



Tablo® Hemodialysis System Cartridge Receives FDA 510(k) Clearance Enabling Production in North America

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Cartridge manufacturing in the new location localizes production, reduces cost and mitigates future supply chain risks

SAN JOSE, Calif.--(BUSINESS WIRE)--Nov. 29, 2021-- [Outset Medical, Inc.](#) (Nasdaq: OM) ("Outset"), a medical technology company reducing the cost and complexity of dialysis, announced today that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for a new sterilization method of the cartridge utilized in its Tablo® Hemodialysis System, enabling full production in North America. The Tablo cartridge is a single-use disposable that works in concert with the console to deliver dialysis treatment. Its "one-touch" design speeds and simplifies treatment set-up and take-down.

The new FDA clearance enables Outset to start cartridge production through a manufacturing partner in Mexico, facilitating the localization of the cartridge, in addition to the Tablo console, in North America. In addition, the new location reduces the need for expensive and capacity-constrained air freight delivery of the cartridges, thereby simplifying distribution and logistics for the company, its customers and patients.

"This clearance is an important milestone on our roadmap to continued gross margin expansion," said Leslie Trigg, President and Chief Executive Officer of Outset. "In addition to cost reduction, we also are now better able to optimize our manufacturing process and mitigate current supply chain challenges around lead time, capacity and logistics."

Another benefit to the FDA clearance is the ability to start using an eco-friendly cartridge sterilization method. E-beam is a non-ionizing technology that can be produced on-demand and does not involve toxic or potentially explosive chemicals. Further details on Outset's sustainability efforts can be found in the company's recently published [ESG Report](#).

About Outset Medical, Inc.

Outset is a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. The Tablo Hemodialysis System, FDA cleared for use from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients and operationally simplifies it for providers. Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by anyone. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels, with 2-way wireless data transmission and a proprietary data analytics platform powering a new holistic approach to dialysis care. Tablo is a registered trademark of Outset Medical, Inc.

Forward-Looking Statements

This press release may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include statements regarding Outset's strategy, plans and objectives. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, which could cause actual results and other events to differ materially from those expressed or implied in such statements. These risks and uncertainties include risks described in the Risk Factors section of Outset's most recent annual report on Form 10-K and quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and should not be unduly relied upon. Outset disclaims any obligation to update these forward-looking statements.

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