Spectral Medical Provides November Tigris Trial Update

- ***79 patients enrolled***

TORONTO, Dec. 04, 2023 -- **Spectral Medical Inc. ("Spectral" or the "Company") (TSX: EDT),** a late-stage theranostic company advancing therapeutic options for sepsis and septic shock, today provided an update for the month of November on the Company's Tigris trial, a Phase 3 follow-on study evaluating the use of Polymyxin B Hemoperfusion ("PMX") in a randomized controlled trial of adults treated for endotoxemia and septic shock.

- 79 patients enrolled to date and continuing to close in on the interim target of 90 patients, an important milestone as the Company's strategic commercial partner, Baxter (NYSE:BAX), will have the opportunity to view the data as well as provide a second milestone payment to Spectral.
- Currently 20 Tigris trial sites, with near term onboarding of new, high quality clinical sites.
- Crude mortality results at both 28-day (primary endpoint) and at 1-year, thus far, continue to exceed efficacy targets.

Dr. John Kellum, Chief Medical Officer of Spectral, commented, "In November we experienced strong enrollment into Tigris despite the U.S. Thanksgiving holiday, with five patient enrollments in the last six weeks. We continue to make progress opening additional sites, which should positively impact the pace of enrollment. Additionally, the high rates of influenza that we are witnessing across the southern U.S. and California could have a positive impact on our enrollment, as influenza is often a trigger for bacterial sepsis. Overall, we are rapidly advancing our Tigris trial and remain highly encouraged by the outlook, given the fact preliminary mortality data continues to exceed our expectations."

"We continue to be very bullish on the outcome of the Tigris trial. We recently published a Bayesian methodology paper in a major scientific journal. The analysis clearly indicates that our trial strategy is highly likely to succeed in our goal of FDA approval for PMX. The simulations involving over 2,000 potential trial results show that using the planned 75% weight on the prior EUPHRATES data, an observed absolute risk reduction for mortality of 7% in Tigris is at approximately the 95% probability threshold for declaring PMX effective. Current results from Tigris are far in excess of this threshold," said Chris Seto, Chief Executive Officer of Spectral. "Additionally, we are making steady headway towards reaching out our interim count of 90 patients, which is expected to play as a major catalyst for the Company."

The Tigris Trial methods paper "**Bayesian methods: a potential path forward for sepsis trials**" can be accessed at: *https://doi.org/10.1186/s13054-023-04717-x*

About Spectral

Spectral is a Phase 3 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 is approved for therapeutic use in Japan and Europe, and has been used safely and effectively on more than 340,000 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. In July 2022, the U.S. FDA granted Breakthrough Device Designation for PMX for the treatment of endotoxic septic shock. Approximately 330,000 patients are diagnosed with 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 company's ability to raise capital and the availability of funds and resources to pursue R&D projects, the recruitment of additional clinical trial sites, the rate of patient enrollment, the successful and timely completion of clinical studies, the success of Baxter's commercialization efforts, 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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