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BAXTER ANNOUNCES U.S. FDA 510(K) CLEARANCE OF AK 98 HEMODIALYSIS MACHINE

- *Latest technology offers a compact, portable and easy-to-use system for dialysis providers*
- *Includes two-way connectivity to securely transfer prescription and treatment data*
- *Can be used alongside* ***Theranova****, Baxter's novel dialysis membrane*

DEERFIELD, Ill., MARCH 12, 2021 – Baxter International Inc. (NYSE:BAX), a global innovator in renal care, today announced U.S. Food and Drug Administration (FDA) clearance of its next-generation Artificial Kidney 98 (**AK 98**) dialysis machine, which is designed to be a portable and easy-to-use system to administer hemodialysis (HD) treatments. **AK 98** offers encrypted, two-way connectivity, which enables the system to pull prescriptions directly from the electronic medical record (EMR) for simplified workflow and data handling.

"We designed this latest version of our **AK 98** system to help dialysis providers minimize the operational challenges that can come with administering multiple hemodialysis sessions per machine per day," said Gavin Campbell, general manager of Baxter's U.S. Renal Care business. "With our recent De Novo authorization of **Theranova**, our novel dialysis membrane, our latest innovations to support HD provide our customers with choices for therapy and treatment modality."

Due to kidney failure, people with end-stage renal disease retain harmful toxins in their blood. During HD therapy, blood is passed through a dialyzer, which acts as the artificial kidney to filter toxins from the blood. **AK 98** offers several key features to help dialysis providers efficiently manage HD treatment sessions across chronic dialysis and hospital care environments, including:

- Automatic Alert Resolution, which enables the machine to self-clear already corrected pressure alarms and avoid unnecessary stoppage of treatment due to brief pressure fluctuations often related to patient movement. This helps streamline patient management by limiting direct exposure and number of redundant device interventions.
- An intuitive, customizable user interface with app-like functionality designed to simplify prescription management and treatment supervision.
- A fast, simple set-up process that can be completed by a technician or nurse, allowing for greater flexibility and utilization of staff time and resources.
- A stable base design that allows for easy concentrate or portable reverse osmosis (RO) storage and transport with the machine.

AK 98 is a proven dialysis platform that builds on Baxter's longstanding tradition of pioneering and delivering groundbreaking advancements in the HD space. **AK 98** is currently used in more than 90 countries globally and will be available in the U.S. in the coming weeks. More information is available at https://hemodialysis.baxter.com/ak98.

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 this device, refer to the full Instructions for Use.

The **AK 98** dialysis machine is intended to be used for intermittent hemodialysis and/or isolated ultrafiltration treatments of patients with chronic or acute renal failure or fluid overload upon prescription by a physician.

The **AK 98** dialysis machine is indicated to be used on patients with a body weight of 25kg or more.

The AK 98 dialysis machine is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis or hospital care environment.

The AK 98 dialysis machine is not intended for selfcare or home use.

The Theranova Dialyzer is indicated for patients with chronic kidney failure who are prescribed intermittent hemodialysis. It provides an expanded solute removal profile with increased removal of various middle molecules (up to 45 kDa) that may play a pathologic role in the uremic clinical syndrome. The Theranova Dialyzer is not intended for hemofiltration or hemodiafiltration therapy. The total extracorporeal blood volume for the Theranova Dialyzer and the set should represent less than 10% of the patient's blood volume.

This release includes forward-looking statements concerning the AK 98 dialysis machine and Theranova, including anticipated availability and potential benefits associated with their 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: satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues (including as a result of a natural disaster, public health crises and epidemics/pandemics, regulatory actions or otherwise); changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and 10-Q 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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