Press Release

Media contact
Christine Peters
T +49 160 60 66 770
christine.peters@freseniusmedicalcare.com

Emanuela Cariolagian
T +1 213 706 0051
emanuela.cariolagian1@freseniusmedicalcare.com

Contact for analysts and investors
Dr. Dominik Heger
T +49 6172 609 2601
dominik.heger@freseniusmedicalcare.com

www.freseniusmedicalcare.com

Fresenius Medical Care Begins Broader U.S. Commercialization of 5008X™ CAREsystem, Achieves Key Milestones in Efforts to Introduce High-Volume Hemodiafiltration Dialysis Therapy to Individuals with Kidney Disease in the U.S.

- Updated 5008X CAREsystem with Additional Features Receives FDA 510(k) Clearance
- Company announces first wave of Fresenius Kidney Care clinics in the U.S. to begin offering high-volume hemodiafiltration therapy to dialysis patients
- Introducing the 5008X CAREsystem and hemodiafiltration kidney replacement therapy is a key pillar of the company's growth strategy

Bad Homburg (June 4, 2025) Fresenius Medical Care (FME), the world's leading provider of products and services for individuals with renal diseases, today begins the second phase of the company's efforts to introduce high-volume hemodiafiltration (HVHDF) kidney replacement therapy across the United States. The company last week received FDA 510(k) clearance for the updated version of its new, hemodiafiltration-capable 5008X CAREsystem with additional features, a key benchmark enabling the next steps in the company's broader commercialization efforts across the U.S. later this year, followed by a full-scale commercial launch in 2026.

"Last week's FDA clearance of our updated 5008X CAREsystem with additional features was a critical milestone in our work to improve the lives of people living with kidney disease by bringing industry-leading, high-volume hemodiafiltration dialysis therapy to the U.S.", said **Helen Giza**, CEO for Fresenius Medical Care AG. "Hemodiafiltration is already the treatment standard across much of Europe, Latin America, and Asia, and we are very well experienced with it. Our great familiarity with

this treatment, combined with the outcome and promising results of the external CONVINCE***** research study, reiterated the significant patient health and well-being benefits available with high-volume hemodiafiltration. With this additional clearance, we now begin the next steps of our national U.S. rollout by deploying the machine to a first wave of Fresenius Kidney Care clinics for the remainder of 2025 and continuing broadly across the U.S. in 2026 and beyond. It's a landmark moment in the industry. We will set the new standard of kidney care in the U.S."

Fresenius Medical Care first received 510(k) clearance for its 5008X CAREsystem in February 2024, which allowed the company to conduct focused testing, clinical evaluations, and user-studies of the device in a pilot clinic. Last week's May 2025 FDA 510(k) notice provided clearance for an updated 5008X CAREsystem with additional features, including the Fresenius Clinical Data Exchange® (CDX), a unique Fresenius Medical Care technology built into the 5008X that enables ONE-TOUCH access to providers' medical information systems (MIS) directly at chairside without the need for additional computer stations. By providing direct access to providers' MIS, the CDX helps to optimize clinic workflows, reduce the risk of cross contamination and CMS V-tag citations, and open up clinic space by reducing computer and cabling clutter.

Beginning in a few months and continuing through the remainder of the year, Fresenius Medical Care's Care Delivery patient care business segment will begin offering hemodiafiltration dialysis therapy in selected first wave clinics across regions in its U.S. Fresenius Kidney Care dialysis clinics. In the U.S. there is an estimated installed base of around 160,000 in-center hemodialysis machines across all service providers that could be replaced to adapt this new standard of care.

The 5008X CAREsystem is one of Fresenius Medical Care's latest medical device innovations. Along with the companion FX CorAL® dialyzer – approved by FDA –, the 5008X CAREsystem combines the latest device engineering and cutting-edge membrane technologies that facilitate high-volume hemodiafiltration with many additional workflow and therapy improvements possible.

The results of the groundbreaking CONVINCE***** study demonstrated that patients treated with high-volume hemodiafiltration experienced a remarkable 23% decrease in mortality rates compared to those treated with the more commonly used high-flux hemodialysis. Funded by the European Union, the CONVINCE study was a multinational research study that compared these two types of hemodialysis techniques in a three-year trial performed at 61 dialysis centers in eight European countries.

*****Funded by the European Union, conducted by the CONVINCE consortium, and led by the University Medical Center Utrecht, the international, randomized controlled CONVINCE trial marked a crucial milestone in comparing high-volume hemodiafiltration with standard, high-flux hemodialysis.

The information in this document is provided as is and no guarantee or warranty is given that the information is fit for any particular purpose. The user thereof uses the information at its sole risk and liability. The opinions expressed in the document are of the authors only and in no way reflect the European Commission's opinions.

The CONVINCE study was exclusively supported by the European Commission Research & Innovation, Horizon 2020, Call H2020-SC1-2016-2017 under the topic SC1-PM-10-2017: Comparing the effectiveness of existing healthcare interventions in the adult population (grant no 754803).

Disclaimer:
This release contains forward-looking statements that are subject to various risks and uncertainties. Actual results could differ materially from those described in these forward-looking statements due to various factors, including, but not limited to, changes in business, economic and competitive conditions, legal changes, regulatory approvals, results of clinical studies, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. These and other risks and uncertainties are detailed in Fresenius Medical Care's reports filed with the U.S. Securities and Exchange Commission. Fresenius Medical Care does not undertake any responsibility to update the forward-looking statements in this release.