



Dialco Medical Inc. Engages CROMSOURCE as Contract Research Organization Partner for DIMI IDE Trial

TORONTO, Canada – June 7, 2021 – Spectral Medical Inc. (“Spectral” or the “Company”) (TSX: EDT), a late stage theranostic company advancing therapeutic options for sepsis and septic shock, as well as commercializing a new proprietary platform targeting the renal replacement therapy market through its wholly-owned subsidiary Dialco Medical Inc. (Dialco), today announced that Dialco has engaged CROMSOURCE, a full-service Contract Research Organization (“CRO”), for its upcoming DIMI IDE usability clinical trial. CROMSOURCE is a high quality, ISO certified international provider of outsourced clinical trial services that has been a trusted partner to pharmaceutical, medical device, and biotechnology companies for more than 20 years.

DIMI is an innovative renal replacement system that is cleared by the FDA to treat patients with acute and/or chronic renal failure with or without fluid overload using hemodialysis, hemodiafiltration, hemofiltration and/or ultrafiltration in hospital or clinical settings. The prospective multicenter, open label, non-randomized and cross-over study is designed to evaluate the safety and efficacy of DIMI in the home setting by analyzing delivered dialysis dose and potential adverse events happening during six weeks of use at home compared to six weeks of use in the hospital setting on the same patients. The trial will include 35 evaluable patients in the United States and is expected to enroll the first patient by the end of the third quarter of 2021.

CROMSOURCE is a recognized global leader in conducting clinical trials for innovative drugs, biologics, and medical devices. Specifically, more than one-fourth of the company’s activities involve the testing of medical devices, translating to more than twenty-five such trials per year. Beyond more than two decades of experience managing medical device clinical trials, CROMSOURCE’s foundation is built upon the delivery of high-quality services, and in fact is one of the only international CROs to be ISO 14155:2011 certified for medical device studies. Moreover, CROMSOURCE has recently completed multiple studies in a dialysis setting, which is one of the critical success factors for this trial. “We are excited to bring on an accomplished partner in CROMSOURCE, which has extensive expertise in managing clinical trials for small to medium size medical device companies like Dialco,” said Dr. Gualtiero Guadagni, President of Dialco Medical Inc. “Onboarding CROMSOURCE is an important milestone in the DIMI trial’s initiation process. We believe that with CROMSOURCE’s broad clinical experience in both the renal and medical device fields, as well as a deep understanding of the DIMI trial, we are poised to achieve key trial milestones within our expected timelines in the United States.”

“We are looking forward to supporting Dialco with their DIMI regulatory trial,” said Dr. Troy W. McCall, Chief Commercial Officer of CROMSOURCE. “DIMI appears to be an easy-to-use device with the potential to overcome many usability barriers to home hemodialysis. We believe the trial is well designed and positioned for successful execution. The CROMSOURCE team is excited to partner with such a recognized global leader as Dialco and their parent, Spectral Medical. While our experience in managing medical device trials is important to Dialco, our flexibility and adaptability, particularly during a global pandemic, makes us the ideal partner. We look forward to a long-term and productive partnership with the Dialco team,” continued Dr. McCall.

Chris Seto, CEO of Spectral, commented, “Dialco is committed to disrupting the current landscape in renal replacement therapies by empowering patients and their care partners to transfer to home hemodialysis (HHD) care and thereby improve their overall quality of life. Currently, just 2% of patients are eligible for HHD, however, we believe that DIMI holds the potential to increase the market for HHD to nearly 30% of patients by addressing key barriers to market adoption. Specifically, we believe DIMI overcomes the inherent complexities and skillsets required for current dialysis systems. Additionally, DIMI provides users greater confidence, is easier to set up,

reduces service and maintenance requirements, lowers overall costs, and addresses water quality issues, through the use of pre-packaged water bags. As a result, we believe DIMI will be the only device capable of performing both peritoneal and home hemodialysis, a key differentiator that we believe will drive rapid market adoption. We look forward to working closely with CROMSOURCE as we rapidly advance this important trial.”

About Spectral

Spectral is a Phase 3 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 FDA cleared diagnostic for the risk of developing sepsis.

PMX is approved for therapeutic use in Japan and Europe, and has been used safely and effectively on more than 300,000 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 330,000 patients are diagnosed with severe sepsis and septic shock in North America each year.

Spectral, through its wholly owned subsidiary, Dialco Medical Inc., is also commercializing a new set of proprietary platforms addressing renal replacement therapy (**RRT**) across the dialysis spectrum. SAMI is targeting the acute RRT market, while DIMI is targeting the chronic RRT market. Dialco is currently pursuing regulatory approval for U.S. in-home use of DIMI, which is based on the same RRT platform as SAMI, but will be intended for home hemodialysis use. DIMI recently received its FDA 510k clearance for use in hospital and clinical settings, and obtained its Health Canada license for use within Canadian hospitals, clinics and in home.

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 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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