



## LARGEST JAPANESE REGISTRY DATA ANALYSIS DEMONSTRATES SIGNIFICANT REDUCTION IN MORTALITY RATE OF SEPTIC PATIENTS TREATED WITH TORAYMYXIN™

- *Data presented at the American Society of Nephrology supports Spectral's EUPHRATES trial design*
- *Toraymyxin™ treatment resulted in an approximate 25% relative reduction in mortality*

**Toronto, Ontario, NOVEMBER 25, 2014 – Spectral Diagnostics Inc. (“Spectral” or the “Company”)** (TSX: SDI) (OTC QX: DIAGF), a Phase III company developing the first theranostic treatment for patients with septic shock, today announced the presentation of the largest ever analysis of Japanese registry data on the significant mortality rate reduction in patients with septic shock treated with Toraymyxin™ (“PMX”). The results of the study and analysis were presented at the American Society of Nephrology and support Spectral’s EUPHRATES trial design.

The study, conducted by Dr. M. Iwagami of the University of Tokyo in Japan and supported by the Japanese government, reviewed the Japanese Diagnosis Procedure Combination Database (based on the ICD-10 international classification) and compared 1,116 patients with septic shock treated with PMX who also received continuous renal replacement therapy (“CRRT”) to 1,115 patients with septic shock who were treated with CRRT only. CRRT is a form of dialysis reserved for some of the sickest patients in intensive care units.

The mortality rate of patients treated with two PMX cartridges was 34.5% compared to 47.0% in the untreated group, representing an approximate 25% relative reduction in mortality at 28 days. The authors contrasted these results with those of a study they had conducted one year earlier, in which they evaluated the effect of PMX treatment on a cohort of less severe septic patients and found little difference in survival rates between the treated and untreated groups. The authors concluded, in their presentation at the American Society of Nephrology, that PMX therapy is most effective in patients at the highest risk of death. Furthermore, they noted that those patients who were treated with two PMX cartridges demonstrated a more meaningful benefit versus those treated with only one cartridge. This is the same treatment methodology used in the EUPHRATES trial.

“The results of this very large analysis support our EUPHRATES trial design wherein only the most severe septic shock patients (organ failure score > 9) are eligible for randomization into the trial. These are the patients with the highest risk of death from septic shock and this analysis emphasizes the benefit of PMX in high risk groups,” noted Dr. Paul Walker, President and Chief Executive Officer of Spectral. “Furthermore, the analysis clearly shows a significant reduction in mortality of patients with septic shock using the same two cartridge treatment methodology as in our trial.”

## **About Spectral Diagnostics Inc.**

Spectral is a Phase III company seeking U.S. FDA approval for its lead theranostics product for the treatment of endotoxemic septic shock. PMX is a therapeutic hemoperfusion device that removes endotoxin, a main trigger of sepsis, 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 100,000 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 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 SDI, and on the OTCQX under the symbol DIAGF. 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 take advantage of business opportunities in the biomedical industry, the commercialization of Spectral's septic shock treatment, 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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