



## **SPECTRAL ANNOUNCES HEALTH CANADA APPROVAL OF ITS PROPRIETARY STAND-ALONE PUMP FOR CRRT AND HEMOPERFUSION**

Toronto Canada – Thursday, February 15, 2018– Spectral Medical Inc., (TSX: EDT), a Phase III company developing a treatment for patients with endotoxemic septic shock, today announced that Health Canada (HC) has approved, under Licence No. 100541, the Spectral Apheresis Machine (“SAM”) for use in continuous renal replacement therapy (“CRRT”), therapeutic plasma exchange (“TPE”) as well as for Hemoperfusion (HP), a modality specifically designed to facilitate patient treatment with the Toraymyxin™ (“PMX”), cartridge used for endotoxin removal in patients with septic shock.

SAM was initially developed to be user friendly and support the commercialization of PMX by removing the need to use more cumbersome dialysis instruments by providing specific hemoperfusion capabilities. However, SAM’s final design allows it to now meet all acute dialysis needs in the critical care environment. The company has exclusive license rights for SAM in North America for all CRRT applications and has worldwide exclusivity for hemoperfusion applications.

"We believe that SAM with its innovative patented technology, represents a significant innovation for patients in ICU needing CRRT for acute kidney injury, as well as the potential to become a flexible open platform for other extracorporeal blood treatments, already available as well as some under development," said Dr. Gualtiero Guadagni, Vice President of Sales & Marketing at Spectral.

Spectral Medical Inc. is an importer of Class I and Class III medical devices and as such is subject to regulatory inspections by Health Canada to assess compliance with the Food and Drugs Act and Medical Device Regulations under Health Canada’s Medical Devices Inspection Programme. This past week Health Canada inspected Spectral’s establishment and gave Spectral a compliant rating.

“In 2017, Spectral Medical Inc. has expanded the scope of its quality system certificate to add the Spectral Apheresis Machine (“SAM”) and has undergone an upgrade to the Medical Device Single Audit Program (“MDSAP”) which covers ISO13485:2003,” said Danijela Domljanovic, Director of Quality for Spectral.

### **About Spectral Medical**

Spectral Medical 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:

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