



## **SPECTRAL TO FILE FINAL PMA MODULE WITH THE FDA**

### **FOR ITS TORAYMYXIN™ TREATMENT OF ENDOTOXEMIC SEPTIC SHOCK**

**TORONTO, Canada – February 23, 2017 – Spectral Medical Inc., (“Spectral” or the “Company”), (TSX: EDT)** a Phase III company developing the first treatment for patients with endotoxemic septic shock using a medical device, today announced that it plans to file the fourth of four modules of its premarket approval application (PMA) submission, containing the clinical study report, with the FDA for Toraymyxin™ early in the second quarter of this year. The EUPHRATES trial is the first in North America to use a companion diagnostic, the EAA, in the area of sepsis to select patients most likely to benefit from the therapy.

On October 3, 2016, the Company announced that its EUPHRATES trial showed a mortality benefit at 28 days of 5 percent in a pre-specified per protocol patient population with a MODS score greater than nine. This benefit did not reach statistical significance according to the SAP (statistical analysis plan). However, the initial data analyses also showed beneficial treatment effects across multiple secondary endpoints.

Over the last few months a thorough review and analyses of the trial data base has been completed with guidance from the Steering Committee. The information from the EAA measurements has been instrumental in the data review process and has led the Company to its strongly held belief that the Toraymyxin™ column is safe with clinically significant evidence of efficacy. Based on this data review and analyses, the Company has informed the FDA that it plans to submit its final PMA module early in the second quarter of this year, in keeping with the regulatory pathway en route to approval of Toraymyxin™. It is also the intention of the Company to release further detailed results of the clinical trial at a scientific meeting soon after the filing of PMA.

“We are very encouraged by the results of our analyses and the merit of our data. As such, we intend to proceed diligently with our regulatory program. Septic shock continues to claim a significant number of lives each year in North America and no other treatment is currently available for these patients,” stated Dr. Paul Walker, President and CEO of Spectral.

For further information on the FDA regulatory process the Company directs readers to the FDA website, including: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm>

#### **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 the availability of funds and resources to pursue R&D projects, whether the FDA will accept the Company's submission of the final PMA module seeking potential approval of Toraymyxin™, the successful and timely completion of clinical studies, the safety or efficacy of the Toraymyxin™, column, 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 Businskas  
Executive Vice President and CFO  
Spectral Medical Inc.  
416-626-3233 ext. 2200  
[tbusinskas@spectraldx.com](mailto:tbusinskas@spectraldx.com)

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