



Results from Prospective, Multicenter Trial Evaluating the Use of the Tablo® Hemodialysis System for Home Dialysis Released at the American Society of Nephrology Scientific Meeting

November 8, 2019

First New Device Trial Completed for Home Hemodialysis In 15 Years

SAN JOSE, Calif., Nov. 7, 2019 /PRNewswire/ — Outset Medical, a commercial-stage company delivering first-of-its-kind technology into the growing, global, dialysis market today announced publication of a multicenter, prospective, open-label study in Hemodialysis International. Titled “Safety and Efficacy of the Tablo Hemodialysis System for In-center and In-home hemodialysis,” the 30-patient study met both the safety and efficacy endpoints. Tablo is currently FDA-cleared for use in hospitals and clinics and is under evaluation by FDA for use in the home.

Over 21 consecutive weeks, patients went through four treatment periods in which hemodialysis was prescribed four times weekly: one-week Run-In; eight-week In-Center; four-week Transition; eight-week In-Home. The data showed a mean weekly standard Kt/V ≥ 2.8 for participants during the In-Center and In-Home treatment periods (compared to the trial endpoint of a standard Kt/V ≥ 2.1) and delivered ultrafiltration (UF) within 10% of prescribed UF. There were no device-related pre-specified adverse events throughout the trial. All patients who started the home arm with Tablo completed it, resulting in a 0% home arm drop-out rate.

“The trial results and patient feedback were compelling,” said Troy Plumb, M.D., principal investigator of the study and Division Chief of Nephrology and Associate Professor of Medicine at the University of Nebraska Medical Center College of Medicine in Omaha. “Many patients have expressed enthusiasm for home use since they want more lifestyle flexibility and control of their care.”

In addition to online publication of the study on November 7, Dr. Plumb will be presenting the data in Washington, D.C. this week at the American Society of Nephrology annual scientific meeting.

“The results of this study suggest the success patients can have when they manage their dialysis care at home,” said Outset Medical Chief Executive Office Leslie Trigg. “We believe a new technology option for patients who want to dialyze at home will help support the White House initiative to improve care and expand treatment in the home.”

Outset Medical’s Chief Medical Officer, nephrologist Michael Aragon, M.D., added, “More than 500,000 Americans are on dialysis, and approximately 100,000 more begin treatment each year. The more that care can be easily accessible, the better it is for patients and our country’s health care system.”

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About the Tablo Hemodialysis System

Tablo is an FDA-cleared enterprise solution for dialysis, designed specifically to reduce the cost and complexity of dialysis across all care settings. Requiring only an electrical outlet and tap water to operate, the mobile Tablo system frees patients and providers from the burdensome infrastructure required to operate conventional dialysis machines. The machine’s integrated functionality enables it to serve as a dialysis clinic on wheels and enables providers to standardize to a single platform that can be used across a wide spectrum of care settings. Wireless data, sensor-based automation and an animated touchscreen make the system easy to learn and use. Leading health systems and medical centers across the U.S. have adopted Tablo for hospital and clinic dialysis, and the U.S. Department of Health and Human Services (HHS) awarded a contract for the use of Tablo in communities hit by natural disasters.

About Outset Medical

Outset Medical is dedicated to technology-driven service model innovation aimed at reducing cost and transforming the patient care experience. Outset’s Tablo System is FDA-cleared for use in acute and chronic care settings. In addition to its acute and chronic care commercial expansion, the company has concluded a clinical trial to expand Tablo’s labeled indication to include home use. For more information visit www.outsetmedical.com and follow the company on Twitter at @OutsetMedical.