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#### BAXTER SUPPORTED NINE NEW ABSTRACT PRESENTATIONS AT THE 55<sup>th</sup> ERA-EDTA CONGRESS THAT FURTHER DEMONSTRATE VALUE OF HDX THERAPY ENABLED BY THERANOVA

- Data indicated HDx is superior to standard high-flux HD in the removal of middle and larger middle molecules
- Findings also indicated stable serum albumin levels using HDx therapy enabled by THERANOVA

**COPHENHAGEN, MAY 30, 2018** — Baxter International Inc. (NYSE: BAX), a global innovator in renal care, announced new data reinforcing that expanded hemodialysis (HDx) enabled by the THERANOVA dialyzer clears large middle molecules at a higher rate when compared to standard hemodialysis (HD), and equivalent or higher removal rates compared to high-volume hemodiafiltration (HDF). Two studies presented also found that albumin levels remained stable during HDx treatment. The findings were shared during scientific exchange at the 55<sup>th</sup> Congress of the European Renal Association and European Dialysis and Transplant Association (ERA-EDTA), May 24-27.

"HDx therapy enabled by THERANOVA was designed to filter a wider range of toxins from the blood than conventional HD filters, because we believe this is a critical step to transforming renal care and improving patient outcomes," said Laura Angelini, general manager of Baxter's Renal Care business. "We are committed to fully exploring and supporting robust scientific exchange about HDx therapy to understand its full potential for dialysis patients."

HDx enabled by THERANOVA is a unique type of HD therapy that targets the removal of large middle molecules<sup>1</sup>, many of which are linked to the development of inflammation, cardiovascular disease, and other co-morbidities in dialysis patients<sup>2</sup>. By extending the range of molecules that can be filtered from the blood, HDx results in a clearance profile that more



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closely mimics the natural kidney<sup>3,4</sup>. 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.

One independent study specifically looked at the effects of HDx in comparison to high-flux HD in a conventional setting and found no loss of serum albumin or serum protein after using a new medium cut-off membrane (THERANOVA) in conventional HD compared to a high-flux dialyzer in hemodialfiltration: "Effects on Clinical and Dialytic Parameters with a New Medium Cut Off Membrane Dialyzer in Conventional Hemodialysis Compared to a High Flux Dialyzer in Online Hemodiafiltration" (Abstract SP468).

In addition, no relevant differences were found in adequacy, anemia or parameters of bone mineral metabolism. These initial findings were a result of a controlled observational study with eight patients. For at least three months before the study, seven patients were on hemodiafiltration and one patient was on conventional HD, both with a high-flux dialyzer.

Another independent study indicated HDx is superior to standard high-flux HD in the removal of middle and larger middle molecules, and it is not inferior to hemodiafiltration in the clearance of small and larger middle molecules: "Evaluation of the Efficacy of a Medium Cut Off Dialyzer and Comparison to other High Flux Dialyzers in Conventional Hemodialysis and Online Hemodiafiltration" (Abstract SaO041).

These observations were made following a cross-over study of 18 prevalent HD patients in three single mid-week dialysis treatments during three consecutive weeks. Therapy was conducted the first week with hemodiafiltration, using a standard high-flux dialyzer; the second week treatment consisted of conventional HD with a standard high-flux dialyzer; and the third week conventional HD with the THERANOVA dialyzer. Reduction ratios of different sized molecules and albumin losses were collected for dialyzer use.



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Additional key data presentations on HDx enabled by THERANOVA included:

- Plasma Molecular Changes in Hemodialysis Patients with Polyarylethersulfone-Polyvinylpyrrolidone Membrane Dialyzer (THERANOVA 400 Baxter): Abstract FP444
- Expanded Hemodialysis vs Online Hemodiafiltration for Middle Sized Molecules Clearance: Abstract FP453
- Comparison of High Flux Hemodialyzers with Medium Cut-Off Dialyzer on the Removal of Middle High Size Uremic Toxins: Abstract FP458
- New Medium Cut-Off Membrane vs Online Hemodiafiltration in Clearance of Middle Molecules. Preliminary Results from Our Centre: Abstract FP466
- A Mid-Term Report of HD Treatments with the New Dialyzers with Medium Cut-Off Membrane (MCO THERANOVA®): Abstract SP481
- Middle Cut Off (MCO) Dialyzers in Patients with Multiple Myeloma Removal of Light Chains with HDx-Therapy: Abstract SP486
- Mid-Term Evaluation of the New Medium Cut-Off Filter (THERANOVA) on Removal Efficiency and Quality of Life: Abstract SP489

A recent in vivo study published in *Clinical Nephrology* also had consistent findings, indicating no significant changes in albumin levels with equivalent removal of small and middle-sized molecules when comparing the THERANOVA 400 dialyzer with high-flux OL-HDF<sup>5</sup>.

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

In the fall of 2017, Baxter announced enrollment of the first patients in two new HDx therapy enabled by THERANOVA clinical trials, including a multi-center, prospective,



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randomized controlled clinical trial to support submission for marketing authorization from the U.S. Food and Drug Administration.

*For prescription only.* For safe and proper use of the devices mentioned herein, refer to the THERANOVA Instructions for Use. It cannot be used with hemodiafiltration.

#### **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 <u>www.baxter.com</u> and follow us on <u>Twitter, LinkedIn</u> and <u>Facebook</u>.

This release includes forward-looking statements concerning 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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<sup>1</sup> Ronco C, et al. *The rise of Expanded Hemodialysis*. Blood Purif 2017; 44:1--VIII.

<sup>2</sup> Hutchison CA, et al. The Rationale for Expanded Hemodialysis Therapy (HDx). Contrib Nephrol 2017; 191:142-52.

<sup>3</sup> Boschetti-de-Fierro A, et al. MCO membranes: Enhanced Selectivity in High-Flux Class. Scientific Reports (2015); 5: 18448.

<sup>4</sup> Kirsch AH, et al. Performance of hemodialysis with novel medium cut-off dialyzers. Nephrol Dial Transplant. 2017;32:165-172.

<sup>5</sup> Belmouaz M, et al. Comparison of hemodialysis with medium cut-off dialyzer and on-line hemodiafiltration on the removal of small and middle size molecules. Clinical Nephro 2018; 89 (1): 50-56.