FOR IMMEDIATE RELEASE

# BAXTER ANNOUNCES U.S. FDA CLEARANCE OF ST SET USED TO HELP TREAT ACUTE KIDNEY INJURY PATIENTS IN THE HOSPITAL

- *ST Set previously obtained FDA Emergency Use Authorization (EUA) to help meet increased demand for continuous renal replacement therapy (CRRT) products during the COVID-19 pandemic*
- *Offers additional option to provide CRRT for patients in an acute care environment*

**DEERFIELD, Ill., APRIL 5, 2022** – Baxter International Inc. (NYSE:BAX), a global leader in acute care, today announced the U.S. Food and Drug Administration (FDA) 510(k) clearance of the company's ST Set used in continuous renal replacement therapy (CRRT). The ST Set is a pre-connected, disposable, extracorporeal (outside the body) circuit that provides blood purification through a semipermeable membrane to be used with the **PrisMax** or **Prismaflex** control units (monitors). It has been available to customers in the U.S. since August 2020, when it received Emergency Use Authorization (EUA) from the FDA to provide CRRT to treat patients in an acute care environment during the COVID-19 pandemic. The ST Set is currently in use across countries in Europe, Asia Pacific and North and South America.

"We are pleased to offer the ST Set to healthcare providers and hospitals in the U.S. on a permanent basis to continue helping them meet the diverse needs of patients treated with CRRT," said Reaz Rasul, general manager of Baxter's Acute Therapies business. "The ST Set has played an important role in increasing the availability of CRRT sets, which have been in high demand during the COVID-19 pandemic, and this clearance will help expand access to CRRT for patients with acute kidney injury (AKI)."

AKI is a sudden decrease in kidney function over a period of hours to days, often as a result of illness, trauma or infection. The sudden loss of kidney function leads to the accumulation of toxins and fluid in the blood that, if left untreated, may lead to death. AKI is an increasingly common complication of acute illnesses in intensive care units and hospitals[1] [2] [3] and is one of many complications affecting COVID-19 patients. CRRT mimics many of the functions of the natural kidney and is the cornerstone of treatment in patients with severe AKI.[4] During CRRT, the patient's blood

passes through a special filter, such as the ST Set, where fluid and uremic toxins are removed before the cleaned blood is returned to the body.

The ST Set includes three sizes (ST60, ST100 and ST150) 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. The ST Set works with all CRRT modalities and most commonly used anti-coagulants.

## About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions 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

The **Prismaflex** ST set is a single use device that provides blood purification through a semipermeable membrane. The **Prismaflex** ST set is for use only in conjunction with the **Prismaflex** control unit or with the **PrisMax** control unit (in countries where **PrisMax** is cleared or registered). All treatments administered via the **Prismaflex** ST sets must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

If patients suffer from acute kidney injury and / or volume overload, the **Prismaflex** ST set is indicated for continuous renal replacement therapies (CRRT), in modalities such as:

- Slow Continuous UltraFiltration (SCUF)
- Continuous Veno-Venous Hemofiltration (CVVH)
- Continuous Veno-Venous HemoDialysis (CVVHD)
- Continuous Veno-Venous HemoDiaFiltration (CVVHDF)

to perform fluid management and reduction of uremic toxins.

The **Prismaflex** ST100 set and ST150 is indicated for use in patients with a body weight equal or greater than 30kg (66lb) and **Prismaflex** ST60 set is indicated to patients with a body weight greater than 11kg (24lb).

*This release includes forward-looking statements concerning the ST Set, including potential benefits associated with its use. 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: demand for and market acceptance for new and existing products; product development risks; inability to create additional production capacity in a timely manner or the occurrence of other manufacturing or supply difficulties (including as a result of natural disasters, public health crises and epidemics/pandemics, regulatory actions or otherwise); satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; 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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[2] O'Connor ME, Kirwan CJ, Pearse RM, Prowle JR: Incidence and associations of acute kidney injury after major abdominal surgery. Intensive Care Med 2016;42:521-530.

[3] Susantitaphong P, Cruz DN, Cerda J, Abulfaraj M, Alqahtani F, Koulouridis I, Jaber BL: World incidence of AKI: a meta-analysis. Clin J Am Soc Nephrol 2013;8:1482-1493.

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