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BAXTER LAUNCHES HDx THERAPY ENABLED BY THERANOVA TO PROVIDE HIGH PERFORMANCE HEMODIALYSIS TREATMENTS

- By more closely mimicking the filtration profile of the natural kidney, HDx enabled by THERANOVA is a major advancement in hemodialysis therapy¹
- HDx enabled by THERANOVA provides greater clearances of middle and large middle molecules⁴
- HDx enabled by THERANOVA can be used with standard hemodialysis infrastructure and equipment

DEERFIELD, Ill. (October 24, 2016) — Baxter International Inc. (NYSE: BAX), a leader in developing technologies that transform renal care, today announced the global launch of HDx enabled by THERANOVA, a new type of hemodialysis (HD) therapy that provides high performance treatments with integration into existing healthcare infrastructure. Baxter will launch HDx enabled by THERANOVA in Australia, New Zealand, France, Germany, Switzerland and Belgium this year.

“Through HDx enabled by THERANOVA, Baxter is introducing a major advancement in hemodialysis, an area that has seen little improvement in recent years,” said Giuseppe Accogli, corporate vice president and president, Baxter Renal. “We expect HDx enabled by THERANOVA to advance hemodialysis care for millions of patients around the world.”

HDx, or expanded hemodialysis, uses Baxter’s new THERANOVA dialyzer to extend the range of molecules that can be filtered from the blood during therapy, resulting in a filtration profile that more closely mimics the natural kidney.¹ THERANOVA dialyzers are indicated for treatment of chronic and acute renal failure by hemodialysis.

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Due to kidney failure, people with end-stage renal disease retain harmful molecules in their blood. Hemodialysis therapy is performed to remove those molecules, with the dialyzer acting as the artificial kidney. Current hemodialysis therapies, including conventional HD using a low-flux or high-flux dialyzer and hemodiafiltration (HDF), are effective at removing urea and smaller middle molecules but are limited in removing large middle molecules.² Large middle molecules may affect a range of biological functions, including inflammation and cardiovascular risk. The retention of these molecules has also been associated with higher mortality in chronic kidney disease patients.³

[In a recent study published in *Nephrology Dialysis Transplantation*](#), researchers found that THERANOVA removes a wide range of middle molecules more effectively than FX CorDiax, a high-flux dialyzer, and can exceed the performance of high-volume HDF for large solutes, with moderate albumin removal.⁴

In addition to its clearance profile, HDx enabled by THERANOVA is as simple to perform as conventional HD therapy and was designed to work with most 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. HDF is a type of dialysis therapy that also targets larger middle molecules, but is not as widely available as HD and cannot be performed effectively in all patients.⁵

Baxter previously received regulatory clearance for THERANOVA in Australia, New Zealand, France, Germany, Switzerland and Belgium. THERANOVA is not currently available in the United States.

ABOUT THE STUDY

Led by Alexander R. Rosenkranz, M.D., Clinical Division of Nephrology, Medical University of Graz, Austria, and Detlef H. Krieter, M.D., Division of Nephrology, University Hospital Würzburg, Germany, researchers conducted two prospective, randomized, crossover pilot studies in three dialysis centers in Austria and Germany.

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A total of 39 patients were included. The studies focused on clearance of free immunoglobulin light chains (FLC), as FLC levels have been associated with increased mortality risk in chronic kidney disease⁶ and high-flux dialyzers are limited in their ability to remove these molecules. The study found that THERANOVA had higher clearance of middle molecules including FLCs, compared to both HD and HDF.

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.

Forward-Looking Statements *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: 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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¹ Boschetti-de-Fierro A, et al. MCO membranes: Enhanced Selectivity in High-Flux Class. *Scientific Reports* (2015); 5: 18448

² Leyboldt K, et al; Clearance of Middle Molecules during Haemodialysis and Haemodiafiltration: New Insights. *Nephrology Dialysis Transplantation* (2012); 27 (12): 4245-4247.

³ Neiryneck N, et al. An update on uremic toxins. *Int Urol Nephrol*. 2013;45:139-50

⁴ Kirsch A. H., et al. Performance of hemodialysis with novel medium cut-off dialyzers. *Nephrol Dial Transplant* (2016) September 1 Advance Access.

⁵ Golper TA. Is hemodiafiltration ready for broader use? *Kidney Int* 2015; 88:940–942

⁶ Ritchie et al. *Clin J Am Soc Nephrol*. 2015;10:740-9