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BAXTER ENROLLS FIRST PATIENTS IN U.S. AND COLOMBIA CLINICAL TRIALS FOR HDx THERAPY ENABLED BY THERANOVA

- *Expanded hemodialysis (HDx) therapy enabled by THERANOVA is designed to closely mimic the natural kidney through clearance of small to large middle molecules during dialysis*
- *Two new clinical trials will evaluate effectiveness, safety and health-related quality of life associated with HDx therapy enabled by THERANOVA*
- *THERANOVA dialyzer works with standard hemodialysis equipment without the need for replacement fluid*

DEERFIELD, Ill., Oct. 2, 2017 – Baxter International Inc. (NYSE:BAX), a global innovator in renal care, today announced enrollment of first patients in two new clinical trials for a unique expanded hemodialysis (HDx) therapy enabled by THERANOVA. The U.S. trial is a multi-center, prospective, randomized controlled study to evaluate the effectiveness and safety of THERANOVA, which will support submission for marketing authorization from the U.S. Food and Drug Administration. In addition, health-related quality of life and the potential to reduce medication use will be assessed.

Baxter's HDx therapy enabled by THERANOVA was designed to remove large molecular weight toxins that have been associated with inflammation and cardiovascular health for end-stage renal disease (ESRD) patients.^{1,2,3} The dialyzer is available in select countries around the world including Colombia, where Baxter initiated a second large multi-center, prospective, observational trial designed to understand the impact of removing large uremic toxins on survival and hospitalization.

"These clinical trials allow us to examine the effectiveness and safety of THERANOVA and assess patient relevant outcomes, including health-related quality of life measures and dialysis symptoms," said Dheerendra Kommala, M.D. vice president Renal Medical Affairs, Baxter. "We are dedicated to building evidence to support this unique innovation in hopes of improving standards of care for ESRD patients who rely on HD to stay alive."

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Hemodialysis (HD) therapy is used to treat nearly three million ESRD patients worldwide, and is most often performed three times a week in a clinic. The therapy works by cleaning the blood of toxins and removing extra fluids when it is pumped through an artificial kidney filter or dialyzer, such as THERANOVA.

HDx therapy extends the range of molecules that can be cleared from the blood during HD, resulting in a clearance profile that more closely mimics the natural kidney.⁴ HDx therapy enabled by THERANOVA is performed during conventional HD therapy, does not require generation of replacement fluid and works on standard equipment for operational efficiencies.

In a previous study published in [*Nephrology Dialysis Transplantation*](#), researchers found that HDx enabled by the THERANOVA dialyzer can exceed the performance of other types of dialysis, including high flux hemodialysis and high-volume hemodiafiltration (HDF) for specific large middle molecules, with acceptable albumin removal.⁵ Additionally, independent data presented at ERA-EDTA 2017 indicated HDx therapy effectively removed small and mid-sized toxins at similar rates when compared to high-volume HDF using a larger hemofilter.⁶

“Millions of patients with chronic kidney disease rely on renal innovations every day, many of whom have ESRD and require HD therapy to stay alive,” said Laura Angelini, general manager, Baxter’s Chronic Renal business. “HDx therapy enabled by THERANOVA was designed to build on Baxter’s legacy of providing meaningful innovations, and it is testament of our commitment to supporting the best possible outcomes for HD patients.”

HDx enabled by THERANOVA is available in Europe, select markets in Latin America, the Middle East and Far East, as well as in Australia and New Zealand. It is not yet available for use in the United States.

For prescription only. For safe and proper use of the devices mentioned herein, refer to the THERANOVA Instructions for Use.

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About Baxter

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; surgery 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 HDx enabled by THERANOVA, one of Baxter's dialysis membranes, including expectations regarding 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: 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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¹ Chmielewski et al. *The Peptidic Middle Molecules: Is Molecular Weight Doing the Trick?* Sem Nephrol 2014;34:118–34.

² Neiryneck N, et al. *An update on uremic toxins.* Int Urol Nephrol. 2013; 45:139-50.

³ Duranton F, et al. *European Uremic Toxin Work Group. Normal and pathologic concentrations of uremic toxins.* J Am Soc Nephrol. 2012 Jul;23(7):1258-70.

⁴ Boschetti-de-Fierro A, et al. *MCO membranes: Enhanced Selectivity in High-Flux Class.* Scientific Reports (2015); 5: 18448.

⁵ Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers.* Nephrol Dial Transplant. 2017 ;32:165-172.

⁶ Teatini, U et al. [A short-term report of HD treatments with the new dialyzers Theranova](#). ERA-EDTA 2017, Abstract #MP538