

Spectral Medical Provides Tigris Trial Update

- **81 patients enrolled**

TORONTO, Dec. 14, 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 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.

Enrollment:

- Robust enrollment activity since the end of October, with 81 patients enrolled to date,
 - Seven patients enrolled over the last eight weeks
 - Screening activity at current sites remains strong with 100+ patients screened per week
- Closing in on the interim enrollment target of 90 patients ("Interim Enrollment"); at Interim Enrollment, Baxter has the option to make the second milestone payment to Spectral to maintain its PMX exclusive distribution rights.
- Crude mortality results at both 28-day (primary endpoint) and at one year, thus far, continue to exceed efficacy targets.

Trial Sites:

- Currently 20 Tigris trial sites, with near term onboarding of new, high quality clinical sites.
 - Clinical Trial Agreements ("CTA") either executed or in final revision phase at six new clinical sites.

EDEN Study:

- Completed the EDEN study, a parallel observational study, in which data is collected on patients with septic shock even if ineligible for Tigris. The EDEN study is among the largest ever to examine the full range of septic shock and its relation to organ failure and endotoxin activity. These data will inform subsequent discussions with the FDA on labelling for PMX and provide important data on potential expanded indications for PMX.

Dr. John Kellum, Chief Medical Officer of Spectral, commented, "Since the end of October, we experienced strong enrollment into Tigris despite the U.S. Thanksgiving holiday, with seven patient enrollments in the last eight 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 are pleased with the pace of enrollment activity since holding our Investigator Meeting this past May. The sustained enrollment activity over these past seven months has put Spectral within striking distance of our interim enrollment milestone of 90 patients, which is expected to play as a major catalyst for the Company," said Chris Seto, Chief Executive Officer of Spectral Medical.

As a reminder, under the exclusive distribution agreement between Spectral and Baxter International (NYSE: BAX), following the enrollment of 90 patients, Baxter has the option to provide a second milestone payment to Spectral in order to affirm and maintain its exclusive distribution rights to PMX.

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.

The Tigris Trial is a confirmatory study of PMX in addition to standard care vs standard care alone and is designed as a 2:1 randomized trial of 150 patients using Bayesian statistics. Endotoxic septic shock is a malignant form of sepsis <https://www.youtube.com/watch?v=6RANrHHi9L8>.

The trial methods are detailed in "[Bayesian methods: a potential path forward for sepsis trials](#)".

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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