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# BAXTER OBTAINS U.S. FDA EMERGENCY USE AUTHORIZATION FOR REGIOCIT REPLACEMENT SOLUTION USED IN CRRT

- *Only authorized citrate-based replacement solution available in the U.S. for use in continuous renal replacement therapy (CRRT) during COVID-19 pandemic*
- *Supports need for regional citrate anticoagulation in patients at increased risk of bleeding during CRRT*
- *Marks Baxter's fourth FDA Emergency Use Authorization during COVID-19 pandemic, reinforcing its commitment to addressing the needs of critically ill patients*

**DEERFIELD, Ill., AUGUST 14, 2020** – Baxter International Inc. (NYSE:BAX), a global leader in acute care, announced it has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for **Regiocit**, the company's replacement solution that contains citrate for regional citrate anticoagulation of the extracorporeal circuit. Under the EUA, **Regiocit** is authorized to be used as a replacement solution only in adult patients being treated with continuous renal replacement therapy (CRRT) and for whom regional citrate anticoagulation is appropriate during the COVID-19 pandemic.

Acute kidney injury (AKI), a potentially life-threatening condition where the kidneys suddenly stop working and fluid and uremic toxins build up in the body, is one of many complications affecting COVID-19 patients. A recent meta-analysis of 20 studies evaluated more than 13,000 hospitalized COVID-19 patients, 43% of whom were in the intensive care unit or had severe infection, and found that AKI prevalence was 17%, with a range of 0.5% - 80.3%.[1] CRRT mimics many of the functions of the natural kidney and is the cornerstone of treatment in patients with severe AKI.[2] A citrate-based replacement solution can be used for regional citrate anticoagulation in patients who are at greater

risk of bleeding during CRRT, as it eliminates the need to administer a blood thinner, such as Heparin, to prevent clotting in the circuit. **Regiocit** is the only authorized citrate-based replacement solution available in the U.S. for use in CRRT during the COVID-19 pandemic.

"Demand for CRRT remains elevated as the COVID-19 pandemic continues to progress, and we're proud to offer **Regiocit** as an important new option to help healthcare providers in the U.S. optimize care for critically ill patients requiring CRRT and regional citrate anticoagulation, while bringing an additional supply of replacement solutions to the U.S.," said Reaz Rasul, general manager of Baxter's Acute Therapies business.

During CRRT, the patient's blood passes through an extracorporeal filter where fluid and uremic toxins are removed before the cleaned blood is returned to the body. CRRT allows for slow and continuous removal of fluid and toxins, which can be better tolerated than other conventional treatments in patients who are hemodynamically unstable. Replacement fluids are needed during CRRT to flush toxins from the body and replace electrolytes and volume lost during the filtration process. There have been reports of increased filter clotting in COVID-19 patients during CRRT, which may result from cytokine storms that occur in some patients when high levels of inflammatory mediators circulate in the blood as an intense immune reaction to the virus.[3] Clotting can disrupt the flow of blood and impact the effectiveness of treatment. An anticoagulant is often infused into the blood circuit to help prevent clotting during CRRT.[4]

**Regiocit** contains physiological concentrations of sodium (140 mmol/l), chloride (86 mmol/l) and a low concentration of citrate (18 mmol/L) and can provide the necessary pre-filter volumes required to replace filtration losses during convective therapies. It is used in combination with other standard dialysis and replacement solutions that supplement missing electrolytes such as potassium, magnesium and phosphate.

**Regiocit** has not been approved by FDA in the U.S. but is currently in use in countries around the world, including in Europe and Asia. A limited initial shipment will be available in the U.S. immediately, with more significant production ramping up throughout the coming weeks and months.

## Supporting Acute Dialysis in COVID-19 Patient Care

Baxter continues to provide CRRT machines, fluids and sets to help healthcare facilities address patient needs around the world. Baxter has received EUAs for several of its products used in CRRT, including **Oxiris**, the HF20 Set and the ST Set. **Oxiris** is the only filter set available in the U.S. to reduce pro-inflammatory cytokine levels in the blood, including for use in CRRT, for confirmed COVID-19 cases admitted to the ICU with confirmed or imminent respiratory failure who require blood purification. Under its EUA, the HF20 Set is authorized to deliver CRRT to treat patients of low weight (8-20 kg) and low blood volume who cannot tolerate a larger extracorporeal circuit volume in an acute care environment during the COVID-19 pandemic. The ST Set is authorized for use under its EUA to provide CRRT to treat patients in an acute care environment during the COVID-19 pandemic. Both the HF20 Set and ST Set can be used with the **PrisMax** or **Prismaflex** control units (monitors). The FDA has not cleared or approved **Oxiris**, the HF20 Set and the ST Set. Rather, the EUAs authorize the products for use in CRRT during the COVID-19 pandemic. As the pandemic evolves, Baxter remains focused on supporting healthcare providers during these extraordinary circumstances.

## 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 and follow us on Twitter, LinkedIn and Facebook.

**Rx Only.** Please see full Instructions for Use.

## Important Safety Information for Regiocit

**Regiocit** is authorized by FDA under an Emergency Use Authorization to be used as a replacement solution only in adult patients being treated with CRRT and for whom regional citrate anticoagulation is appropriate during the COVID-19 pandemic. **Regiocit** will be administered only by a licensed healthcare provider in a critical care setting and will be available for use only in facilities that Baxter has qualified and provided appropriate training on the use of **Regiocit**. **Regiocit** is authorized for use for no longer than the duration of the COVID-19 public health emergency and has neither been

cleared or approved by the FDA. **Regiocit** is intended to be used in continuous venovenous hemofiltration (CVVH) and hemodiafiltration (CVVHDF) modalities.

Contraindications for the use of **Regiocit** include:

- Severe liver failure
- Shock with muscle hypoperfusion
- Known hypersensitivity to any component of **Regiocit**

All treatments with **Regiocit** must be prescribed by a physician. The size, weight, metabolic and fluid balance, cardiac status, and general clinical condition of the patient must be carefully monitored by the prescribing physician before each treatment.

*This release includes forward-looking statements concerning **Regiocit**, including potential benefits associated with its use (in connection with the COVID-19 epidemic or otherwise) and its anticipated availability. 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: ability to maintain supply continuity; actions of regulatory bodies and other governmental authorities (including with respect to the granting, potential extension or termination of any new or existing EUA by FDA); contractual requirements, product quality, manufacturing or supply, or patient safety issues; changes in law 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 Baxter's website. Baxter does not undertake to update its forward-looking statements.*



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[1] Shelief Y. Robbins-Juarez, BA, Long Qian, MD, Kristen L. King, MPH, Jacob S. Stevens, MD, S. Ali Husain, MD, MPH, Jai Radhakrishnan, MD, Sumit Mohan, MD, MPH. A Systematic Review and Meta-Analysis Of Outcomes for Patients with COVID-19 and Acute Kidney Injury. Kidney Int Rep. Published online June 24, 2020

[2] Lins RL, Nephrol Dial Transplant. 2012;27:4252-4255

[3] Rabb H. Kidney diseases in the time of COVID-19: major challenges to patient care. J Clin Invest. 2020;130(6):2749-2751.

[4] Ashita Tolwani, M.D. Continuous Renal-Replacement Therapy for Acute Kidney Injury. N Engl J Med 2012; 367:2505-2514.