

Interim clinical study results indicate Pursuit Vascular ClearGuard® HD Antimicrobial Barrier Caps reduce both bloodstream infection and hospitalizations

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MAPLE GROVE, Minn.--(BUSINESS WIRE)--Pursuit Vascular announced today that a clinical study, in collaboration with Fresenius Medical Care and Frenova Renal Research, found a statistically significant reduction in both bloodstream infection and hospitalization due to infection when ClearGuard HD Antimicrobial Barrier Caps were utilized for patients receiving dialysis treatment via central venous catheters (CVCs).

The 12-month, prospective, multi-center randomized clinical study was conducted at 40 Fresenius Medical Care clinics in the U.S. The goal of the study was to assess the impact to bloodstream infection rates (represented by positive blood cultures (PBCs)) and hospitalization due to infection resulting from use of ClearGuard HD Antimicrobial Barrier Caps as compared to conventional caps, the current standard of care. Results from a planned interim analysis of data collected after 9-months of usage in more than 2,000 patients and over 250,000 CVC-days demonstrated ClearGuard HD Antimicrobial Barrier Caps decreased the incidence of PBCs by 73% ($p < 0.001$) during the third quarter of the study, decreased the overall incidence of PBCs in *de novo* catheters by 76% ($p = 0.020$) and reduced the overall incidence of hospitalization due to infection by 37% ($p = 0.019$). Final results are expected to be published in 2016.

“These are significant results and document an important potential benefit to patient health while receiving positive feedback from our staff about the ease of use,” said principal investigator Jeffrey Hymes, M.D., Chief Medical Officer at Fresenius Medical Services.

Despite infection-control protocols and quality clinical care, the prevalence of CVCs for hemodialysis remains high, predisposing patients to costly and potentially deadly bloodstream infections. With this initial study in the hemodialysis market, Pursuit Vascular believes its patented ClearGuard technology platform could play an important role in reducing infections and keeping patients out of the hospital, which are all critical drivers as we enter an era of value-based care.

“These clinical results represent a historic milestone in our effort to commercialize in the U.S., and we appreciate the dedication Fresenius Medical Care has shown to improving patient care by engaging in the study,” said Doug Killion, President and CEO of Pursuit Vascular. “The ClearGuard HD Antimicrobial Barrier Cap is a first-of-its-kind device, and the interim results of this study indicate it can effectively address one of the greatest unmet clinical needs in hemodialysis. We are excited to share these results as we prepare to launch and distribute the device across the country in early 2016.”

About the ClearGuard HD Antimicrobial Barrier Cap

The ClearGuard HD Antimicrobial Barrier Cap is the first and only device cleared for sale in the U.S. that kills infection-causing bacteria inside a long-term hemodialysis catheter. This simple yet revolutionary single-use device triggered the creation of a new Product Code (PEH) by the Food and Drug Administration (FDA) “for use in hemodialysis catheters to reduce hub infection”. For more information visit www.clearguardhd.com

About Pursuit Vascular

Headquartered in Maple Grove, Minnesota, Pursuit Vascular, Inc. is developing a family of innovative single-use products designed to protect patients from acquiring life-threatening infections associated with long-term catheter and port use. Routine use of these products could result in substantial savings to the health care system. For more information visit www.pursuitvascular.com

About Frenova Renal Research

Frenova is the only Phase I-IV drug and device clinical development services provider dedicated exclusively to renal research. As a [Fresenius Medical Care North America](#) company, Frenova maintains a world-class network of resources encompassing more than 200 principal investigators and 250 dialysis research sites, and also offers access to more than 183,000 active ESRD patients and 390,000 active CKD patients. For more information visit www.frenovarenalresearch.com

About Fresenius Medical Care North America

Fresenius Medical Care North America is the premier health care company focused on delivering the highest quality care to people with renal and other chronic conditions. Through its industry-leading network of dialysis facilities, outpatient cardiac and vascular labs and urgent care centers, as well as the country's largest practice of hospitalist and post-acute providers, Fresenius Medical Care provides coordinated health care services at pivotal care points for hundreds of thousands of chronically ill customers throughout the continent. As the world's only fully vertically integrated renal company, it offers specialty pharmacy and laboratory services, and manufactures and distributes the most comprehensive line of dialysis equipment, disposable products and renal pharmaceuticals. (www.freseniusmedicalcare.us)

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