

OPSENS SUCCESSFULLY COMPLETES 20-PATIENT IN HUMAN CLINICAL STUDY FOR TAVR PROCEDURE

TAVR market outlook for procedural growth remains highly attractive globally

Quebec City, Quebec, November 23, 2021 – OpSens Inc. (“OpSens” or the “Company”) (TSX:OPS) (OTCQX:OPSSF), a medical device cardiology-focused company delivering innovative solutions based on its proprietary technology, is pleased to announce the successful treatment of 20 patients leading to the completion of the first in-man clinical study utilizing the SavvyWire. The wire was designed and developed to improve the intervention workflow for transcatheter aortic valve replacement (“TAVR”) and is the first guidewire able to both deliver a valvular prosthesis while allowing continuous hemodynamic pressure measurement during the procedure. The SavvyWire is not yet approved for commercialization.

“We are extremely pleased to have completed this important safety and efficacy study with all patients successfully treated without any adverse effects related to the use of the SavvyWire,” said Louis Laflamme, President and Chief Executive Officer of OpSens. “Structural heart procedures are rapidly growing worldwide, driven by the TAVR procedure and the expansion of its indications. As the TAVR procedure benefits a larger group of patients and with the minimalist approach growing in popularity within the medical community, the benefits of our product - the SavvyWire could be significant. The SavvyWire is an active guidewire that allows physicians to precisely deliver the valve and monitor deployment to ensure optimal implantation without guidewire exchanges. We believe the procedural benefits of our SavvyWire will improve the intervention and patient outcomes for TAVR procedures.”

20-patients clinical study with the SavvyWire completed

The safety study was conducted with 20 patients in two world renowned structural heart institutions with Dr. Josep Rodés-Cabau at the Quebec Heart and Lung Institute (*Institut Universitaire de Cardiologie et de Pneumologie de Québec* or “IUCPQ”), in Quebec City and Dr. Réda Ibrahim at The Montreal Heart Institute (“MHI”) in Montreal, as primary investigators.

Dr. Josep Rodés-Cabau of Quebec Heart and Lung Institute, stated: “this device has the potential to improve workflow and clinical outcomes in TAVR patients, especially in specific clinical indications where pressure measurement is of major importance such as Valve-in-Valve and patients with small aortic annulus. The SavvyWire is optimizing the intervention, in line with the evolution of TAVR through minimalist approach. We are proud to collaborate with OpSens to bring this leading-edge technology to market.”

Dr. Réda Ibrahim of The Montreal Heart Institute, said: “pressure gradient is a hot topic in the TAVR landscape. Invasive pressure measurement has been critical for the adoption of TAVR, and we slowly moved away by using echography. The OpSens device allows us to come back to the precision of invasive pressure measurement while making the procedure safer and more efficient. I have been a fan of the idea from the start and it’s a pleasure to now see this concept becoming a reality.”

The SavvyWire, a new intelligent, pre-shaped, structural guidewire with integrated pressure monitoring, aims at improving procedural efficiency and clinical outcomes by allowing multiple steps over the same device without exchange. This device has been designed to support the minimalist TAVR approach which has been growing among structural heart physicians. With the SavvyWire, physicians can expect to diagnose and implant the percutaneous valve over the same device while getting continuous and accurate hemodynamic measurements. OpSens is targeting the commercial launch of its SavvyWire in calendar year 2022.

TAVR Procedure Evolution

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 III" and "Evolut Low Risk", 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. (www.OpSens.com or www.OpSensmedical.com)

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.

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