HAEMONETICS®

Haemonetics Receives FDA Clearance For NexSys PCS® With Persona™ Technology

October 3, 2020

BOSTON, Oct. 2, 2020 /PRNewswire/ -- Haemonetics Corporation (NYSE: HAE), a global medical technology company focused on delivering innovative hematology solutions to drive better patient outcomes, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its NexSys PCS® system with Persona™ technology. The new, proprietary Persona technology is the latest innovation on the NexSys PCS system and it customizes plasma collection based on an individual donor's body composition.

"The NexSys PCS system has transformed and improved the way our customers can collect plasma," said Chris Simon, Haemonetics' President and CEO. "Persona builds on that legacy by delivering meaningful innovation and reinforces our commitment to supporting the plasma industry."

The 510(k) clearance was supported by clinical data from the IMPACT (IMproving PlasmA CollecTion) study, a multicenter, prospective, double-blinded, randomized controlled clinical trial involving 3,443 donors who underwent 23,137 plasma donations. The study was one of the largest clinical trials on the topic of plasmapheresis and it demonstrated that the NexSys PCS system with Persona technology was safe and effective. Using NexSys PCS with Persona technology, which incorporates a novel, personalized percent plasma nomogram, study results showed an average 8.2% increase in volume of plasma collected per donation across the study population when compared with NexSys PCS® with YES® technology. Additionally, the average number of repeat donations was not impacted and increasing plasma collection volume up to a maximum of 1,000 mL was well tolerated in eligible donors.

The amount of plasma a donor can donate is currently based on a variable calculation, also called a nomogram, which is solely correlated to an individual's weight. The IMPACT study showed that, compared to the current industry standard nomogram, the Persona technology and nomogram customizes collection to an individual donor's body mass index (BMI) and hematocrit to optimize each collection and yield a greater average volume of plasma collected per donation.

"Plasma is an essential component used to make life-saving and life-improving medicines for many conditions, and the current nomogram has been a safe and effective method for collecting plasma for decades," said Dr. Jan Hartmann, Haemonetics' Vice President, Medical Affairs, Clinical Development and Medical Safety. "Persona now sets a new paradigm by leveraging improved technology and taking a personalized approach to optimize plasma collection for each individual donor."

"Octapharma strives to improve the health and lives of people worldwide and our participation in this randomized clinical trial reinforces our commitment to advancing science in plasma collection," said Judy Smith, Executive Vice President and Chief Operating Officer at Octapharma Plasma, Inc., whose collection centers served as the IMPACT study trial sites. "We are excited about the prospect of using this new technology to help meet the rising demand for plasma-derived therapies."

According to the Plasma Protein Therapeutics Association (PPTA), approximately 750,000 people across Europe and North America rely on plasma for life-saving therapies. Plasma-derived medicines are used to treat hundreds of conditions[1], like primary immunodeficiency, hemophilia and others, and it can take hundreds of plasma donations to treat a single patient[2].

The results of the IMPACT study will be presented at the AABB 2020 Virtual Annual Meeting in the Plenary Oral Abstract Session on October 4.

About NexSys PCS® with Persona™ Technology

The NexSys PCS® plasma collection system with Persona™ technology is intended for use as an automated cell separator system and blood component collector in conjunction with single-use sterile disposable sets, with or without saline compensation. Products that can be collected using the NexSys PCS system include source plasma and plasma for transfusion. The Persona technology builds on NexSys PCS® with YES® technology, which received FDA 510(k) clearance in 2018 and has been used to perform approximately 11 million collections to date. The NexSys PCS system with Persona technology includes disposables and the ability to integrate with NexLynk DMS® donor management system.
Visit www.nexsyspcs.com to learn more.

About Haemonetics

Haemonetics (NYSE: HAE) is a global healthcare company dedicated to providing a suite of innovative hematology 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. To learn more about Haemonetics, visit www.haemonetics.com.

Cautionary Statement Regarding Forward-Looking Information

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 NexSys PCS® system with Persona™ technology, 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 outbreak, government actions and restrictive measures implemented in response; the impact of competitive products and pricing; blood product reimbursement policies and practices; and the effect of industry consolidation as seen in the plasma market. 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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[1] https://primaryimmune.org/about-primary-immunodeficiencies/specific-disease-types

[2] https://www.donatingplasma.org/plasma-protein-therapies/who-needs-plasma-therapies

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