



## **SPECTRAL ANNOUNCES CLINICAL TRIAL RESULTS**

- Clinical data demonstrates a positive benefit for patients in septic shock-**
- Significant improvement in cardiovascular function was observed-**
- Mortality benefit in the pre specified per protocol patient population with a MODS score greater than nine was 5%-**
- Mortality benefit increased significantly as a function of the amount of endotoxin removed, reaching 18%-**
- Company plans to meet with FDA to discuss regulatory pathway -**

**Toronto, Ontario, October 3, 2016 – Spectral Medical Inc. (“Spectral” or the “Company”) (TSX: EDT) (OTC QX: EDTXF)** a Phase III company developing the first treatment for patients with endotoxemic septic shock using a medical device, today announced the top line results of its Phase III pivotal trial which enrolled a total of 450 patients, including a pre specified population of 243 patients with a high multiple organ dysfunction score (“MODS”) either treated with two Toraymyxin™ columns or given two shams (the per protocol group).

While the trial did not, with this sample size, statistically achieve its primary end point target of absolute reduction in mortality at 28 days, it did demonstrate beneficial treatment effects across multiple end points. The trial clearly showed that mortality benefit significantly increased as a function of the amount of endotoxin removed, as measured by the EAA™ assay. In addition, cardiovascular function improved and the use of vasopressors decreased. Based on these outcomes, the Company intends to consult with its clinical and regulatory advisors and then meet with the United States Food and Drug Administration (“FDA”) to discuss its regulatory pathway going forward.

“The trial clearly showed that the Toraymyxin™ medical device is safe and, even though statistically significant reduction in 28 day mortality was not achieved with this sample size, the 5% mortality reduction in the per protocol population combined with the other positive benefits observed in treated septic shock patients is encouraging,” stated Dr. Bert Spilker, Chairman of the Data Safety Monitoring Board.

“The data demonstrates a very clear correlation between the amount of endotoxin removal and reduction in mortality. The basic premise of a dose response relationship between the amount of endotoxin removed and related benefits is seen,” said Dr. Paul Walker, President and CEO of Spectral. “The overall data from our pivotal Phase III trial clearly demonstrates a clinically relevant impact on patient lives. We plan to take this robust information to the FDA to discuss our regulatory pathway towards potential approval.”

## **About Spectral Medical Inc.**

Spectral is a Phase III company seeking U.S. FDA approval for its unique product Toraymyxin™ (“PMX”) for the treatment of patients with septic shock. PMX is a therapeutic hemoperfusion device that removes endotoxin, which can cause sepsis, from the bloodstream and is directed 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. Approximately 350,000 patients are diagnosed with severe sepsis and septic shock in North America each year, representing a greater than \$3 billion market opportunity for Spectral. Currently there is no specific treatment available for this condition.

Spectral is listed on the Toronto Stock Exchange under the symbol EDT, and on the OTCQX under the symbol EDTXF. 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 commercialize its products, 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 more information, please contact:

Anthony Busiskas  
Executive Vice President and CFO  
Spectral Medical Inc.  
416-626-3233 ext. 2200  
[tbusiskas@spectraldx.com](mailto:tbusiskas@spectraldx.com)  
[www.spectraldx.com](http://www.spectraldx.com)

Ali Mahdavi  
Capital Markets & Investor Relations  
416-962-3300  
am@spinnakercmi.com