

Spectral Expands its Renal Replacement Therapy Development Program to Include the Home Dialysis Market

TORONTO, March 20, 2019 (GLOBE NEWSWIRE) -- Spectral Medical Inc. ("Spectral" or the "Company") (TSX: EDT), a Phase III company developing the first treatment for patients with endotoxemic septic shock guided by a companion diagnostic, today announces that it has entered into an agreement with Infomed SA to extend its license for the CRRT (Continuous Renal Replacement Therapy) market to include the home-dialysis market in the US and Canada.

CRRT and Home Hemodialysis represent important opportunities in the comprehensive dialysis market. They are both characterized by double digit annual growth rates, as well as a favorable competitive landscape in North America. In addition, the hemoperfusion function of the CRRT instrument can be used to deliver PMX therapy for patients in the ICU when it is approved for use in the US.

"Our successful collaboration with Infomed facilitated FDA and Health Canada clearances for our innovative CRRT Machine "SAMI", which is now entering the market. We are pleased to extend this relationship to the home hemodialysis market where we can enhance the life style of chronic dialysis patients by empowering them to take control of their life through a simple, safe and affordable home hemodialysis system," said, Dr. Gualtiero Guadagni, Vice President at Spectral.

As part of the transaction, Spectral transferred in its Renal Replacement Therapy (RRT) business to a newly created wholly owned subsidiary to be run by Dr. Gualtiero Guadagni. That subsidiary will be focused on the commercial development of SAMI, its proprietary CRRT machine, as well as on the regulatory development of a Home Hemodialysis Machine (DIMI) based on the same platform.

"At Spectral we remain committed to completing the TIGRIS trial in as short a time as possible," said Dr. Paul Walker CEO of Spectral. "By creating a separate subsidiary and program for Renal Replacement Therapy we can develop its full potential without distracting from the Company's core commitment to Regulatory approval in the US for the PMX cartridge."

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 US FDA cleared diagnostic for the risk of developing sepsis.

PMX has been approved for therapeutic use in Japan, Europe and Asia 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 PMX, 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 and clinical trials, 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, general economic, market and business conditions, as well as other risks and uncertainties which are more fully described in Spectral's Annual Information Form dated March 28, 2018, and in other filings of Spectral with securities and regulatory authorities which are available at www.sedar.com. Spectral does not undertake any obligation to update forward-looking statements should these assumptions change. Nothing in this document should be construed as either an offer to sell or a solicitation to buy or sell Spectral securities.

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

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