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HEALTH CANADA APPROVES BAXTER'S 3-IN-1 BLOOD PURIFICATION SET FOR USE IN CONTINUOUS RENAL REPLACEMENT THERAPY AND SEPSIS MANAGEMENT PROTOCOLS

- *New indication to help remove excessive levels of cytokines and endotoxins in patients needing blood purification makes oXiris the first 3-in-1 set available in Canada*
- *Elevated levels of specific cytokines and endotoxins are frequently seen in patients with sepsis, a serious medical condition and 12th leading cause of death in Canada*[1]

MISSISSAUGA, ON, July 10, 2018 – Baxter Canada today announced Health Canada's approval of a new indication for the company's **oXiris** set, which can now be used to help remove excessive levels of cytokines, endotoxins and other inflammatory mediators from a patient's blood. **oXiris** is Canada's first blood purification set for simultaneous use in continuous renal replacement therapy (CRRT) and sepsis management protocols.

Previously, the **oXiris** set was only indicated for CRRT – a type of extracorporeal (outside of the body) blood purification (EBP) used with Baxter's **Prismaflex** system to manage patients with acute kidney injury (AKI). Often the result of illness, trauma or infection, AKI, is the sudden loss of kidney function that can create an accumulation of toxins and fluid in the blood that, if left untreated, may lead to death.

"Our mission to save and sustain lives is grounded in our determination to innovate across our portfolio in order to more effectively treat patients," said Stephen Thompson, President and General Manager, Baxter Canada. "The ICU is a particular focus, as patients are often battling very serious, complex, life-threatening conditions. Introducing products like **oXiris**, intended to advance care opportunities for the most critically ill, is a priority."

The use of EBP to remove cytokines and endotoxins from the blood represents a promising approach to treat conditions in patients with excessive levels of inflammatory mediators like cytokines and endotoxins, which are released by cells into the blood when the body becomes inflamed. One such condition is sepsis, which affects up to 40 percent of ICU patients worldwide[2,3,4,5,6,7,8] and currently has no proven effective therapies for treatment[9]. Research indicates that cytokines and endotoxins may contribute to the condition[10,11,12].

Even with improvements in health care, the frequency of sepsis continues to increase. It is estimated that 1 in 18 deaths in Canada are related to sepsis, making it the 12th leading cause of death nationally. Although sepsis is not commonly cited as the primary cause of death, it is often a significant contributing factor. Approximately $325 million is spent annually in Canada to treat these complex patients[1].

While EBP is being studied for its potential to help address sepsis, confirmation of an association is challenging due to the complexities of critically ill patients with AKI and/or sepsis, whom often require multiple therapeutic interventions[13], making it difficult to assess individual treatment outcomes.

"It's extremely important for Baxter to bring our latest innovations to Canada," said Victoria Jurincic, Business Unit Head, Baxter Renal in Canada. "We are excited to launch this indication that will provide Canadian healthcare practitioners access to a promising new therapy option."

Baxter first showcased the indication in September 2017 when it received CE mark and regulatory approval for the label expansion in more than 30 countries in Europe and certain countries in the Middle East and Africa. Baxter currently plans to file for the expanded indication in additional countries. The **oXiris** set is not currently approved in the United States.

About Our Acute Therapies Portfolio

A leader in multi-organ support therapy options, Baxter has been at the forefront of advancing new technologies and revolutionizing treatment for critically ill patients around the world. Baxter's leading **Prismaflex** system offers clinicians the flexibility to meet patients' diverse needs and powers our portfolio of products to deliver a complete range of extracorporeal (outside the body) blood purification (EBP) therapies to help manage patients with AKI, acute respiratory distress syndrome, autoimmune

diseases and/or sepsis. **PrisMax**, Baxter's next generation EBP system, is currently expected to launch commercially in select countries later in 2018.

About Baxter Canada

Every day, millions of patients and caregivers rely on Baxter's leading portfolio of critical care, nutrition, renal, hospital and surgical products. In Canada, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen for 80 years. 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. Baxter Canada and its nearly 1,000 employees are located primarily in Ontario at the Head Office, CIVA Admixing and Technical Services Centres in Mississauga, and in Alliston – where Baxter operates Canada's only large scale manufacturing plant producing life-sustaining intravenous and dialysis solutions. To learn more, visit www.baxter.ca and follow us on Twitter, LinkedIn and Facebook.

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