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BAXTER ACHIEVES REGULATORY MILESTONE FOR NEW PERITONEAL DIALYSIS TECHNOLOGY

- Innovative home dialysis solution generation system designed to enhance patients' therapy experience
- New system may reduce barriers and offer more patients access to home therapy

DEERFIELD, III., May 3, 2017 — Baxter International Inc. (NYSE: BAX), a global innovator in renal care, received guidance from the U.S. Food and Drug Administration (FDA) clarifying the regulatory pathway for an innovative, home peritoneal dialysis (PD) solution system to improve patient access to home dialysis. The new system is designed to produce sterile PD solutions using a small water filtration device that would be placed in the patient's home and integrated with Baxter's unique AMIA automated peritoneal dialysis (APD) system with SHARESOURCE telehealth platform. Following FDA guidance, Baxter's PD solution generation system will follow a regulatory pathway as a combination product, which is the process the agency uses for products that include a device and pharmaceutical component.

Baxter's home solution system is the first known technology designed to reduce storage and weight handling requirements that come with traditional PD therapy. Today, patients must have space to store approximately a one-month supply of PD solutions, which could be up to 40 boxes, requiring significant storage space in a patient's home. In addition, each box of PD solution weighs approximately 30 pounds and can present a burden for a patient to lift and carry around the home.

"The FDA's guidance is a pivotal milestone in advancing our new system forward for use by renal patients in an expedient manner," said Laura Angelini, general manager of Baxter's Chronic Renal business. "These technology advancements have the potential to greatly enhance home dialysis therapy for patients by providing solution generation on-demand and eliminating some of the barriers that today may keep patients from the lifestyle benefits that home dialysis offers."



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Baxter plans to have the first patient on therapy with the new system, as part of a clinical trial in 2018. Regulatory submission is expected in 2019.

PD is a self-administered therapy managed at home by end-stage renal disease (ESRD) patients. The therapy works inside the body, using the abdominal lining (peritoneal membrane) as a natural filter to remove toxins from the bloodstream. PD solution dwells in the cavity before draining. The process then repeats itself three to four times during each therapy session. Solutions with higher concentrations of dextrose are sometimes used to remove higher amounts of fluid and waste that can be pulled from the body¹.

Baxter's PD solution generation technology is designed to integrate with AMIA and SHARESOURCE, and allow a physician to tailor the treatment regimen for each patient. Baxter's new system would provide physicians the flexibility to prescribe different dextrose concentrations for each dwell cycle, depending on each patient's needs.

Baxter's AMIA with SHARESOURCE, which won the 2016 Chicago Innovation Award, is now in about 1,700 U.S. patients' homes, where more than 250,000 PD treatments have been performed, to date. AMIA with SHARESOURCE is the first and only APD system to include patient-centric features that help guide ESRD patients through their home PD therapy, while allowing their healthcare providers to remotely view and manage their treatment progress. Features include voice guidance, a touchscreen control panel and the SHARESOURCE two-way, cloud-based platform.

SHARESOURCE allows healthcare providers to securely view their patients' recently completed home dialysis-related treatment data, which is automatically collected after each PD session. The healthcare team also has better visibility to any missed treatments, providing the opportunity to proactively address patient compliance and resulting potential clinical issues.

Baxter's on-demand solution technology is an investigative product and not approved for use. AMIA with SHARESOURCE is by Rx Only. For safe and proper use of the devices mentioned herein, refer to the complete instructions in the Operator's Manual.



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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.

This release includes forward-looking statements concerning Baxter's AMIA APD system, ondemand solutions technology and the SHARESOURCE remote patient management platform, including anticipated benefits associated with its use and anticipated timing associated with its release. 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 issues; patient safety issues; changes in law and regulations; breaches or failures of the company's information technology systems; 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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¹Peritoneal Dialysis: Dose & Adequacy. National Institute of Diabetes and Digestive and Kidney Diseases. Accessed April 27, 2017.