

Spectral Medical Provides Update on PMA Submission Timing for PMX-20R

TORONTO, Feb. 26, 2026 -- **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 timing of its Premarket Approval (“PMA”) submission to the U.S. Food and Drug Administration (“FDA”) for its hemoadsorption device to treat endotoxic septic shock.

Following recent interaction with the FDA, the Company now expects to submit its PMA around the end of April to mid-May 2026, compared to its previously disclosed target of Q1 2026.

The updated timing reflects ongoing FDA feedback to incorporate complete 12-month mortality data from the Tigris study into the PMA submission, as well as the completion of certain non-clinical module items, including human factors engineering testing, to support a complete and compliant submission.

The Company believes the inclusion of complete 12-month mortality outcomes will further inform the FDA’s review and contribute to the totality of clinical evidence supporting PMX for the treatment of endotoxic septic shock.

Spectral currently anticipates being in a position to report topline 12-month mortality data in late May or early June 2026, subject to the completion of additional data analysis.

“We continue to work constructively with the FDA to ensure a high-quality PMA submission,” said Chris Seto, Chief Executive Officer of Spectral Medical. “The inclusion of longer-term mortality data and completion of the remaining non-clinical components are intended to support a comprehensive submission and will position PMX for an efficient review process.”

Spectral continues to work closely with the FDA on the PMA submission process and will provide updates as appropriate.

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 FDA cleared Endotoxin Activity Assay (EAA™), the clinically available test for endotoxin in blood.

PMX is approved for therapeutic use in Japan and Europe, licensed by Health Canada, and has been used safely and effectively with over 360,000 units sold worldwide 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 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 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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