



OPSENS ANNOUNCES FDA CLEARANCE FOR THE SAVVYWIRE™ FOR USE IN TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) PROCEDURES

Quebec City, Quebec, September 15, 2022 – OpSens Inc. ("OpSens" or the "Company") (TSX:OPS) (OTCQX:OPSSF), a medical device cardiology-focused company delivering innovative solutions based on its proprietary optical technology, today announced that it has received 510(k) regulatory clearance from the U.S. Food & Drug Administration ("FDA") for the SavvyWire™ ("SavvyWire"), its new guidewire for transcatheter aortic valve replacement procedures, or TAVR.

"For OpSens, FDA clearance is a key milestone and an achievement, introducing an entirely new category of innovation to the structural heart device market segment. The SavvyWire has been designed to provide best in class valve delivery capability and improve workflow in the TAVR procedure," commented Louis Laflamme, President and Chief Executive Officer of OpSens. "SavvyWire uniquely provides a 3-in-1 solution for stable aortic valve delivery and positioning, continuous accurate hemodynamic measurement during the procedure, and reliable left ventricular pacing without the need for adjunct devices or venous access. We look forward to introducing physicians to the SavvyWire at the upcoming TCT meeting in Boston later this week and then initiating our limited market release of the product to a select number of physician thought-leaders during the coming weeks," concluded Mr. Laflamme.

The SavvyWire is the first and only Sensor-Guided TAVR solution, designed to support TAVR efficiency and lifetime patient management. The SavvyWire enables significant TAVR procedural benefits by supporting multiple steps over the same device without exchange, while delivering continuous, accurate hemodynamic measurements and display.

The Evolution of TAVR

Aortic valve stenosis occurs when the heart's aortic valve narrows, preventing it from opening completely and restricting blood flow from the heart to the main artery (aorta) and then to the rest of the body.

The TAVR procedure was initially only indicated for inoperable patients with severe symptomatic aortic stenosis, and later for patients at high surgical risk. Clinical programs such as PARTNER and COREVALVE have since shown better or equivalent clinical outcomes in intermediate and low surgical risk patients. The TAVR procedure is rapidly evolving toward a minimalist approach that advances the procedure and allows patients to leave the hospital earlier, sometimes the same day.

The TAVR procedure is growing rapidly globally, driven by the aging population and recent studies that demonstrate its benefits for a broader array of patients. The global TAVR market is currently estimated at over 200,000 procedures and is expected to reach 400,000 in 2027.

About OpSens Inc. (www.OpSens.com or www.OpSensmedical.com)

OpSens focuses mainly 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.

Neither TSX nor its Regulation Services Provider (as that term is defined in the policies of the TSX) accepts responsibility for the adequacy or accuracy of this release.

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