



## **SPECTRAL PROVIDES UPDATE ON FDA MEETING REGARDING ITS PMA SUBMISSION FOR TORAYMYXIN™**

**Toronto, Canada – October 31, 2017 – Spectral Medical Inc., (TSX: EDT)**, a Phase III company developing the first treatment for patients with endotoxemic septic shock, today announced the results of its recent meeting with the United States Food and Drug Administration (“FDA”) concerning the status of its PMA application for Toraymyxin™.

The meeting consisted of a general discussion of issues identified by the FDA after the first 100 days of regulatory review and suggestions for clarification of those issues. The Company committed to a timely response to the FDA’s questions, which is expected to occur during the month of November 2017. The next review cycle in the process is expected to begin after answers are provided by the Company and are deemed by the FDA to be complete. Generally, FDA guidelines suggest a 180-day anticipated timeframe for completion of review, excluding time required by the Company to satisfactorily respond to any issues.

“We had a productive discussion with the FDA review team, committed to answer the FDA’s questions in a complete and expeditious manner and reaffirmed that we will work diligently with the FDA to address all aspects of their review. The Company remains focused on making a beneficial treatment for endotoxemic septic shock available for a specific group of patients where no other therapy exists”, said Dr. Paul Walker, President and CEO of Spectral.

### **About Spectral**

Spectral is a Phase III company seeking U.S. FDA approval for its unique product for the treatment of patients with septic shock, Toraymyxin™ (“PMX”). PMX is a therapeutic hemoperfusion device that removes endotoxin, which can cause sepsis, from the bloodstream and is guided by the Company’s Endotoxin Activity Assay (EAA™), the only FDA cleared diagnostic for the risk of developing sepsis.

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 whether the FDA will approve of the Company's PMA application for Toraymyxin™, 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.*

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