



US Food and Drug Administration (FDA) provides communication to Spectral

TORONTO, Canada – March 19, 2018– Spectral Medical Inc., (TSX: EDT), a Phase III company developing the first targeted treatment for patients with septic shock today announced that the FDA has determined that more evidence is required to make a final determination to approve the PMX cartridge.

The FDA acknowledged the unmet need for therapies in septic shock patients who face a high risk of death, and the challenges in performing clinical studies in this vulnerable patient population. Therefore the FDA encouraged Spectral to utilize mechanisms other than randomized placebo-controlled trials (such as the EUPHRATES trial) to add to the evidence already submitted, and they provided Spectral with several less burdensome examples, including single arm studies, data obtained outside the US and real world registries.

In addition, the FDA offered to discuss Spectral's proposal for further data collection in order to develop a mutually agreeable plan.

"Today with this communication from the FDA, we see Spectral as being much closer to obtaining approval of PMX in the United States," said Dr. Paul Walker, CEO of Spectral. "We are looking forward to working with the FDA to determine the next step to getting the PMX cartridge approved, and in the shortest possible time frame."

The Company, today, considers its US clinical development program to be as follows:

- The EUPHRATES trial identified a clearly defined per protocol subgroup where PMX provides a 42% relative risk reduction in 28 day mortality, with improvement in several secondary endpoints. This treatment benefit was seen in the 194 patients with pre-treatment EAA between 0.6 and 0.9, and multiple failing organ systems (MODS>9).
- As set out in its guidance documents, any sub-group analysis presents certain "non-approvable" challenges for the FDA to overcome, with the FDA preferring to see prospective hypothesis-confirming data coming from an entire study patient group.
- We are pleased the FDA undertook such a thorough review of the data, consider their response to be supportive for a path forward, and expect to schedule a meeting with the FDA in the near future to develop a plan that generates additional data under a "least burdensome" approach. We anticipate this plan to be substantially limited in cost and time lines compared to the EUPHRATES trial.

Once the Company has determined its regulatory path forward with the FDA it will be in a position to further announce those plans, and provide updates on financial and other strategic matters.

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.

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. There is no guarantee that Spectral will obtain the FDA approval of PMX in the United States

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

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