

# FOR IMMEDIATE RELEASE

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# NEW DATA DEMONSTRATES HIGH PERFORMANCE OF HDx ENABLED BY THERANOVA, BAXTER'S NOVEL HEMODIALYSIS THERAPY

- New data from observational studies showed that HDx (expanded hemodialysis) removal performance comparable to HDF therapy
- HDx enabled by the THERANOVA dialyzer offers operational simplicity because it can be delivered with standard hemodialysis equipment

**MADRID**, **JUNE 5**, **2017** — Baxter International Inc. (NYSE:BAX), a global innovator in renal care, highlighted new data on its novel HDx therapy enabled by the THERANOVA dialyzer at the 54<sup>th</sup> Congress of the European Renal Association and European Dialysis and Transplant Association (ERA-EDTA), June 3-6. Data from two independent studies concluded that HDx, or expanded hemodialysis therapy, enabled by the THERANOVA dialyzer effectively removed small and mid-sized toxins at similar rates when compared to hemodiafiltration (HDF), another type of dialysis.

HDx therapy extends the range of molecules that can be filtered from the blood during dialysis, resulting in a filtration profile that more closely mimics the natural kidney.<sup>1</sup> In addition to its clearance profile, HDx enabled by THERANOVA is as simple to perform as conventional hemodialysis (HD) and was designed to work with all HD machines. This allows clinics to offer HDx therapy using existing resources, and eliminates the need for special equipment and added clinic workflow, which is required for HDF. Additionally, HDF cannot be performed effectively for all patients.<sup>2</sup>



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In the first study (*Comparison of hemodialysis with medium cut-off dialyzer and on-line hemodiafiltration on the removal of small and middle size molecules*, Abstract #MP530), Mohamed Belmouaz, M.D. and his colleagues at CHU Poitiers, Université de Poitiers in France, followed 10 patients over a 12-month period, with patients receiving HDF therapy for six months followed by treatment with HDx using a THERANOVA 500 dialyzer for six months. The study evaluated levels of urea, creatinine, beta-2m, and myoglobin in the blood, every two months. These four molecules build up in the blood as a result of kidney failure; HD is performed to filter toxins from the blood with the dialyzer acting as the artificial kidney.

The study concluded that HDx therapy was able to clear the four molecules to a similar extent as high-volume HDF treatment. In addition, the study authors found that albumin levels were maintained during HDx therapy and were similar to the HDF treatment period. Albumin is one of the most important proteins in the body, and a lower serum albumin level has been associated with mortality.<sup>3</sup>

"Based on our experience, we believe that treatment with the THERANOVA dialyzer is a good alternative to HDF treatment," said Dr. Belmouaz. "We saw that HDx offers equivalent clearance of middle molecules coupled with the operational simplicity of using standard hemodialysis infrastructure, equipment, protocols and staffing. Additionally, some patients do not tolerate HDF treatment due to its requirements for ideal vascular access to deliver high blood flows."

In a second observational study (*A short-term report of HD treatments with the new dialyzers Theranova,* Abstract #MP538), Ugo Teatini, M.D. and his colleagues at ASST Rhodense, Garbagnate in Italy, followed eight patients for five weeks where they were assessed at the first week and last week by measuring pre- and post-treatment samples of urea, creatinine, beta2-m, myoglobin, hemoglobin, albumin and total serum protein. HDx offered



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removal rates for both small and medium-sized molecules (beta2-m, myoglobin) comparable to those achieved in high-volume HDF treatments, and maintained albumin levels.

"We see the new HDx therapy as an excellent option for our patients, in particular in frail hemodialysis patients with a central venous catheter (CVC)," said Dr. Teatini. "In these patients, using HDx allows us to administer therapy via the CVC at lower flow rates, whereas HDF would require higher blood flow rates that are hard to attain with a CVC."

In a previous study <u>published in *Nephrology Dialysis Transplantation*</u>, researchers found that HDx enabled by the THERANOVA dialyzer can exceed the performance of high flux hemodialysis and high-volume HDF for specific large middle molecules, with acceptable albumin removal.

ERA-EDTA presentations may be available on the congress website following the meeting. For more information, log on to <u>era-edta2017.org</u>.

THERANOVA dialyzers are indicated for treatment of chronic and acute renal failure by hemodialysis. HDx enabled by the THERANOVA dialyzer 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. More information is available at

hdxtheranova.com.

*For prescription only*. For safe and proper use of the devices mentioned herein, refer to the complete instructions in the Operator's Manual.

### 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



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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 and THERANOVA, one of Baxter's dialysis membranes, including expectations regarding the planned launch of the therapy, 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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<sup>&</sup>lt;sup>1</sup>Boschetti-de-Fierro A, et al. *MCO membranes: Enhanced Selectivity in High-Flux Class*. Scientific Reports (2015); 5: 18448.

<sup>&</sup>lt;sup>2</sup>Golper TA. *Is hemodiafiltration ready for broader use?* Kidney Int 2015; 88:940–942

<sup>&</sup>lt;sup>3</sup><u>Mehrotra R<sup>1</sup>, Duong U, Jiwakanon S, Kovesdy CP, Moran J, Kopple JD, Kalantar-Zadeh K</u> Serum albumin as a predictor of mortality in peritoneal dialysis: comparisons with hemodialysis. <u>Am J Kidney Dis.</u> (2011) 58:418-28.