



## **Spectral Medical Announces Acceptance of Pre-Clinical PMA Module for Toraymyxin™ by FDA**

**Company remains on track and anticipates final submission in Q4 2016**

**FDA accepts Spectral's 510(k) filing for its standalone pump for review**

**Toronto, Ontario, June 16, 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 the U.S. Food and Drug Administration (FDA) has reviewed and accepted one of the two pre-clinical modules in its PMA application for Toraymyxin™, the Company's investigational therapeutic hemoperfusion device that removes endotoxin from the bloodstream. With acceptance of this module the Company remains on track to complete its full PMA submission by the end of 2016.

“As we look toward completing our submission to the FDA this year, the Agency’s acceptance of this module is a significant milestone,” said Dr. Paul Walker, President and CEO of Spectral. “This particular section contains key pre-clinical data on the use of Toraymyxin™ for patients with septic shock, including the device’s engineering and bench testing; sterilization and shelf life; packaging and transport details. We are encouraged that the FDA accepted this data, which is critical to our submission, as we continue to advance our regulatory filing with the goal of bringing this treatment to people in need.”

A novel therapy for certain patients in septic shock, Toraymyxin™ is specifically targeted at those with elevated levels of endotoxin in the blood. Toraymyxin™ is a direct hemoperfusion adsorption column that has been shown to be highly effective in removing endotoxin. Studies have shown that this medical device can remove up to 90 percent of an endotoxemic patient’s circulating endotoxin when administered twice within a 24 hour period.

As part of the modular PMA filing, Spectral will submit a total of four modules of documentation for review in stages by the FDA. Two of the modules include pre-clinical information, one describes the manufacturing process and the last module contains clinical data. Three modules have been submitted and one of the pre-clinical modules has now been fully reviewed and accepted. Spectral plans to submit its fourth and final module, comprising data from its pivotal EUPHRATES trial, by the end of 2016.

In related news, Spectral announced that the FDA has also accepted for review the Company's separate 510(k) filing for a standalone pump that could facilitate treatment delivery in the Intensive Care Unit (ICU) and increase options available to clinicians.

### **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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