Spectral Announces Results of a Face-to-Face meeting with the U.S. FDA

TORONTO, Canada – December 17, 2018 – Spectral Medical Inc. ("Spectral" or the "Company") (TSX:EDT), a Phase III company developing the first treatment for patients with endotoxemic septic shock guided by a companion diagnostic, today announces the result of a favourable face-to-face meeting with the U.S. FDA.

Spectral has been engaged with the U.S. FDA in an interactive Q-sub process for the design and format of the next trial needed to add to the safety and efficacy data from the EUPHRATES trial. With many of the U.S. FDA's major concerns addressed, the Company expects to update shareholders in the near future with respect to the timing for the initiation of the TIGRIS trial. The TIGRIS Trial is expected to focus specifically on the population of patients that showed a benefit from this therapy in the EUPHRATES trial. TIGRIS is expected to be run exclusively in the United States, preferably in centres that enrolled patients in the EUPHRATES trial.

"Spectral has benefitted greatly from the guidance that the FDA has provided. We believe that, having implemented a majority of their suggestions, that the study will produce robust findings that will add important information on the use of PMX hemoperfusion, and support a potential FDA approval in the future," stated Dr. Paul Walker, President and CEO of Spectral.

A recent publication in Critical Care Medicine reporting on over 2.5 million patients in the U.S. stated that patients who develop sepsis and organ failure while in hospital, such as the EUPHRATES trial patients, had a mortality of 48 percent. This unacceptable mortality and the associated costs, estimated in the paper as over USD$50,000 per patient, makes sepsis/septic shock an enormous burden for patients and their families, and on the healthcare system in the United States and thus a major unmet medical need. (Critical Care Medicine December 2018 • Volume 46 • Number 12)

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.

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 and the TIGRIS Trial, 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, general economic, market and business conditions, as well as other risks and uncertainties which are more fully described in Spectral's Annual Information Form dated March 28, 2018, and in other filings of Spectral with securities and regulatory authorities which are available at www.sedar.com. Spectral does not undertake any obligation to update forward-looking statements should these assumptions change. Nothing in this document should be construed as either an offer to sell or a solicitation to buy or sell Spectral securities.

The TSX has not reviewed and does not accept responsibility for the adequacy or accuracy of this statement.

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