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**BAXTER ANNOUNCES U.S. FDA DE NOVO AUTHORIZATION FOR THERANOVA DIALYZERS  
ENABLING HDX THERAPY**

- *U.S. patients with kidney failure now have access to expanded hemodialysis (HDX) therapy delivered by **Theranova**, a new class of dialyzer*
- ***Theranova** dialyzer's unique membrane design offers a filtration profile that more closely mimics that of the natural kidney and can be used with existing hemodialysis machines<sup>1,2</sup>*
- ***Theranova** was reviewed by FDA through the De Novo process, a pathway for novel low- to moderate-risk devices*

**DEERFIELD, III., AUGUST 31, 2020** – Baxter International Inc. (NYSE:BAX), a global innovator in renal care, today announced the U.S. Food and Drug Administration (FDA) has granted the De Novo application for [Theranova](#), the company's novel dialysis membrane. **Theranova** was designed to deliver expanded hemodialysis (HDX) therapy, which filters a wider range of molecules from the blood than traditional hemodialysis (HD) filters, like high-flux membranes, by targeting effective removal of conventional (500 Da to 25 kDa) and large middle molecules (25 kDa to 45 kDa)<sup>3,4,5</sup>. These middle molecules may be associated with inflammation and cardiovascular disease in patients with kidney failure<sup>3,4,5</sup>.

By granting a De Novo application, the FDA is establishing a new class of dialyzer technology with unique performance standards. The FDA utilizes the De Novo pathway for low and moderate risk medical devices that have no existing predicate in the United States; such designations are rare in the dialysis space. In fact, less than 1% of devices granted marketing authorization under [De Novo](#) have been for the care of patients with kidney failure since the pathway's inception in 1997.

HDx is performed the same way as conventional HD, with only a change of the dialyzer membrane required. Once in the machine, the **Theranova** dialyzer's innovative Medium Cut-Off® membrane combines high permeability and selectivity for uremic toxins (up to 45 kDa), while retaining essential proteins and maintaining albumin levels during treatment<sup>2,3</sup>. This unique cut-off and high retention onset profile expands clearance, allowing for filtration closer to that of the natural kidney<sup>2,6</sup>.

“U.S. patients on HD deserve more options than are currently available to them, and we are taking extraordinary steps to support their access to **Theranova**,” said Gavin Campbell, general manager of Baxter's U.S. Renal Care business. “Patients are currently treated with HDx enabled by **Theranova** in more than 40 countries worldwide, and we are doing everything we can in the U.S. to ensure healthcare providers can also realize the full value of this therapy for their patients on HD.”

To date, over 90 independent and Baxter-led or sponsored studies have been conducted on HDx therapy enabled by **Theranova**. The studies evaluated a range of clinical and quality-of-life measures, including the ability to clear conventional and large middle molecules, albumin retention, chronic inflammation and other side effects of standard HD therapy.

“Individually, the side effects from standard HD, which patients typically undertake three days a week, four hours per day, may seem manageable. However, the chronic effects of treatment accumulate and over time, cause some patients to give up on therapy,” explained Mary Gellens, M.D., nephrologist and senior medical director at Baxter. “HDx therapy enabled by **Theranova** is a promising alternative to what is currently available because it delivers a filtration profile that is closer to the natural kidney.”

Due to the novel nature of **Theranova**, Baxter conducted a randomized controlled clinical study in the United States that evaluated the safety and efficacy of HDx therapy enabled by **Theranova**. During the study, as reported during the 2019 American Society of Nephrology Kidney Week, 172 hemodialysis patients received therapy with either a medium cut-off dialyzer (**Theranova** 400) or a high-flux dialyzer (ELISIO-17H) over 24 weeks of treatment, with a primary efficacy endpoint measuring the reduction ratio of lambda ( $\lambda$ ) free light chains at 24 weeks of treatment, while maintaining pre-dialysis serum albumin levels. Data from the study, which was just [published](#) in the Clinical Journal of the American Society of Nephrology (CJASN), found that expanded hemodialysis therapy with the **Theranova** 400 dialyzer provides superior removal of large middle

molecules, as exemplified by  $\lambda$  free light chains, as compared to a similarly sized high flux dialyzer while maintaining serum albumin levels<sup>7</sup>. Large middle molecules are a diverse group of uremic toxins that are believed to contribute to the high cardiovascular disease burden in end stage kidney disease<sup>8</sup>. Dialysis technologies available to date offer limited clearance of these molecules<sup>8</sup>. The ability to efficiently remove these large middle molecules provides dialysis patients with a new alternative therapy.

### **About Theranova**

Launched outside of the U.S. in 2016, **Theranova** is currently available in 44 countries across Europe, Latin America, Asia, and in Canada, and used in more than 850 clinics globally.

### **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 [www.baxter.com](http://www.baxter.com) and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

**Rx Only.** For safe and proper use of this device, refer to the Instructions for Use.

The **Theranova** Dialyzer is indicated for patients with chronic kidney failure who are prescribed intermittent hemodialysis. It provides an expanded solute removal profile with increased removal of various middle molecules (up to 45 kDa) that may play a pathologic role in the uremic clinical syndrome. The **Theranova** Dialyzer is not intended for hemofiltration or hemodiafiltration therapy. The total extracorporeal blood volume for the **Theranova** Dialyzer and the set should represent less than 10% of the patient's blood volume.

*This release includes forward-looking statements concerning **Theranova**, including potential 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.*

Baxter, MCO and Theranova are trademarks of Baxter International Inc or its subsidiaries.

Elisio is a trademark of Nipro Medical Corporation.

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- <sup>1</sup> Kirsch AH, et al. Performance of hemodialysis with novel medium cut-off dialyzers. *Nephrol Dial Transplant.* 2017; 32:165-172.
- <sup>2</sup> Zweigart C, et al. Medium cut-off membranes – closer to the natural kidney removal function. *Int J Artif Organs.* 2017; 40(7):328-334
- <sup>3</sup> Hutchison CA, et al. The Rationale for Expanded Hemodialysis Therapy (HDx). *Contrib Nephrol.* 2017; 191:142-52.
- <sup>4</sup> Neiryck N, et al. An update on uremic toxins. *Int Urol Nephrol.* 2013; 45:139-50.
- <sup>5</sup> 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.
- <sup>6</sup> Boschetti-de-Fierro A, et al. MCO membranes: Enhanced Selectivity in High-Flux Class. *Scientific Reports* 2015; 5:18448.
- <sup>7</sup> Weiner D, et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer. *CJASN* doi: 10.2215/CJN.01210120.
- <sup>8</sup> Wolley M et al. Large uremic toxins: an unsolved problem in end-stage kidney disease. *Nephrol Dial Transplant.* 2018; 33: iii6–iii11.