



## **FDA GRANTS 510(K) CLEARANCE FOR SPECTRAL'S PROPRIETARY STAND-ALONE PUMP**

**TORONTO, Canada – Monday, December 18, 2017– Spectral Medical Inc., (TSX: EDT),** a Phase III company developing the first treatment for patients with septic shock guided by a companion diagnostic, today announced that the United States Food and Drug Administration ("FDA") has granted 510(k) clearance for the Spectral Apheresis Machine ("SAM") for use in continuous renal replacement therapy ("CRRT") and therapeutic plasma exchange ("TPE"). The Company has also submitted final documentation seeking approval of SAM from Health Canada and anticipates a decision in the first half of 2018.

SAM was initially developed with the intent of supporting the potential commercialization of Toraymyxin™ ("PMX"), whereby intensive care units could use SAM to efficiently and safely deliver the PMX treatment to septic shock patients and not rely on third party CRRT machines. The regulatory path led the Company to first seek 510(k) clearance of SAM for CRRT applications, which has now been achieved. SAM has also been designed as an open platform hemoperfusion delivery device and the Company intends to seek further 510(k) clearance for this purpose when there is an FDA approved hemoperfusion cartridge available for use in the US market, including potentially Spectral's PMX treatment.

Because SAM was designed to be user friendly and to be built on a small footprint, the Company believes that there is an opportunity to pursue use of SAM in the broader CRRT market (not just potentially for PMX). The global CRRT market is projected to reach USD\$1.5 billion in 2022, from approximately USD\$1.1 billion in 2017. It is likely that any commercialization would be undertaken with a partner that has experience in these markets. The Company has exclusive license rights for SAM in North America for all CRRT applications and has worldwide exclusivity for any hemoperfusion applications.

"The 510(k) clearance for SAM has been achieved through extensive collaboration between the project management team at Spectral and the development team at Infomed SA in Geneva, Switzerland. We believe that SAM represents a landmark innovation in the CRRT field and we now plan to explore opportunities for the clinical deployment of this innovative patented technology, beginning initially with further testing of the instrumentation in hospital settings," said Dr. Gualtiero Guadagni, Vice President of Sales & Marketing at Spectral.

### **About Spectral**

Spectral is a Phase III company seeking U.S. FDA approval for its unique product for the treatment of patients with endotoxemic septic shock, Toraymyxin™ ("PMX"). PMX is a therapeutic hemoperfusion device that removes endotoxin, which can cause sepsis, from the bloodstream.

PMX has been approved for therapeutic use in Japan and Europe, and has been used safely and effectively on more than 150,000 patients to date. In March 2009, Spectral obtained the exclusive development and commercial rights in the U.S. for PMX, and in November 2010, signed an exclusive distribution agreement for this product in Canada. Approximately 350,000 patients are diagnosed with severe sepsis and septic shock in North America each year. Spectral is listed on the Toronto Stock Exchange under the symbol EDT. For more information, please visit [www.spectraldx.com](http://www.spectraldx.com)

### **Forward-looking statement**

*Information in this news release that is not current or historical factual information may constitute forward-looking information within the meaning of securities laws. Implicit in this information, particularly in respect of the future outlook of Spectral and anticipated events or results, are assumptions based on beliefs of Spectral's senior management as well as information currently available to it. While these assumptions were considered reasonable by Spectral at the time of preparation, they may prove to be*

*incorrect. Readers are cautioned that actual results are subject to a number of risks and uncertainties, including the availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, the ability of Spectral to take advantage of business opportunities in the biomedical industry, the granting of necessary approvals by regulatory authorities as well as general economic, market and business conditions, and could differ materially from what is currently expected.*

*The TSX has not reviewed and does not accept responsibility for the adequacy or accuracy of this statement.*

For further information, please contact:

Anthony Businkas  
Executive Vice President and CFO  
Spectral Medical Inc.  
416-626-3233 ext. 2200  
[tbusinkas@spectraldx.com](mailto:tbusinkas@spectraldx.com)

Ali Mahdavi  
Capital Markets & Investor Relations  
416-962-3300  
[am@spinnakercmi.com](mailto:am@spinnakercmi.com)