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BAXTER HIGHLIGHTS NEW CLINICAL DATA SHOWING HDx ENABLED BY THERANOVA REMOVES MID-SIZED UREMIC TOXINS DURING DIALYSIS

- *Studies show expanded hemodialysis (HDx) therapy removes middle molecular weight uremic toxins with minimal albumin loss*
- *HDx enabled by THERANOVA is designed to closely mimic the natural kidney through clearance of small to large middle molecular weight toxins*
- *THERANOVA dialyzer works with standard hemodialysis equipment without the need for replacement fluid*

NEW ORLEANS, NOV. 6, 2017 – Baxter International Inc., a global innovator in renal care, highlighted new data on its expanded hemodialysis (HDx) therapy enabled by the THERANOVA dialyzer, adding to the growing body of evidence demonstrating the novel therapy's removal of mid-sized uremic toxins from the blood with minimal albumin loss. The studies were conducted by clinicians in the United Kingdom and Germany, and were presented at the American Society of Nephrology's annual Kidney Week Congress, Oct. 31-Nov. 5.

Baxter's HDx therapy enabled by THERANOVA was designed to filter a wider range of molecules from the blood than conventional hemodialysis filters, including mid-sized molecular weight uremic toxins that may be associated with inflammation and cardiovascular health for end-stage renal disease (ESRD) patients.[1,2,3] By extending the range of molecules that can be filtered from the blood, HDx results in a clearance profile that more closely mimics the natural kidney.[4,5] HDx is performed the same way as conventional hemodialysis (HD), does not require generation of replacement fluid and works on standard equipment for operational efficiencies.

"We found that HDx therapy was convenient and simple to implement at our hospitals," said Jyoti Baharani, M.D., one of the lead abstract authors from Heart of England NHS Foundation Trust, Birmingham, U.K. "The therapy is promising because it offers effective clearance of middle molecules. This is especially important for patients who are unable to get the prescribed dose of hemodiafiltration."

In the study, "*U.K. clinical experience of a new expanded hemodialysis therapy with novel medium cut-off dialyzer"* (Abstract #SA-PO760), clinicians at Heartlands Hospital and Morristown Hospital compared clearance of β2m, a mid-weight toxin, and albumin levels between HDx and high-flux hemodialysis (HD), and HDx and hemodiafiltration (HDF). At Heartlands Hospital, patients were switched from high-flux HD using the FX60 or FX80 dialyzer to HDx therapy with the THERANOVA dialyzer. Following nine weeks of HDx therapy, pre-dialysis levels of β2m were reduced by 11.7 percent, on average, and no difference in serum albumin level was seen. At Morristown Hospital, the study included 14 patients who failed to tolerate HDF and four who had tolerated HDF. The study demonstrated HDx and HDF were able to effectively remove β2m, with minimal albumin loss.

In a second study conducted in Rostock, Germany, "*Comparison of albumin binding capacity and uremic toxins in hemodiafiltration vs novel dialysis membrane" (*Abstract #SA-PO761), clinicians compared HDx and HDF in 32 patients undergoing dialysis. The study focused on the extent to which each therapy improved albumin binding capacity (ABiC) and removed uremic toxins. ABiC is reduced in patients with advanced stages of chronic kidney disease, which may contribute to increased uremic toxicity.[6]

Patients in the study were treated with six HDF treatments, followed by six HDx treatments. Blood samples taken throughout the study period showed HDx and HDF treatments to provide similar improvements in ABiC and to be similarly effective in reducing levels of uremic toxins. Additionally, albumin concentration remained steady during HDx treatment.

HDx therapy was recently explained in a new clinical publication, "Expanded Hemodialysis: Innovative Clinical Approach in Dialysis"[7] that was edited by Claudio Ronco, M.D., Director, International Renal Research Institute, San Bortolo Hospital, Vincenza, Italy, and includes contributions from several nephrologists interested in implementing new therapy options for patients. The book is intended for healthcare professionals wanting to learn more about emerging science, practice and application of HDx therapy.

"Improving standards of care for dialysis patients will require a combination of innovation, experience, technology, scientific exchange and new mindsets," Dr. Ronco said. "This book is intended to help healthcare professionals better understand how innovation can expand therapy options for patients."

HDx enabled by THERANOVA is available in Canada, Europe, select markets in Latin America, the Middle East and Far East, as well as in Australia and New Zealand. THERANOVA is an investigational device in the United States, and is not available for commercial sale in that market.

In October, Baxter announced enrollment of the first patients in two new HDx therapy enabled by THERANOVA clinical trials, including a multi-center, prospective, randomized controlled clinical trial to support submission for marketing authorization from the U.S. Food and Drug Administration.

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.

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

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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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