



## **SPECTRAL MEDICAL FILES EXPANDED ACCESS PROTOCOL WITH FDA FOR TORAYMYXIN™ SEPTIC SHOCK TREATMENT**

**Four patients remaining to enroll in the EUPHRATES clinical trial**

**Company expects to announce trial results and submit final PMA module before end of 2016**

**Toronto, Ontario, May 31, 2016** – Spectral Medical Inc. ("**Spectral**" or the "**Company**"), (TSX:EDT) (OTCQX:EDTXF), a Phase III Company advancing a precision treatment targeting specific patients at high risk of death from septic shock, today announced that it has filed a protocol and is in discussions with the U.S. Food and Drug Administration (FDA) for Expanded Access of Toraymyxin™, the Company's investigational therapeutic hemoperfusion device that removes endotoxin from the bloodstream. The Company also announced several significant updates and milestones achieved on its path to potential regulatory approval and anticipated commercial availability of its treatment in the United States.

The Expanded Access program, sometimes referred to as Compassionate Use, if approved by the FDA, would begin upon the completion of patient enrollment – expected no later than June 30, 2016 – at most of the 29 U.S. hospitals currently participating in the Phase III EUPHRATES clinical trial. Patients who meet the clinical criteria for septic shock, are in multiple organ failure and who have elevated levels of endotoxin in the blood, as measured by the Company's FDA cleared Endotoxin Activity Assay (EAA™), would be eligible for the treatment. A similar program is planned for Canada, where there are 12 hospitals engaged in the clinical trial.

"Currently, there is no approved treatment for patients in septic shock, the most advanced and lethal stage of sepsis, and clinicians are left with very few options to treat the sickest of patients," said Dr. Paul Walker, President and CEO of Spectral. "Toraymyxin™ represents a new solution for sepsis treatment and has been used on more than 150,000 patients outside of North America over the course of more than a decade. Provided the FDA approves our Expanded Access program, this treatment could be available soon for use in select patients at participating clinical trial locations in the United States."

Spectral also provided guidance today on several significant clinical and regulatory milestones:

- As of today, only four patients remain to be enrolled in the EUPHRATES trial, which is fully on track to be completed by no later than June 30, 2016.
- The FDA has accepted Spectral's statistical analysis plan for the PMA submission of Toraymyxin™. Subsequent to analysis of the trial data, the Company expects to announce primary end point results around the end of September 2016 and will then submit the last module of the PMA. The first three modules have already been submitted to the FDA. Assuming positive clinical data and barring any unexpected delays, Spectral anticipates a decision from the FDA as early as the first quarter of 2017.
- The Company has submitted a 510K to the FDA for a proprietary stand-alone pump dedicated to the Toraymyxin™ therapy that would facilitate treatment delivery in the Intensive Care Unit (ICU) and increase options available to clinicians. The pump is also designed to provide an open platform for other hemoperfusion cartridges and to deliver continuous renal replacement therapy when indicated. A decision is expected in Q3 2016 and, if approved, the pump will be available for use in the Expanded Access program where needed.
- In anticipation of potential FDA approval of Toraymyxin™, Spectral and Toray Industries Inc. (Toray) are both taking the necessary operational steps to scale up manufacturing capabilities in order to be ready to begin sales in the first half of 2017. A new plant has been built by Toray in Japan for the manufacture of Toraymyxin™ and EAA™ manufacturing capacity has been expanded in Toronto. The Company is also currently engaged in confidential discussions with potential interested partners that have existing sales and marketing infrastructures and it will be evaluating all potential options going forward.

“The progress we have demonstrated so far represents the culmination of six years of diligent work on clinical, regulatory and commercialization programs to bring the first approved product for endotoxemic septic shock to market and the finish line is in sight,” added Dr. Paul Walker. “The imminent completion of patient enrollment in the EUPHRATES trial is an important step that brings Spectral significantly closer to addressing an enormous unmet medical need.”

Over 1,000,000 patients are diagnosed with sepsis in the United States each year and over 300,000 of these patients die annually despite best practices employed by critical care and intensive care unit hospital staff.

## **About Spectral Medical Inc.**

Spectral is a Phase III company seeking U.S. FDA approval for its lead theranostics product for the treatment of endotoxemic septic shock. Toraymyxin™ (PMX) is a therapeutic hemoperfusion device that removes endotoxin, a main trigger of sepsis and septic shock, from the bloodstream. Directed by the Company's Endotoxin Activity Assay (EAA™), the only FDA cleared diagnostic for the risk of developing sepsis, Spectral's EUPHRATES trial is the world's only active and most innovative Phase III study for a medical device in the area of septic shock.

PMX has been approved for therapeutic use in Japan and Europe, and has been used 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. Over 350,000 patients are diagnosed with septic shock in North America each year, representing a greater than \$3 billion market opportunity for Spectral.

Spectral is listed on the Toronto Stock Exchange under the symbol EDT, and on the OTCQX under the symbol EDTXF. For more information, please visit [www.spectraldx.com](http://www.spectraldx.com).

## **Forward-looking statements**

*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 commercialize its products, the ability of Spectral to take advantage of business opportunities in the biomedical industry, the granting of necessary approvals by regulatory authorities, the ability of Spectral to complete the Offering as expected 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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