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Haemonetics Announces VASCADE MVP® Venous Vascular Closure System Gains the First and Only FDA Approval for Same-Day Discharge Following Atrial Fibrillation Ablation

September 30, 2021

The AMBULATE Same-Day Discharge Clinical Study Series demonstrates safe and effective use of VASCADE MVP in three studies to date, with more than 800 AF ablation patients discharged the same calendar day

BOSTON, Sept. 30, 2021 /PRNewswire/ -- Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative medical solutions to drive better patient outcomes, announced that the VASCADE MVP® Venous Vascular Closure System is now the first and only vascular closure device to receive FDA indication for same-day discharge following atrial fibrillation (AF) ablation.

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The Same-Day Discharge labeling was granted following the conclusion of the first two registries in the AMBULATE Same-Day Discharge (SDD) clinical study series, which evaluated the safety and efficacy of using VASCADE MVP to facilitate same-day discharge of AF ablation patients. As of July 2021, Cardiva Medical Inc., an industry-leading manufacturer of vascular closure systems acquired by Haemonetics earlier this year, has completed three of its four planned registries in the AMBULATE Same-Day Discharge Clinical Study Series.

The first study was a multi-center retrospective study that enrolled 497 subjects across four U.S. centers, and the second study was a prospective, multi-center, single-arm study, referred to as SDD #1. SDD #1 enrolled 151 paroxysmal AF patients at eight U.S. centers under the direction of 27 investigators. The most recent study, AMBULATE Same-Day Discharge #2, was a multi-center, prospective, single-arm study that enrolled 203 persistent AF patients at 13 U.S. centers under the direction of 37 investigators. The studies demonstrated the following:

- Retrospective Study – 99.4% of subjects treated for AF with venous closure using the VASCADE MVP were sent home the same day without additional intervention post-discharge.
- SDD #1 - 98.6% of subjects treated for paroxysmal AF with venous closure using the VASCADE MVP were sent home the same day without additional intervention post-discharge.
- SDD #2 – 99.5% of subjects treated for persistent AF with venous closure using the VASCADE MVP were sent home the same day without additional intervention post-discharge.

Vascular access safety in all three studies was similar to that in the AMBULATE Pivotal Study, i.e. zero major access site-related complications. Same-Day Discharge #3, an all-comers study for patients undergoing AF ablation with venous closure using VASCADE MVP, will begin enrollment in 2022. It is planned to be a multi-center prospective registry of 300 subjects.

"By using VASCADE MVP following AF ablation, the AMBULATE SDD Clinical Study investigators achieved reproducible, consistent and durable vascular closure, facilitating same-day discharge," said Zayd A. Eldadah, M.D., Ph.D., Principal Investigator and Director of Cardiac Electrophysiology at the MedStar Health System, based in the Baltimore, MD – Washington, DC region.

VASCADE MVP is the only marketed vascular closure system proven and labeled specifically for procedures requiring multiple access site venous closure with standard 6-12 French inner diameter (15 French maximum outer diameter) sheaths used in cardiac electrophysiology procedures. In previous studies, VASCADE MVP has been proven to enable earlier ambulation, earlier discharge eligibility and higher patient satisfaction.

According to Chris Simon, Haemonetics' President and CEO, "COVID has accelerated the need to enhance safety and efficacy to optimize the patient experience in meaningful ways. VASCADE MVP earning the first and only indication for same-day discharge for AF ablation patients speaks to our industry leadership and continued commitment to improving the standards of care."

About Haemonetics

Haemonetics (NYSE: HAE) is a global healthcare company dedicated to providing a suite of innovative medical products and solutions for customers, to help them improve patient care and reduce the cost of healthcare. Our technology addresses important medical markets: blood and plasma component collection, the surgical suite and hospital transfusion services. In 2021, Haemonetics acquired Cardiva Medical, Inc., a Santa Clara-based industry-leading manufacturer focused on transforming vascular closure for the benefit of patients, hospitals and physicians in the over 5.5 million catheter-based coronary, peripheral and electrophysiology procedures in the United States that require access site closure each year. To learn more about Haemonetics, visit www.haemonetics.com.

Cautionary Note Regarding Forward Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Forward-looking statements in this press release may include, without limitation, statements regarding plans and objectives of management for the operation of Haemonetics, including statements regarding potential benefits associated with the VASCADE MVP® Venous Vascular Closure System, and Haemonetics' plans or objectives related to the development and commercialization of this product. Such forward-looking statements are not meant to predict or guarantee actual results, performance, events or circumstances and may not be realized because they are based upon Haemonetics' current projections, plans, objectives, beliefs, expectations, estimates and assumptions and are subject to a number of risks and uncertainties and other influences.


Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation, product quality; market acceptance; the effect of economic and political conditions; the impact of the COVID-19 pandemic, including the scope and duration of the pandemic, government actions and restrictive measures implemented in response; the impact of competitive products and pricing; and vascular closure product reimbursement policies and practices. These and other factors are identified and described in more detail in the Company's periodic reports and other filings with the U.S. Securities and Exchange Commission. The Company does not undertake to update these forward-looking statements.

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