

#### FOR IMMEDIATE RELEASE

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### BAXTER INITIATES CLINICAL TRIAL FOR CITRATE ANTICOAGULANT FOR USE DURING CONTINUOUS RENAL REPLACEMENT THERAPY

- Trial will determine if and to what extent citrate anticoagulant extends circuit life by reducing blood clotting during continuous renal replacement therapy (CRRT)
- If approved, this product has the potential to be the first citrate anticoagulant cleared for use during CRRT in the U.S.

DEERFIELD, III. (November 2, 2016) — Baxter International Inc. (NYSE: BAX), a global leader in renal innovation, today announced the start of a Phase 3 clinical trial evaluating an investigational drug that combines a citrate anticoagulant and renal replacement solution to determine if and to what extent it lengthens the extracorporeal circuit life in acute kidney injury patients treated with continuous renal replacement therapy (CRRT). Currently, there is no citrate anticoagulant approved for use in CRRT in the United States.

The first patient has been enrolled in the clinical trial and has received CRRT. The multi-center, prospective, randomized, controlled clinical trial, which is expected to run through 2017, will include an estimated 160 ICU patients in the United States and Canada. Patients will be randomly assigned to receive either CRRT with regional citrate anticoagulant (Prismocitrate 18) or CRRT with no anticoagulant. Additional details of the study can be found on clinicaltrials.gov.

"One potential obstacle in delivering effective CRRT occurs when blood flow through the circuit is slowed or completely stopped by blood clots," said Farah Ali, M.D., medical director for Acute therapies at Baxter. "Extending the life of the extracorporeal circuit can help patients with acute kidney injury remain on renal replacement therapy



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as prescribed, while reducing potential complications that can occur when the blood circuit needs to be replaced."

During CRRT, blood passes through the extracorporeal (outside the body) circuit to help clear waste products in the blood, returning it to a normal state. This cleaned blood is then returned to the body. Clinicians can prescribe an anticoagulant to help reduce the likelihood of circuit clotting. When blood flow through the circuit is interrupted, patients may not receive the prescribed dose of CRRT, which may impact its effectiveness.<sup>i</sup> One retrospective study estimated that nearly one-third of patients did not receive the prescribed dose of CRRT, and that interruptions in CRRT were most commonly due to circuit downtime.<sup>ii</sup>

If approved, the product will provide a standardized formulation of renal replacement fluid combined with a citrate anticoagulant. Combining two different drug solutions together may make it easier for healthcare providers to administer therapy at the bedside.

Baxter's citrate anticoagulant combined with renal replacement solution is an investigational drug not currently approved for use in the U.S.

### **About Acute Kidney Injury**

Acute kidney injury (AKI) is a sudden decrease in kidney function over a period of hours to days, often the 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. The most severe stage of AKI requires renal replacement therapy to replace the function of healthy kidneys.



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# About Baxter International Inc.

Baxter provides a broad portfolio of essential renal and hospital products, including home, acute and in-center dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; biosurgery products and anesthetics; and pharmacy automation, software and services. The company's global footprint and the critical nature of its products and services play a key role in expanding access to healthcare in emerging and developed countries. Baxter's employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care.

This release includes forward-looking statements concerning Baxter's investigational citrate anticoagulant and renal replacement solution, including expectations regarding the availability of the drug in the United States, its potential impact on patients and anticipated 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: actions of regulatory bodies and other governmental authorities; satisfaction of regulatory and other requirements; product quality or patient safety issues; changes in laws 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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Baxter is a registered trademark of Baxter International Inc.

<sup>&</sup>lt;sup>1</sup> Ashita Tolwani, M.D. Continuous Renal-Replacement Therapy for Acute Kidney Injury. N Engl J Med 2012; 367:2505-2514.

<sup>&</sup>lt;sup>ii</sup> Venkataraman R, Kellum JA, Palevsky P. Dosing patterns for continuous renal replacement therapy at a large academic medical center in the United States. J Crit Care 2002;17:246-250