Fresenius Medical Care Introduces Leading Dialysis Therapy for U.S. Kidney Patients

- Fresenius Medical Care (FME) receives U.S. Food and Drug Administration (FDA) 510(k) clearance of the company's 5008X Hemodialysis System.
- This will enable Fresenius Medical Care to offer the industry-leading, high-volume hemodiafiltration (Hv-HDF) dialysis therapy – already widely used in Europe – for people living with kidney diseases in the U.S.
- The 510(k) clearance allows the start of clinical evaluations and user-studies in the U.S., with a planned broad commercial launch of the 5008X Hemodialysis System in 2025.
- The 5008X Hemodialysis System and companion FX CorAL dialyzer demonstrate the company's global innovation leadership in medical device and membrane engineering technologies.

Fresenius Medical Care (FME), the world's leading provider of products and services for individuals with renal diseases announced the company has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the company's 5008X Hemodialysis System. Now the company wants to bring a new standard of care in dialysis therapy to people living with kidney diseases in the U.S.

"Making new and innovative therapies available to patients is core to our goal of improving the lives of people living with kidney diseases," says **Helen Giza**, CEO for Fresenius Medical Care AG." The 5008X Hemodialysis System demonstrates our company's ability to innovate at scale. This innovation builds on the proven track record of our hemodialysis system series in Europe, Latin America and Asia Pacific." Helen Giza says: "We're pleased to achieve this important milestone to bring a new standard of care in dialysis therapy to one of the world's largest healthcare markets, where there is significant opportunity to make meaningful impact."

Dialysis is a life-saving treatment for people whose kidneys are failing and who can no longer naturally filter their blood in order to remove excess water, solutes, and toxins from the body. Unlike conventional high-flux hemodialysis, which primarily employs diffusion to remove small molecules and fluid from the blood, high-volume hemodiafiltration incorporates both diffusion and convection techniques to eliminate larger molecules and effectively manage fluid replacement through convection.

The results of the recently published 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. This study was a multinational research study that compared these two types of hemodialysis techniques. It was a three-year trial performed at 61 dialysis centers in eight European countries.

Cleared for the start of U.S.-based clinical evaluations and user studies ahead of a planned broad market launch in 2025, the 5008X Hemodialysis System is one of Fresenius Medical Care's latest medical device innovations, capable of providing industry-leading, high-volume hemodiafiltration dialysis therapy. Along with the companion FX CorAL dialyzer - already registered in the U.S. -, the 5008X Hemodialysis System combines the latest device engineering and cutting-edge membrane technologies required to make high-volume hemodiafiltration possible.

In the U.S. there is currently 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.

Source: Fresenius Medical Care

*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

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