and break off and travel to the lungs. Edoxaban was discovered and developed by Daiichi Sankyo Co., Ltd. On June 27, 2016, Daiichi Sankyo entered into a strategic agreement for Servier Canada to commercialize Lixiana in Canada.

Lixiana® was approved in Canada in November 2016 under the brand name Lixiana® for the prevention of stroke and systemic embolic events (SEE) in patients with AF in whom anticoagulation is appropriate and for treatment of VTE (DVT, PE) and the prevention of recurrent DVT and PE.<sup>7</sup> In addition, edoxaban is marketed under the brand name Lixiana® in Japan, South Korea, Hong Kong, Taiwan, Thailand, Switzerland, the U.K., Germany, Ireland, the Netherlands, Italy, Spain, Belgium, Austria, Portugal, and other European countries and under the brand name Savaysa® in the United States.

### About Servier

Servier Canada was established in 1978 in Laval, Quebec and employs over 320 people across Canada. Servier Canada is currently marketing medicines in Cardiology, Hematology and Diabetes, and will soon market oncology products indicated as treatment options in hematological malignancies. More information is available at [www.servier.ca](http://www.servier.ca)

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