



## **SPECTRAL COMMENDS INCLUSION OF ORGAN DYSFUNCTION IN NEW EXPERT CONSENSUS DEFINITIONS OF SEPSIS AND SEPTIC SHOCK**

New sepsis definitions align with Spectral's pivotal trial design for Toramyxin™

**Toronto, Ontario, March 7, 2016** – Spectral Medical Inc. (“**Spectral**” or the “**Company**”), (TSX: EDT) (OTCQX: EDTXF) a Phase III company advancing a precision treatment targeting specific patients at high risk of death from septic shock, today commented on the potential life-saving ramifications of the recently announced Third International Consensus Definitions for Sepsis and Septic Shock. Specifically, Spectral cites the definitions’ new emphasis on organ dysfunction as a major contributor to the underlying pathology of sepsis and the main cause of death from septic shock. The updated definitions were issued on Feb. 23<sup>rd</sup> by a joint task force convened by the Society of Critical Care Medicine and the European Society of Intensive Care Medicine and published online by the [Journal of the American Medical Association](#)<sup>1</sup>.

“We are pleased that these new definitions are fully consistent with the hypothesis and patient identification protocol of our Phase III EUPHRATES clinical trial for Toramyxin™, an investigational therapeutic hemoperfusion device that removes endotoxin from the bloodstream,” said Dr. Paul Walker, President and Chief Executive Officer of Spectral Medical.

The EUPHRATES trial is nearing completion and is based on prior evidence that high levels of endotoxin are associated with organ dysfunction and increased mortality from septic shock. Investigational Toramyxin™ treatment for study eligible patients is guided by the Company's FDA-cleared Endotoxin Activity Assay (EAA™) which measures endotoxin levels in the blood. The new definition and its alignment with the Surviving Sepsis Campaign Guidelines are also reflected in the EUPHRATES study protocol which presumes that fluid resuscitation requirements have been met and that vasopressors are being used to maintain normal blood pressure in the patient.

Over 350,000 patients are diagnosed with septic shock in North America each year. An estimated 150,000 U.S. patients die annually from septic shock despite best

practices employed by critical care and intensive care unit hospital staff. Septic shock is the most advanced and most lethal stage of sepsis.

### **About Spectral Medical Inc.**

Spectral is a Phase III company seeking U.S. FDA approval for its lead theranostics product for the treatment of endotoxemic septic shock. Toraymyxin™ (PMX) is a therapeutic hemoperfusion device that removes endotoxin, a main trigger of sepsis, from the bloodstream. Directed by the Company's Endotoxin Activity Assay (EAA™), the only FDA cleared diagnostic for the risk of developing sepsis, Spectral's EUPHRATES trial is the world's only active and most innovative Phase III study for a medical device in the area of septic shock.

PMX has been approved for therapeutic use in Japan and Europe, and has been used 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. Over 350,000 patients are diagnosed with septic shock in North America each year, representing a greater than \$3 billion market opportunity for Spectral.

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).

<sup>1</sup>Singer, Deutschman et al, JAMA2016;315(8):801-810

### **Forward-looking statements**

*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, the ability of Spectral to complete the Offering as expected 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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