FOR IMMEDIATE RELEASE

**Media Contact**
Andrea Johnson, (224) 948-5353
media@baxter.com

**Investor Contact**
Clare Trachtman, (224) 948-3020

# BAXTER OBTAINS U.S. FDA EMERGENCY USE AUTHORIZATIONS FOR HF20 SET AND ST SET USED IN CRRT DURING COVID-19 PANDEMIC

- *Provides additional options to help meet increased demand for continuous renal replacement therapy (CRRT) products resulting from COVID-19 pandemic*
- *Most recent example of Baxter's efforts to increase supply of dialysis products used in an acute care environment*

**DEERFIELD, Ill., AUGUST 12, 2020** – Baxter International Inc. (NYSE:BAX), a global leader in acute care, announced it has received Emergency Use Authorizations (EUAs) from the U.S. Food and Drug Administration (FDA) for the company's HF20 Set and ST Set used in continuous renal replacement therapy (CRRT). 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 Prismaflex or PrisMax control units (monitors).

"With the continued need for CRRT products, the addition of the HF20 Set and ST Set offers healthcare providers and hospitals greater flexibility to meet the varying needs of patients, while making more CRRT sets available in the U.S.," said Reaz Rasul, general manager of Baxter's Acute Therapies business. "With the HF20 Set, we are thrilled to help expand access to CRRT to low weight patients 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 median 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] During CRRT, the patient's blood passes through a special filter where fluid and uremic toxins are removed before the cleaned blood is returned to the body.

The HF20 Set offers low extracorporeal blood volumes (58mL) and the PolyArylEtherSulfone (PAES) filter membrane to clear uremic toxins and manage fluid overload. The ST Set includes three sizes that allow the healthcare provider to choose the most appropriate option for the patient. It features Baxter's proprietary **AN69** membrane, which can adsorb toxins with basic residues on the surface by means of ionic interactions.

Both the HF20 Set and ST Set are pre-connected disposable sets used with Baxter's **Prismaflex** and **PrisMax** monitors, and work with all CRRT modalities and most commonly used anti-coagulants. The HF20 Set and ST Set have not been cleared or approved by FDA in the U.S. but have been in use for more than 10 years across countries in Europe. A limited initial shipment will be available in the U.S. as soon as possible, 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. In April, Baxter received EUA from the FDA for its **Oxiris** filter set. **Oxiris** is the only filter set currently 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. The FDA has not cleared or approved the **Oxiris** filter set; rather, the EUA authorizes the use of **Oxiris** 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.** For safe and proper use of these devices, including contraindications, refer to the full Instructions for Use.

## Important Safety Information for the HF20 Set

The HF20 Set is authorized by FDA under an Emergency Use Authorization 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 HF20 Set should only be used with the **Prismaflex** or **PrisMax** monitors. There are no FDA-approved or -cleared devices for use to provide CRRT to treat low weight (8-20 kg) patients who have low blood volume and who cannot tolerate a larger extracorporeal circuit volume in an acute care environment. The HF20 Set 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 to provide CRRT in an acute care environment during the COVID-19 pandemic.

Relative contraindications (individual risk/benefit to be determined by treating physician) for the use of HF20 Sets include:

- The inability to establish vascular access
- Severe hemodynamic instability
- Known hypersensitivity to any component of the HF20 Set

This set is intended for use in the following veno-venous therapies: Slow Continuous Ultrafiltration (SCUF); Continuous Veno-Venous Hemofiltration (CVVH); Continuous Veno-Venous Hemodialysis (CVVHD); Continuous Veno-Venous Hemodiafiltration (CVVHDF).

All treatments administered with the HF20 Set 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 evaluated by the prescribing physician before each treatment.

## Important Safety Information for the ST Set

The ST Set is authorized by FDA under an Emergency Use Authorization to deliver CRRT to patients in an acute care environment during the COVID-19 pandemic. The system is intended for patients who have acute renal failure, fluid overload or both. The ST Set should only be used with the **Prismaflex** or **PrisMax** monitors. The ST Set 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 to treat patients in an acute care environment during the COVID-19 pandemic.

*This release includes forward-looking statements concerning the HF20 Set, the ST Set and Oxiris, including potential benefits associated with their use (in connection with the COVID-19 epidemic or otherwise) and 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.*



###

[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