



SPECTRAL FILES THIRD MODULE OF ROLLING PMA SUBMISSION TO FDA

- Company now enrolling last 65 patients into its Phase III trial -

Toronto, Ontario, November 12, 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 that it has filed the third of four required Pre-Market Approval (“PMA”) modules to the FDA. This module details the manufacturing processes for the Toraymyxin™ (“PMX”) hemoperfusion cartridge. Spectral is in the later stages of a Phase III registration trial for PMX as it seeks FDA approval for this medical device in the United States. The fourth PMA module, related to clinical data, is expected to be filed by no later than the last quarter of 2016 as a final step towards anticipated FDA approval.

As of November 11, 2015 the Company has enrolled 381, or 85%, of the required 446 evaluable patients in its EUPHRATES trial. Enrolment support activities have recently been enhanced and the Company is confident that the trial should be fully enrolled by the end of the second quarter of 2016.

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 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

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 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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