

Pursuit Vascular Announces CE Mark Approval for ClearGuard® HD Caps

- *Milestone opens international markets for the company*

Maple Grove, Minn. April 3, 2019/PRNewswire—Pursuit Vascular, Inc., manufacturer of ClearGuard® HD Antimicrobial Barrier Caps, today announced that the company has received both Conformité Européene (CE) Mark and Medical Device Single Audit Program (MDSAP) certificates for its ClearGuard HD caps, paving the way for launch in international markets.

The CE marking confirms that the ClearGuard HD cap meets the requirements of the European Medical Devices Directive, which now allows Pursuit Vascular to commercialize ClearGuard HD caps in the European Union and other CE Mark geographies. The MDSAP certificate demonstrates compliance with regulations in Canada, Australia and Brazil. The company is pursuing applications to market in these countries to facilitate launch of ClearGuard HD caps internationally later this year.

“The CE Mark and MDSAP approvals are significant accomplishments for Pursuit Vascular as it allows the company to expand sales to Europe and other key international markets,” said Doug Killion, President and CEO. “We look forward to working with hospitals and physicians in these countries to bring this lifesaving technology to more patients worldwide.”

The company has seen rapid uptake of ClearGuard HD caps in the US following publication of landmark clinical studies demonstrating a ~70% reduction in bloodstream infections in patients using ClearGuard HD caps vs. patients using standard caps or needleless connectors. The ClearGuard HD cap is the first and only device available for sale that kills infection-causing microorganisms inside a catheter hub between dialysis treatments. Bloodstream infection is the second leading cause of death and a leading cause for hospitalization in hemodialysis patients, with catheters causing the majority of these infections.

“The extraordinary success of ClearGuard HD caps in the US clearly demonstrates that we’ve been able to provide a highly effective product that is rapidly becoming the standard of care for dialysis treatment,” continued Killion. “Pursuit Vascular is committed to creating technologies that aid in the prevention of catheter-related infection to enhance and extend the lives of patients around the world, and to reduce healthcare costs.”

About Pursuit Vascular

Headquartered in Maple Grove, Minnesota, Pursuit Vascular, Inc., develops innovative products designed to protect patients from life-threatening infections, their associated complications, and death, while reducing healthcare costs worldwide. The company’s ClearGuard HD Antimicrobial Barrier Cap is the first and only device available for sale in the US that is proven to reduce central line-associated bloodstream infections in hemodialysis patients. For more information, visit www.pursuitvascular.com.

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