

SPECTRAL FILES FINAL PMA MODULE FOR TORAYMYXIN™ WITH FDA

Further analysis demonstrates population with significant mortality benefit

TORONTO, Canada – May 30, 2017 – Spectral Medical Inc., (“Spectral” or the “Company”), (TSX: EDT), a Phase III company developing the first treatment for patients with septic shock guided by a companion diagnostic, today announced that it has submitted the fourth and final module of its PMA application to the United States Food and Drug Administration (“FDA”) based on further analysis of the EUPHRATES trial - a randomized, blinded trial of patients in endotoxemic septic shock comparing use of Toraymyxin™ (“the PMX cartridge”) versus sham hemoperfusion.

As previously communicated, the trial did not meet its primary end point, but did show a non-statistically significant mortality reduction at 28 days of slightly less than five per cent in the per protocol population of patients with septic shock, Endotoxin Activity Assay (“EAA”) ≥ 0.6 and Multiple Organ Dysfunction Score (MODS) > 9 ($n=244$), when treated with the PMX cartridge.

A further detailed analysis of the EUPHRATES trial data base, however, has shown that there appears to be an upper limit to a patient’s pre-treatment burden of endotoxin as measured by the EAA, above which the trial could not demonstrate benefit for the PMX cartridge. This magnitude of burden, when EAA is ≥ 0.9 , has recently been described in an article in press for upcoming publication.

In patients with septic shock, MODS >9 and a baseline EAA ≥ 0.6 and < 0.9 ($n=194$) the PMX treatment group demonstrated an absolute reduction in mortality of 14% at 14 days ($p=0.0103$), 10.7% at 28 days ($p=0.0474$) and 11% at 90 days ($p=0.0383$), when baseline APACHE and mean arterial pressure were controlled in each arm. At 28 days, the relative reduction in mortality was 30%. Survival over time analysis showed a statistically significant and sustained increase in survival at all three time points: 52% risk reduction at 14 days (Hazard Ratio [“HR”] 0.48, $p=0.0189$), 42% risk reduction at 28 days (HR 0.585, $p=0.0429$) and 41% risk reduction at 90 days (HR 0.594, $p=0.0373$).

In this patient population, an improvement in organ function was seen in the PMX treated group compared to the sham group. There was a statistically significant increase in mean arterial blood pressure 72 hours post treatment for the PMX group ($p=0.0462$) and a substantial increase in days alive and free from mechanical ventilator support [median difference of 14 days, ($p=0.0043$)].

Furthermore, the trial data indicates that for patients where no bacteria could be identified by culture yet were highly endotoxemic (approximately one third of the $n=194$ group), treatment with the PMX cartridge had a 28 day mortality of 21% versus 42% for the sham group ($p=0.046$), a relative risk reduction of 50%. These patients appear to be at higher risk for baseline mortality, with endotoxemia likely due to translocation of endotoxin from the gastro-intestinal system. With no microbiology targets to treat there are fewer options left to help these patients.

“The design of the EUPHRATES trial, using a targeted diagnostic and therapeutic, has allowed major progress to be made in understanding the pathophysiology of endotoxemic septic shock. We found that a patient population, identified by the EAA and with clinical features of significant organ dysfunction, may benefit from use of the PMX cartridge. The trial also demonstrated the ease of use of the products, based on approximately 95% of patients being treated within protocol timelines and a very low rate of clotting of the cartridge. The safety of the PMX cartridge has been demonstrated by the lack of any serious unanticipated adverse device effects. This is a significant step forward in



demonstrating a potential benefit in a personalized approach to the treatment of patients with endotoxemic septic shock”, stated Dr. Paul Walker, president and CEO of Spectral. “The EUPHRATES trial also demonstrated that over one third of septic shock patients continue to die despite the highest level of care provided by top North American medical centres,” added Dr. Walker.

Key Results of the EUPHRATES trial will be presented at the International Nephrology Congress in Vicenza, Italy on June 14, 2017 and will be the subject of a manuscript currently in preparation for submission to a major peer-reviewed medical journal. The Company plans a live webcast of the Vicenza presentation.

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”). The PMX cartridge is a therapeutic hemoperfusion device that removes endotoxin, which is a potent mediator of 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.

The PMX cartridge is currently approved for therapeutic use in many countries outside of the United States 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 the PMX cartridge 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 review of the data from the clinical trial, 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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