



## **SPECTRAL PROVIDES REGULATORY UPDATE ON ITS PMA SUBMISSION FOR TORAYMYXIN™**

**TORONTO, Canada – September 21, 2017 – Spectral Medical Inc., (TSX: EDT)**, a Phase III company developing the first treatment for patients with endotoxemic septic shock, today announced that, pursuant to the acceptance by the United States Food and Drug Administration (“FDA”) of its PMA submission for Toraymyxin™ for filing on July 20, 2017, it has been engaged in an ongoing interactive review process with the FDA. Based on the filing acceptance date of July 20, 2017, the Company expects to receive more detailed feedback from the FDA on its PMA submission in the fourth quarter of this year.

Spectral also announced that a full manuscript has been submitted for review by a major international medical journal.

EUPHRATES trial results will be presented at two key medical conferences. The European Society of Intensive Care Medicine Conference (ESICM 2017 LIVE) will be held on September 25, 2017 in Vienna and will include an industry symposium promoting Toraymyxin™ sponsored by Toray Industries Inc.. The Canadian Critical Care Forum (CCCF 2017) will be held on October 2- 4, 2017 in Toronto, where EUPHRATES trial results will be presented in a special plenary session called “What’s New in Critical Care”. In addition, during CCCF 2017, the Company will host a private panel discussion with select Canadian clinicians focused on the utilization of Toraymyxin™ in anticipation of the launch of this treatment in Canada.

Spectral continues to be involved in a review process with the FDA and Health Canada for its SAM continuous renal replacement therapy instrument.

“We are continuing our interactive review process with the FDA of the submitted PMA targeting the treatment of septic shock due to endotoxemia. Sepsis continues to be an increasing unmet medical need, with the Centre for Disease Control reporting that there are now approximately 1.7 million patients in the U.S. diagnosed with sepsis each year and 270,000 patients dying annually from this condition,” stated Dr. Paul Walker, President and CEO of Spectral Medical.

### **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 1.7 million patients are diagnosed with sepsis in the United States alone 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.*

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