



## **SPECTRAL ON TRACK FOR POTENTIAL COMMERCIALIZATION IN THE FIRST HALF OF 2016**

**Toronto, Ontario, JANUARY 26, 2015 – Spectral Medical Inc. (“Spectral” or the “Company”) (TSX: EDT) (OTC QX: EDTXF)**, a Phase III company developing the first treatment for patients with septic shock that comprises a therapeutic device guided by a companion diagnostic, today announced continuing progress towards commercialization of a medical device that addresses the critical care needs of patients in a \$3 billion market.

Spectral's septic shock treatment is the only medical device currently in an active U.S. Food and Drug Administration (**the “FDA”**) approved Phase III clinical trial to address this deadly condition which has a mortality rate in excess of forty percent. The product has been in use in Japan and Europe, with published study results and data from medical registries showing success in significantly reducing mortality rates caused by septic shock and demonstrating that the most severely ill patients benefit most from a two column treatment protocol. The Company's EUPHRATES trial targets the same severely ill patient population with a similar treatment protocol. Over 100,000 patients have now been treated with this medical device outside of North America

The current status of commercialization activities is as follows:

- The Company continues to be on track to begin its modular PMA submission in the first half of this year
- A working prototype of our state-of-the-art standalone pump will be demonstrated at the CRRT conference in San Diego in mid-February. This pump is specific to our treatment and is designed to be used in the intensive care unit under the direction of the intensive care doctor and nurse. A 510K submission is targeted by the end of the first half of 2015
- 322 patients have been randomized into the EUPHRATES trial (52 since implementation of the additional exclusion criterion in April, 2014)
- The composite mortality rate of randomized patients in the trial since implementation of the exclusion criterion has risen significantly, which trend continues to suggest a strong clinical indication and that those patients most likely to benefit from the treatment are being properly identified and randomized into the trial
- Statistical modelling suggests a much smaller sample size than previously anticipated to reach a statistically significant outcome. If directed by the Data Safety Monitoring Board and approved by the FDA, we would anticipate that an interim analysis with stopping rules for safety and efficacy could occur before the end of the year
- We expect to close the second \$5 million tranche of our previously announced financing in the second quarter and are confident that we should have access to adequate funds to implement our commercialization initiatives

“We continue to execute our commercialization strategy as planned and anticipate that we could be ready for market launch as early as the first half of 2016,” stated Dr. Paul Walker, President and CEO of Spectral. “Regular updates on our progress will be provided to all of our stakeholders throughout the year,” added Dr. Walker.

## **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. 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 100,000 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 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).

### **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 take advantage of business opportunities in the biomedical industry, the commercialization of Spectral's septic shock treatment, 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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