



## **SPECTRAL ANNOUNCES APPROVAL OF TIGRIS TRIAL BY THE US FDA**

**TORONTO, Canada – February 19, 2019 – 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 announced that the Tigris clinical trial has been approved by the US FDA as an amendment to the original EUPHRATES’s IDE and, as such it will add to the data from the EUPHRATES trial. Patients will be enrolled in the Tigris trial using the same eligibility criteria as those that showed a clinically significant mortality benefit within the EUPHRATES trial.

TIGRIS will use the same primary endpoint of 28 day mortality, is expected to enroll 150 septic shock patients with a MODS score >9 and Endotoxin Activity Assay (EAA) levels between 0.60 and 0.90, will be randomized 2:1 for treatment vs control arm and will be open label. The study will employ a Bayesian statistical approach to combine data from the EUPHRATES trial with data from the Tigris trial. Tigris will be run exclusively in US hospital sites experienced in using the PMX cartridge and who demonstrated a good enrollment rate in the EUPHRATES trial.

“The Company has been engaged in a detailed interactive process with the US FDA to determine the optimal pathway forward with the Toraymyxin™ (“PMX”) cartridge,” said Dr Paul Walker, President and CEO of Spectral. “We are pleased with the guidance from the US FDA, and are confident in the program we have designed to demonstrate efficacy and safety to support a future application for approval of this potentially lifesaving treatment. The incidence of sepsis and septic shock continues to rise in the United States and continues to carry an unacceptably high mortality rate, which in this patient group has been shown to be in excess of 40%.

We anticipate that the Tigris trial will begin enrollment in the near future, and will provide necessary efficacy and safety confirmatory data for the use of Toraymyxin (PMX) in septic shock patients. Identifying patients most likely to respond to this treatment based on knowledge gained from the EUPHRATES trial remains a unique aspect of this trial. The EUPHRATES trial demonstrated that when the endotoxin activity was in the critical treatment range of 0.6 to 0.9 a clinical benefit of mortality reduction and improvement in organ function was seen. The EAA remains the only assay cleared by the FDA for measurement of endotoxin activity.

The US FDA has also recently reviewed a new special 510(k) submission for the EAA, wherein the company upgraded some of the assay features including rigorous data in support of the sensitivity and reliability of the assay at the 0.9 EA units cut-off.

### **About the EUPHRATES Trial**

The EUPHRATES trial was a prospective double blinded trial design to assess safety and effectiveness of the PMX treatment in patient with endotoxemic septic shock. Although, overall, the trial did not show a mortality benefit, a subgroup was identified that had a clinically significant mortality benefit when treated with the PMX cartridge. The data showed that for patients with high levels of endotoxin activity in the range of 0.60 to 0.90 EA units and that received the full dose of the PMX cartridge exposure, there was a mortality benefit, (absolute reduction in mortality of 10.7% a 30% relative risk reduction), as well as

important secondary endpoints related to organ function (days alive and free of mechanical ventilation and renal support). These findings were published in the November issue of Intensive Care Medicine.

### **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 US FDA cleared diagnostic for the risk of developing sepsis.

PMX has been approved for therapeutic use in Japan, Europe and Asia 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](http://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 clinical trials, 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](http://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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