



## **ENVISAGE-TAVI AF Study Investigating Once-Daily LIXIANA® (edoxaban) in Patients with Atrial Fibrillation Undergoing Transcatheter Aortic Valve Implantation was initiated**

**Laval, QC (May 2, 2017)** – Servier Canada Inc. announced today that the first patient has been enrolled into the **E**doxaba**N** Versus standard of care and their effect**S** on clinical outcomes in p**A**tients having**G** undergone**E** Transcatheter **A**ortic **V**alve **I**mplantation – **A**trial **F**ibrillation (ENVISAGE-TAVI AF). The ENVISAGE-TAVI AF study is a prospective, randomized, open-label, blinded endpoint evaluation, parallel-group phase 3b study, evaluating the efficacy and safety of once-daily edoxaban against a regimen of a vitamin K antagonist, with or without antiplatelet therapy, in AF patients following successful transcatheter aortic valve implantation (TAVI).<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 primary efficacy endpoint is incidence of net adverse clinical events (NACE), i.e., the composite of all-cause death, myocardial infarction, ischemic stroke, systemic thromboembolism, valve thrombosis, and major bleeding (International Society on Thrombosis and Haemostasis [ISTH] definition). The primary safety endpoint is major bleeding (ISTH definition). Approximately 1,400 patients will be enrolled in ENVISAGE-TAVI AF from 200 clinical sites across Canada, the United States and Europe.<sup>1</sup> For more information, please visit: <https://clinicaltrials.gov/ct2/show/NCT02943785>

“Aortic stenosis is a severe and progressing condition that is more and more frequently being treated by TAVI. Patients undergoing TAVI often have concomitant AF which requires chronic oral anticoagulation treatment. This study will provide insight on the efficacy and safety of edoxaban and vitamin K antagonists after successful TAVI in non-valvular AF patients” said Jeffrey Weitz, MD, Professor of Medicine and Biochemistry at McMaster University and Executive Director of the Thrombosis and Atherosclerosis Research Institute in Hamilton, Ontario.

### **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 the 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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