



U.S. FDA APPROVES SPECTRAL'S THIRD PMA MODULE FOR ITS TORAYMYXIN™ TREATMENT OF ENDOTOXEMIC SEPTIC SHOCK

TORONTO, Canada – March 7, 2017 – Spectral Medical Inc., (“Spectral” or the “Company”), (TSX: EDT) a Phase III company developing the first treatment for patients with endotoxemic septic shock using a medical device, today announced that it has received approval of the third module of its rolling PMA submission from the United States Food and Drug Administration (“FDA”) for Toraymyxin™. The third PMA module details the device description and principles of operation and all manufacturing processes, including risk management and quality system integration.

“We are very encouraged with the FDA’s response and approval of the third module. This follows our announcement on February 23, 2017, that we plan to file our fourth and final module containing clinical data early in the second quarter of this year,” stated Dr. Paul Walker, President and CEO of Spectral. “The acceptance of the third PMA module by the FDA is another step forward on our regulatory pathway.”

About Spectral

Spectral is a Phase III 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 has been approved for therapeutic use in Japan and Europe, and has been used safely and effectively 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. Approximately 350,000 patients are diagnosed with severe sepsis and 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 availability of funds and resources to pursue R&D projects, whether the FDA will accept the Company’s submission of the final PMA module seeking potential approval of Toraymyxin™, the successful and timely completion of clinical studies, the safety or efficacy of the Toraymyxin™, column, 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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