



OPSENS ANNOUNCES 510(K) SUBMISSION TO U.S. FDA FOR NEW GUIDEWIRE FOR THE TAVR PROCEDURE

Quebec City, Quebec, December 13, 2021 – 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 filed a 510(k) submission with the U.S. Food & Drug Administration (“FDA”) for regulatory clearance of its new guidewire (“SavvyWire”) for transcatheter aortic valve replacement, or TAVR procedures. OpSens has also filed for approval with Health Canada.

“The FDA submission is a key milestone for OpSens, in introducing our innovative product to the cardiovascular market. The SavvyWire has been designed and developed to improve the workflow in transcatheter aortic valve replacement,” commented Louis Laflamme, President and Chief Executive Officer of OpSens. “The introduction of a novel and advanced guidewire that has the ability to both deliver a valvular prosthesis while allowing continuous hemodynamic pressure measurement during the procedure is considered to be a significant benefit to the medical community, especially given the rapid growth in TAVR procedures. We look forward to the agencies review of our application and will continue to prepare our organization for an anticipated approval in late summer or fall of 2022.”

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.

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.

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