SPECTRAL PROVIDES UPDATE ON ITS PATH TO COMMERCIALIZATION

U.S. FDA Confirms Regulatory Pathway through a Modular PMA, with Submission Targeted for the First Half of 2015

Spectral Anticipates Commercialization as early as the First Half of 2016

Toronto, Ontario, NOVEMBER 5, 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 provided an update on the Company's recent and upcoming activities, demonstrating a clear commercialization path to address the critical care needs of patients in a $3 billion market.

Spectral's septic shock treatment is the only medical device currently in an active U.S. Food and Drug Administration **(the "FDA")** approved Phase III clinical trial to address this deadly condition which has a mortality rate in excess of forty percent. While the Company is making progress with the FDA ,with the objective of reaching commercialization in North America as early as the first half of 2016, the product has been in use in Japan and Europe, with published results showing success in significantly reducing mortality rates caused by septic shock. Over 100,000 patients have now been treated with this medical device.

Regulatory pathway

In late September, 2014, Spectral received notice from the FDA concerning the Company's overall path to commercialization, whereby the FDA approved the Company's statistical plan subsequent to the second interim analysis of the EUPHRATES trial, and also agreed to a clear regulatory pathway. In that regard, the FDA has agreed to accept a modular Premarket Approach **("PMA")**, which Spectral is targeting to submit in the first half of 2015. The modular submission provides the opportunity to meaningfully accelerate the commercialization period to as early as the first half of 2016 upon FDA approval. The first three modules, covering preclinical and manufacturing matters, are targeted for submission in the first half of 2015.

Clinical trial

The sample size recalculation resulting from the second interim analysis established a maximum of 605 evaluable trial patients. As at October 31, 2014, Spectral has randomized 308 patients into the trial and is currently implementing specific measures on a site by site basis to accelerate enrolment at 50 hospitals in North America. The composite mortality rate of randomized patients in the trial since the implementation of an additional exclusion criterion in early April, 2014 has increased significantly, which trend suggests a strong clinical indication and that those patients most likely to benefit from the treatment are being properly identified and randomized into the trial. This composite mortality rate is similar to that seen in the prior European EUPHAS study, which demonstrated a significant mortality reduction in septic shock

patients with no adverse effects. The enrolment initiatives and the composite mortality trend should help to further accelerate the path to commercialization.

Commercialization

The Company has also taken a number of other operational and strategic measures to prepare itself for commercialization in 2016. These measures include the development of a proprietary stand-alone pump dedicated to the therapy that enables treatment delivery in the Intensive Care Unit **("ICU")**and reduces reliance on third party instrumentation; the automation of the EAA™ testing to simplify the process and to significantly reduce lab technician time in hospitals; the automation and scale up of the manufacturing process at Spectral's plant in Toronto, Canada to increase production capacity and operational efficiencies; and last, the Company is planning for a sales and distribution infrastructure capable of servicing a large potential market at the appropriate time.

"I am very pleased with the progress we have made in recent months and I am even more confident that the Company is on the right path to successful commercialization in a reasonable timeframe," noted Dr. Paul Walker, President and CEO of Spectral Diagnostics Inc. "We expect to be able to provide all of our stakeholders with regular updates in the upcoming months as we continue to execute on our plan to bring to market an effective and safe treatment for septic shock, an area of significant unmet medical need, as early as 2016."

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

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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