



SPECTRAL ANNOUNCES SUCCESSFUL MANUFACTURING AUDIT OF TORAY BY THE US FDA

TORONTO, Canada – July 18, 2018 – Spectral Medical Inc. (“Spectral” or the “Company”) (TSX: EDT), a Phase III company developing the first treatment for patients with endotoxemic septic shock guided by a companion diagnostic, today announced that Toray Industries, manufacturer of the PMX-20R® cartridge, has successfully passed a GMP Audit with the US FDA. The audit was performed as part of the pre-approval process for Spectral’s ongoing PMA application for the PMX cartridge. A successful GMP audit for Toray means that the methods, the facilities and the controls used for the manufacture, processing, packing, and testing of the device were found adequate to ensure and preserve its identity, strength, quality, and purity.

<https://www.accessdata.fda.gov/scripts/inspsearch/results.cfm>

Dr. Paul Walker, President and CEO of Spectral states that, “while we have been confident in Toray’s manufacturing expertise, this endorsement from FDA, ensures Toray’s readiness for commercial manufacturing for the United States market. This GMP audit along with positive FDA audits of the CRO and study sites, that have recently been completed, confirms the quality and integrity of the EUPHRATES clinical trial data submitted to the FDA.”

Tory built a new manufacturing plant in Okasaki Japan, which has been producing the PMX cartridge since 2014 and was the subject of this recent audit. This plant is capable of meeting the demands of the North American market for PMX required with the potential of FDA approval.

The PMX cartridge is the world’s first device for sepsis that works by selective adsorption of endotoxin from the bloodstream. While the product has received CE Mark approval in Europe and Canada as well as many other countries, the PMA process in the US consists of a compilation of sections or "modules," such as preclinical, clinical, and manufacturing, that together are a complete application.

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, 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, general economic, market and business conditions, as well as other risks and uncertainties which are more fully described in Spectral's Annual Information Form dated March 28, 2018, and in other filings of Spectral with securities and regulatory authorities which are available at www.sedar.com. Spectral does not undertake any obligation to update forward-looking statements these assumptions change. Nothing in this document should be construed as either an offer to sell or a solicitation to buy or sell Spectral securities.

The TSX has not reviewed and does not accept responsibility for the adequacy or accuracy of this statement.

For further information please contact:

Dr. Paul Walker
President and CEO
Spectral Medical Inc.
416-626-3233 ext. 2100
pwalker@spectraldx.com

Ali Mahdavi
Capital Markets & Investor
Relations
416-962-3300
am@spinnakercmi.com