Spectral Announces Publication of the post hoc analysis of EUPHRATES trial in Intensive Care Medicine

TORONTO, Canada – November 26, 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 that a new paper reporting on the population that had a clinically important mortality benefit and other physiologic benefits from PMX within the EUPHRATES trial titled: “Polymyxin B hemoperfusion in endotoxemic septic shock patients without extreme endotoxemia: a post hoc analysis of the EUPHRATES trial” was published in Intensive Care Medicine. The paper is available via “open access – online first” at the following link: https://link.springer.com/article/10.1007/s00134-018-5463-7.

As previously disclosed, the EUPHRATES trial failed to show a statistically significant PMX related survival benefit in the Intention to Treat [all subjects who were randomized] and per protocol [all patients who received two full treatments or full sham event] populations. However, the post hoc analysis revealed there is a population of patients with a high severity of illness (MOD score > 9) and an EAA between 0.6 and 0.89, that showed PMX use is associated with an absolute mortality benefit over sham patients of 10.7% at 28 days. This group of patients also showed improvement in organ function with fewer days relying on mechanical ventilation and renal support in the PMX treated group.

“We have maintained our commitment to learn as much as possible from the EUPHRATES trial database. We have submitted these findings to FDA and are now in discussion with them as to a study design that will allow further efficacy and safety data to be collected on this group of patients; the TIGRIS trial,” said Dr. Paul M Walker, CEO of Spectral.

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, 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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