

Press Release

August 23, 2023

Media Contact

Leif Heussen
T +49 6172 608-4030
leif.heussen@fresenius.com

Emanuela Cariolagian
T +1 800 723-2384
media@freseniusmedicalcare.com

**Contact for analysts and
investors**

Dr. Dominik Heger
T +49 6172 609-2601
dominik.heger@fmc-ag.com

www.freseniusmedicalcare.com

Fresenius Medical Care Announces FDA Clearance of Versi®HD with GuideMe Software

Fresenius Medical Care, the world's leading provider of products and services for individuals with renal diseases, today announced the U.S. Food and Drug Administration (FDA) 510(k) clearance for Versi®HD with GuideMe Software, a completely reinvented self-guided interface for the company's VersiHD chronic home hemodialysis (HHD) system. VersiHD with GuideMe Software aims to transform the experience of HHD for patients and nurses.

As the established leader in HHD, NxStage from Fresenius Medical Care, draws on its experience of over 30 million patient treatments at home over nearly two decades, serving patients in more than 45,000 homes with a broad diversity of water sources across the U.S.

VersiHD with GuideMe Software provides graphical walk-through guidance that aims to enhance ease of use and confidence for both patients and nurses. It is designed to improve patient training time, ease the transition to home, and make the training experience easier for new users.

"With over 13,000 HHD patients in the U.S. alone, we are excited to amplify the innovation NxStage offers with advanced technologies, like VersiHD with GuideMe Software," said Dr. Katarzyna Mazur-Hofsäß, CEO of Fresenius Medical Care's Care Enablement segment. "We are committed to providing cutting-edge solutions to improve

the health and well-being of dialysis patients by challenging the standard of home dialysis with the design of industry-leading products.”

“We expect VersiHD with GuideMe Software to further simplify home hemodialysis for patients during training and at home,” said Dr. Brigitte Schiller, Senior Vice President, Medical Officer, Home Therapies at Fresenius Medical Care. “As a result of this software upgrade, patients and their care partners will have additional support to be confident with the therapy at home. VersiHD with GuideMe Software will support Fresenius Medical Care’s mission of advancing access to home therapies to more patients.”

NxStage has had many significant innovations over the years guided by patient input starting with the first portable HHD machine, NxStage System One™, in 2005 followed by the introduction of the PureFlow™ DI Water Purification System in 2006. Nx2me Connected Health®, the first Connected Health platform for HHD followed in 2014. The NxStage System One was the first machine to receive FDA clearance for Nocturnal HHD indication in 2014 and also the first to receive FDA clearance for Solo HHD indication in 2017. In 2017, NxStage introduced the VersiHD touchscreen cycler. Over 95% of HHD patients in the U.S. use the NxStage HHD system.

VersiHD with GuideMe Software will initially be available in selected markets in 2023. Existing VersiHD systems will be upgradeable to GuideMe Software. For more information about VersiHD with GuideMe Software, please visit www.nxstage.com/hcp/versihdguideme

Despite the health benefits that home hemodialysis may provide to those with chronic kidney disease, this form of therapy is not for everyone. The reported benefits of home hemodialysis may not be experienced by all patients. The risks associated with hemodialysis treatments in any environment include, but are not limited to, high blood pressure, fluid overload, low blood pressure, heart-related issues, and vascular access complications. The medical devices used in hemodialysis therapies may add additional risks including air entering the bloodstream and blood loss due to clotting or accidental disconnection of the blood tubing set. Certain risks are unique to the home. Treatments at home are done without the presence of medical personnel and on-site technical support. Patients and their partners must be trained on what to do and how to get medical or technical help if needed.

© 2023 Fresenius Medical Care. All Rights Reserved. Fresenius Medical Care, NxStage, the triangle logo, VersiHD, PureFlow and Nx2me are trademarks of Fresenius Medical Care Holdings, Inc. or its affiliated companies. All other trademarks are the property of their respective owners.

Fresenius Medical Care is the world's leading provider of products and services for individuals with renal diseases of which around 3.9 million patients worldwide regularly undergo dialysis treatment. Through its network of 4,050 dialysis clinics, Fresenius Medical Care provides dialysis treatments for approximately 344,000 patients around the globe. Fresenius Medical Care is also the leading provider of dialysis products such as dialysis machines or dialyzers. Fresenius Medical Care is listed on the Frankfurt Stock Exchange (FME) and on the New York Stock Exchange (FMS).

For more information visit the Company's website at www.freseniusmedicalcare.com.

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, impacts related to the COVID-19 pandemic 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 AG & Co. KGaA's reports filed with the U.S. Securities and Exchange Commission. Fresenius Medical Care AG & Co. KGaA does not undertake any responsibility to update the forward-looking statements in this release.