

## **OPSENS RECEIVES FDA 510(K) CLEARANCE FOR THE OPTOWIRE II**

**Quebec City, Quebec, March 16, 2016 - Opsens Inc. ("Opsens" or the "Company") (TSXV:OPS) (OTCQX:OPSSF)** today announces the 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for the OptoWire II, an optical guidewire developed to measure Fractional Flow Reserve ("FFR"). FFR measurement is used for the diagnostic of the severity of coronary stenosis for guiding the treatment of patients with coronary artery disease.

Opsens had already received FDA clearance to sell the OptoWire I, the first generation of its optical guidewire. This approval allows Opsens to market the OptoWire II in the world's largest market. The OptoWire II is a new design comprising a hydrophilic coating that further improves the performances of the guidewire in different scenarios, such as in highly calcified and tortuous vessels. The OptoWire II should foster the acceptance rate of Opsens' optical guidewire.

### **Opsens Deploying its FFR Products in the U.S. Market**

"Obtaining 510(k) clearance is a significant milestone in our plan to expand the commercialization of our FFR products. In the past few months, we have taken the necessary steps for a successful launch in the U.S. and in other targeted markets. Specific to the American market, we brought together a strong team with experience and expertise in the sale of FFR products in the U.S. The team has started to deploy our sales and marketing strategy that will lead to the full product launch in the U.S. territory," stated Louis Laflamme, President and Chief Executive Officer of Opsens. "Also, we are glad to report that we have now successfully completed our move into a new state-of-the-art facility that will allow us to increase production and meet the growing demand for our FFR products," Laflamme added. "After a few weeks of relocation activities, production will resume soon. This short break will temporarily affect Opsens' revenue growth, but it is a necessary step to bring forward our long term plan," he concluded.

"Very positive feedback on the performance of the OptoWire II, approval in the U.S. and the new production capability is galvanizing our plan, which is aimed at grabbing market share in the growing FFR market," stated Claude Belleville, Opsens' Vice President, Medical Devices. "We are committed to becoming the first choice of cardiologists, hence helping them to improve the clinical outcome of patients with coronary artery disease," he said.

Opsens aims to become a key player in the guidewire FFR market with the OptoWire, a nitinol-based optical guidewire. The OptoWire provides intra-coronary blood pressure measurements with unique, patented optical pressure guidewire technologies. It is immune to adverse effects related to blood contact, and allows easy and reliable connectivity that leads to reliable FFR measurements in extended conditions of usage. The OptoWire is also designed to provide cardiologists with a guidewire that provides optimal performance to navigate coronary arteries and cross blockages with ease and safety. Based on industry sources, the FFR market represented more than US\$300 million in sales in 2014 and is expected to reach US\$1 billion in the medium-term.

**About Opsens Inc. ([www.opsens.com](http://www.opsens.com) or [www.opsensmedical.com](http://www.opsensmedical.com))**

Opsens focuses mainly on the measure of FFR in interventional cardiology. Opsens offers an advanced optical-based pressure guidewire (OptoWire) that aims at improving the clinical outcome of patients with coronary artery disease. Opsens is also involved in industrial activities. The Company develops, manufactures and installs innovative fibre optic sensing solutions for critical applications such as the monitoring of oil wells and other demanding industrial 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:**

Thierry Dumas, CPA, CA, Chief Financial Officer, 418.781.0333

Louis Laflamme, CPA, CA, Chief Executive Officer, 418.781.0333