

## FORM 51-102F3

### MATERIAL CHANGE REPORT

#### Item 1. Name and Address of Company

Spectral Medical Inc. ("Spectral")  
135-2 The West Mall  
Toronto, Ontario  
M9C 1C2

#### Item 2. Date of Material Change

February 3, 2020.

#### Item 3. News Release

A press release describing the material change was issued by the Corporation on February 4, 2020 and filed on SEDAR and is attached as Schedule "A".

#### Item 4. Summary of Material Change

Baxter International Inc. ("**Baxter**") and Spectral announced a distribution agreement for TORAYMYXIN™ PMX-20R ("**PMX**"), a hemoperfusion filter, and the Endotoxin Activity Assay™ ("**EAA**"), an on-market companion diagnostic tool that aids in the risk assessment of ICU patients for progression to severe sepsis. PMX is an investigational device in the U.S. that removes endotoxin, which contributes to sepsis, from the bloodstream.

As part of the agreement, Baxter has agreed to pay Spectral a series of milestone payments including a US\$5 million upfront rights payment. Baxter will be Spectral's exclusive distributor of the PMX filter in the U.S. and Canada and has non-exclusive rights to distribute the EAA globally. Spectral will receive access to Baxter's market capabilities while retaining control over the PMX regulatory approval process. Baxter has the option to maintain exclusive rights for PMX through future milestone payments and maintaining certain performance obligations.

#### Item 5. Full Description of Material Change

Baxter and Spectral announced a distribution agreement for PMX and EAA, an on-market companion diagnostic tool that aids in the risk assessment of ICU patients for progression to severe sepsis. PMX is an investigational device in the U.S. that removes endotoxin, which contributes to sepsis, from the bloodstream.

As part of the agreement, Baxter has agreed to pay Spectral a series of milestone payments including a US\$5 million upfront rights payment. Baxter will be Spectral's exclusive distributor of the PMX filter in the U.S. and Canada and has non-exclusive rights to distribute the EAA globally. Spectral will receive access to Baxter's market capabilities while retaining control over the PMX regulatory approval process. Baxter has the option to maintain exclusive rights for PMX through future milestone payments and maintaining certain performance obligations.

Recruiting for Spectral's Tigris clinical trial for PMX ([www.clinicaltrials.gov](https://www.clinicaltrials.gov/ct2/show/study/NCT03901807): NCT03901807) is underway in the U.S., and the trial is expected to be completed in late 2021. Tigris is a follow-on study that builds on knowledge gained from the EUPHRATES trial, a large prospective randomized blinded trial performed in North America and completed in 2018. Tigris is a prospective randomized, open labelled trial of 150 patients with a 2:1 randomization favoring the treatment arm. The end point remains a reduction in the 28-day mortality using the PMX filter versus the standard of care.

The EAA, which is the only commercially available, FDA cleared test to measure endotoxin activity in whole blood, is a semi-quantitative test for the measurement of endotoxin activity and allows for rapid measurements to obtain results in approximately 30 minutes. While Spectral's EAA is currently cleared by the FDA, Baxter plans to commercialize the EAA and PMX filter together following successful completion of the Tigris trial and subsequent FDA approval. Baxter plans to market the diagnostic tool in some countries in Europe, where the EAA is currently CE marked, alongside the company's Oxiris blood purification set.

Oxiris is a 3-in-1 set for continuous renal replacement therapy (CRRT)-sepsis management to help simplify multiple treatment challenges for critically ill patients. The Oxiris set is designed to combine three functionalities in a single device: endotoxin removal, cytokine removal, and fluid/uremic toxin removal. Oxiris is not approved for use in the United States.

**Item 6. Reliance on Section 7.1(2) or (3) of National Instrument 51-102**

Not applicable.

**Item 7. Omitted Information**

Not applicable.

**Item 8. Executive Officer**

Chris Seto  
Chief Financial Officer  
Spectral Medical Inc.  
Tel: 416-626-3233 x 2004  
cseto@spectraldx.com

**Item 9. Date of Report**

February 4, 2020.



FOR IMMEDIATE RELEASE

**BAXTER AND SPECTRAL MEDICAL ANNOUNCE EXCLUSIVE  
DISTRIBUTION AGREEMENT FOR BLOOD FILTER IN U.S. AND CANADA**

- *Agreement will enable Baxter to expand its Acute Therapies portfolio to address unmet needs*
- *Agreement provides Spectral with a strategic commercialization partner and their access to a large number of hospitals*
- *Spectral to receive upfront exclusive rights payment*

**DEERFIELD, Ill. and TORONTO, ON FEBRUARY 4, 2020** – Baxter International Inc. (NYSE:BAX), a leading global medical products company, and Spectral Medical Inc. (TSX:EDT), a late stage theranostic company advancing therapeutic options for sepsis and septic shock, today announced a distribution agreement for TORAYMYXIN™ PMX-20R (PMX), a hemoperfusion filter, and the Endotoxin Activity Assay™ (EAA), an on-market companion diagnostic tool that aids in the risk assessment of ICU patients for progression to severe sepsis. PMX is an investigational device in the U.S. that removes endotoxin, which contributes to sepsis, from the bloodstream.

As part of the agreement, Baxter has agreed to pay Spectral a series of milestone payments including a US\$5 million upfront rights payment. Baxter will be Spectral's exclusive distributor of the PMX filter in the U.S. and Canada and has non-exclusive rights to distribute the EAA globally. Spectral will receive access to Baxter's market capabilities while retaining control over the PMX regulatory approval process. Baxter has the option to maintain exclusive rights for PMX through future milestone payments and maintaining certain performance obligations.

"Spectral believes that Baxter is the best industry partner to commercialize the PMX product within the U.S. and Canada," said Dr. Paul Walker, CEO of Spectral. "This agreement provides Spectral access to Baxter's large installed base of critical care devices in hospitals across the U.S. and Canada, and Spectral believes this partnership significantly accelerates the company's commercialization efforts for PMX."

"This agreement provides an opportunity to broaden our portfolio and expand Baxter's offering in sepsis management," said Reaz Rasul, general manager, Baxter's Acute Therapies

business. “We are partnering with Spectral to advance purposeful innovation to help clinicians address a serious issue in critical care.”

Recruiting for Spectral’s Tigris clinical trial for PMX ([www.clinicaltrials.gov](http://www.clinicaltrials.gov): NCT03901807) is underway in the U.S., and the trial is expected to be completed in late 2021. Tigris is a follow-on study that builds on knowledge gained from the EUPHRATES trial, a large prospective randomized blinded trial performed in North America and completed in 2018. Tigris is a prospective randomized, open labelled trial of 150 patients with a 2:1 randomization favoring the treatment arm. The end point remains a reduction in the 28-day mortality using the PMX filter versus the standard of care.

The EAA™, which is the only commercially available, FDA cleared test to measure endotoxin activity in whole blood, is a semi-quantitative test for the measurement of endotoxin activity and allows for rapid measurements to obtain results in approximately 30 minutes. While Spectral’s EAA™ is currently cleared by the FDA, Baxter plans to commercialize the EAA™ and PMX filter together following successful completion of the Tigris trial and subsequent FDA approval. Baxter plans to market the diagnostic tool in some countries in Europe, where the EAA is currently CE marked, alongside the company’s **Oxiris** blood purification set.

**Oxiris** is a 3-in-1 set for continuous renal replacement therapy (CRRT)-sepsis management to help simplify multiple treatment challenges for critically ill patients. The **Oxiris** set is designed to combine three functionalities in a single device: endotoxin removal, cytokine removal, and fluid/uremic toxin removal. **Oxiris** is not approved for use in the United States.

### The Impact of Sepsis and the Role of Endotoxin

Globally, a recent study estimated that 48.9 million incident cases of sepsis were recorded in 2017, resulting in 11 million sepsis-related deaths.<sup>1</sup> In the U.S. alone, sepsis has a high cost of hospitalization consuming more than \$27 billion per year<sup>2</sup> with an estimated 1.5 to 2 million new cases diagnosed each year<sup>3</sup>. Septic shock, the most severe form of sepsis, is predominantly treated in the ICU.

The use of blood purification filters to remove cytokines and endotoxin from the blood represents a promising approach to treat patients with conditions where excessive levels of those inflammatory mediators are often seen, including sepsis. Additional research is ongoing to understand the potential of blood purification to help address sepsis and other conditions.

**PMX is not approved for use in the United States.**

**Rx Only.** For safe and proper use of the devices mentioned, refer to the full Instructions for Use.

### **Intended Use Information for EAA**

The EAA™ is a rapid in vitro diagnostic test that utilizes a specific monoclonal antibody to measure the endotoxin activity in EDTA whole blood specimens.

The information, when used in conjunction with other clinical information and other relevant diagnostic tests, aids in the risk assessment of patients in the ICU for progression to severe sepsis. Patients tested on their first day of admission to the ICU where the endotoxin activity (EA) value is  $\geq 0.60$ , are three times more likely to develop severe sepsis within the next three days than subjects whose EA values are  $< 0.40$  and should be closely monitored for such occurrence.

### **Intended Use Information for Oxiris**

The **Oxiris** set is indicated for use only with the **Prismaflex** control unit or with the **PrisMax** control unit (in countries where PRISMAX is cleared or registered). It is intended for patients in need of blood purification, including continuous renal replacement therapy, and in conditions where excessive endotoxin and inflammatory mediator levels exist.

This set is intended for use in the following veno-venous therapies: SCUF; CVVH; CVVHD; CVVHDF.

All treatments administered with the **Oxiris** set must be prescribed by a physician. It is contraindicated to use the **Oxiris** set where patients present a known allergy to heparin or have type II thrombocytopenia caused by heparin (HIT Syndrome type II).

### **About Spectral Medical**

Spectral is a late stage theranostic 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 has been approved for therapeutic use in Japan and Europe, and has been used on more than 170,000 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.

Spectral, through its wholly owned subsidiary, Dialco Medical Inc. (“Dialco”), is also commercializing a new proprietary platform, “SAMI”, targeting the renal replacement therapy (“RRT”) market. Dialco is also seeking regulatory approval for “DIMI” which is based on the same RRT platform, but will be intended for home hemodialysis use. Spectral is listed on the Toronto Stock Exchange under the symbol EDT. For more information, please visit [spectraldx.com](http://spectraldx.com).

### About Baxter

Every day, millions of patients and caregivers rely on Baxter’s leading portfolio of critical care, nutrition, renal, hospital and surgical products. For more than 85 years, we’ve been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter’s employees worldwide are now building upon the company’s rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit [www.baxter.com](http://www.baxter.com) and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

*Baxter: This release includes forward-looking statements concerning a distribution agreement entered into by Baxter and Spectral Medical, including expectations regarding the financial impact and other benefits of such agreement for Baxter. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: Baxter’s ability successfully commercialize the product and realize the benefits of the agreement; demand for and market acceptance of new and existing Spectral products; the ability of Baxter to develop, manufacture and commercialize, as applicable, new and existing products; product quality or patient safety concerns; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; and other risks identified in Baxter’s most recent filing on Form 10-K and other SEC filings, all of which are available on its website. Baxter does not undertake to update its forward-looking statements.*

*Spectral Medical: 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.***



Baxter and **Oxiris** are registered trademarks of Baxter International Inc. **EAA** is a registered trademark of Spectral Medical. TORAYMYXIN™ PMX is a registered trademark of Toray Industries, Inc.

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<sup>1</sup> Rudd, Kristina E., et al. Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study. *Lancet* 2020; 395: 200–11

<sup>2</sup> AHRQ, 2014

<sup>3</sup> JAMA Netw Open. 2019;2(2):e187571. doi:10.1001/jamanetworkopen.2018.7571