

## OPSENS RECEIVES APPROVAL FROM HEALTH CANADA TO INITIATE FIRST IN-MAN CLINICAL STUDY FOR ITS NEW GUIDEWIRE FOR THE TAVR PROCEDURE

SAVVYWIRE, the first guidewire that aims to improve procedural efficiency and clinical outcomes for patients undergoing minimally invasive, Trans Aortic Valve Replacement (TAVR)

Quebec, Quebec, September 20, 2021 - OpSens Inc. ("OpSens" or the "Company") (TSX:OPS) (OTCQX:OPSSF), a cardiology medical device company providing innovative product solutions based on its patented optical technology, announced today that it has received Health Canada approval to commence the first in-man study with its SavvyWire, a guidewire developed specifically for transcatheter aortic valve replacement ("TAVR"). The SavvyWire is the first guidewire intended to both deliver the aortic valve prosthesis while allowing continuous hemodynamic pressure measurement during the procedure.

"The SavvyWire has the potential to bring important innovation to physicians performing the TAVR procedure and could become a key advancement in performing the procedure. Studies continue to demonstrate the benefit of TAVR to a wide range of patients with severe aortic stenosis," said Louis Laflamme, President and CEO of OpSens. "Health Canada's approval of the first in-man study is an important milestone for the Company and an important step towards filing for 510k clearance with the U.S. Food and Drug Administration ("FDA"). We remain on track to submit for regulatory approval in the United States in early 2022," concluded Mr. Laflamme.

Health Canada's approval allows OpSens to commence the 20-patients study shortly at two world-renowned structural cardiology institutions that contributed to the development of the SavvyWire. Dr. Josep Rodés-Cabau at The Quebec Heart and Lung Institute Research Centre ("IUCPQ") and Dr. Réda Ibrahim at The Montreal Heart Institute ("MHI") will be the primary investigators.

Aortic valve stenosis occurs when the heart's aortic valve narrows, which prevents the valve from opening fully, restricting blood flow from the heart into the main artery (aorta) and onward to the rest of the body.

Initially, the TAVR procedure was only indicated for inoperable patients and then for high-risk surgical patients. Clinical programs like PARTNER or COREVALVE, have since shown better or equivalent clinical outcomes in intermediate and low-risk patients. The TAVR procedure is now evolving quickly with a minimalist approach that allows the procedure to be faster and the patients to be discharged earlier, sometimes on the same day.

The TAVR procedure is on the rise, driven by an aging of the population and recent studies that demonstrate its benefits to patients of all conditions. The TAVR market is currently estimated at US\$5 billion and is expected to reach US\$8 billion by 2025.

## About OpSens Inc. (<u>www.OpSens.com</u> or <u>www.OpSensmedical.com</u>)

OpSens focuses mainly on coronary artery stenosis measurement in interventional cardiology. The Company offers an advanced optical-based pressure guidewire that aims at improving the clinical outcome of patients with coronary artery disease. Its flagship product, the OptoWire, is a second-generation fiber optic pressure guidewire designed to provide the lowest drift in the industry and excellent lesions access. The OptoWire has been used in the diagnosis and treatment of over 150,000 patients in more than 30 countries. It is approved for sale in the United States, European Union, Japan, and Canada.

OpSens is also involved in industrial activities in developing, manufacturing, and installing innovative fiber optic sensing solutions for critical applications.

Forward-looking statements contained in this press release involve known and unknown risks, uncertainties and other factors that may cause actual results, performance, and achievements of OpSens to be materially different from any future results, performance or achievements expressed or implied by the said forward-looking statements.

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For further information, please contact: Louis Laflamme, CPA, CA, Chief Executive Officer, 418.781.0333

Robin Villeneuve, CPA, CA Chief Financial Officer, 418.781.0333