# U.S. FDA APPROVES SPECTRAL'S AMENDED PROTOCOL FOR ITS EUPHRATES TRIAL

**Toronto, Ontario, June 3, 2014 - Spectral Diagnostics Inc. (TSX: SDI) (OTCQX: DIAGF)** (**"Spectral"** or the **"Company"**), a Phase III company developing the first theranostic treatment for patients with septic shock, today announced that the U.S. Food and Drug Administration (FDA) has approved the amended protocol for its EUPHRATES trial, reflecting the recommendations of the Data Safety Monitoring Board (DSMB) of April 9, 2014. The DSMB recommended an additional exclusion criterion be added to the clinical protocol and that the sample size should be increased to 650 patients.

The DSMB recommended that patients with a Multiple Organ Dysfunction Score (MODS) score of ≤ 9 no longer be eligible for randomization in the trial. The MODS score is a recognized scoring system used to evaluate the degree of organ dysfunction which exists in patients with sepsis. This recommendation is consistent with data from previous PMX trials, which demonstrated that the PMX column is most effective in reducing mortality rates of sicker patients.

"These are very important and positive recommendations for our trial," said Dr. Paul Walker, President and CEO of Spectral. "We believe these refinements in our patient population significantly increase our chances for a positive outcome. The depth of information from our second interim analysis, as was originally planned, has enabled our trial to focus on those patients most likely to benefit from our treatment."

"Our trial has been using the new exclusion criterion since its recommendation on April 9, 2014," stated Debra Foster, Vice President of Clinical Development for Spectral. "Our committed trial sites have incorporated this new exclusion criterion and we are targeting enrolment rates consistent with the timelines we have predicted for the completion of the trial by the end of the first half of 2016. To date, 600 patients have met all clinical inclusion criteria and 283 patients with high endotoxin levels have been randomized into the trial."

## About Spectral Diagnostics

Spectral is a Phase III company seeking U.S. FDA approval for its lead theranostics product (Toraymyxin) for the treatment of septic shock. Toraymyxin is a therapeutic hemoperfusion device that removes endotoxin, which can cause 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 first theranostics trial in the area of sepsis.

Spectral is listed on the Toronto Stock Exchange under the symbol SDI, and on the OTC QX under the symbol DIAGF. 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, the ability to manufacture products and supply the market, as well as general economic, market and business conditions, and could differ materially from what is currently expected.

**For more information, please contact:**

**Spectral Diagnostics Inc.**

Dr. Paul Walker
President and CEO
416-626-3233 ext. 2100

Adam Peeler
Investor Relations
416-815-0700 ext. 225
apeeler@tmxequicom.com