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Haemonetics Clinical Study Results On A New, Personalized Approach To Plasma Collection To Be Presented At 2020 AABB Annual Meeting

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BOSTON, Aug. 7, 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 will present results of its IMPACT (IMproving Plasma CollecTion) study at the 2020 AABB Annual Meeting in a Plenary Oral Abstract Session on October 4. The IMPACT study, one of the largest clinical trials on the topic of plasmapheresis, was designed to test a novel, personalized approach to plasma collection using the NexSys PCS® Plasma Collection System.

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The IMPACT study was a multicenter, prospective, double-blinded, randomized controlled clinical trial involving 3,443 donors who underwent 23,137 plasma donations. The trial compared plasma collection using NexSys PCS® with YES® technology, which collects based on a donor's weight per the current industrywide nomogram, to collection with NexSys PCS using a novel, personalized Percent Plasma Nomogram (PPN) based on body mass index (BMI) and hematocrit, enabling a more tailored collection target using individual donor biometric data.

Collection following the novel PPN used with NexSys PCS had a non-inferior safety profile compared to the current NexSys PCS with YES technology, while resulting in an average 8.2% increase in volume of plasma collected per donation across the study population. The number of repeat donations was not impacted and increasing collection volume up to 1,000 mL was well tolerated.

"We are committed to advancing innovation and safety in plasma and the study's positive results build on the demonstrated performance of the NexSys PCS platform while highlighting the potential for enhanced plasma collection in the U.S.," said Chris Simon, Haemonetics' President and CEO. "Plasma is used to make medicines for many important conditions, like primary immune deficiency and autoimmune disorders, and we believe there is significant opportunity to support the growing need for plasma-derived therapies with our technology."

Based on a variable calculation, also called a nomogram, the current approach to determining how much plasma a donor can safely donate is based solely on an individual's weight. This nomogram was put into place in 1992 to reduce the potential for errors, such as transcription error associated with manually entering collection parameters into the device during the collection process. It has since been used to safely collect hundreds of millions of donations over the past few decades. However, today, with improved technology, these risks of human error can be greatly reduced and a more personalized approach to plasma collection may yield greater volume of plasma collected per donation.

"By using donor biometrics and analytics in a new way, plasma collection can become more personalized to better align with an individual's body composition," said Dr. Jan Hartmann, Haemonetics' Vice President, Medical Affairs, Clinical Development and Medical Safety. "At a time when the world needs more plasma, this trial shows the value of a personalized approach."

Donor plasmapheresis is one of the most frequent medical procedures performed in healthy individuals in the U.S. In 2019 alone, there were approximately 53 million plasma collections in the U.S.¹ According to the Plasma Protein Therapeutics Association ([PPTA](#)), approximately 750,000 people across Europe and North America rely on plasma for life-saving therapies.

Visit the [AABB](#) website to learn more about the presentation titled "Use of a Novel, Personalized Nomogram to Optimize Plasma Collection Yields without Increasing Adverse Event Rates: Results from IMPACT, a Randomized Controlled Trial of 23,137 Donations."

This research was limited to and based on protocols established in the U.S. The NexSys PCS device with PPN is pending U.S. Food and Drug Administration (FDA) 510(k) clearance.

About NexSys PCS® with YES® Technology

Haemonetics' NexSys PCS plasmapheresis platform includes its embedded YES technology, a yield enhancing solution enabling increases in plasma yield per collection, its NexLynk DMS® next-generation donor management system, which can help plasma centers operate with efficiency and compliance while enhancing donor safety, and disposables. NexSys PCS with YES technology received FDA 510(k) clearance in 2018 and has performed nearly 11 million collections to date. The NexSys PCS device is also CE marked and available in the European Union and Australia. 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 IMPACT study results and Haemonetics' plans or objectives related to the development and commercialization of, and regulatory approvals related to, PPN for use in the Company's products. 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, regulatory uncertainties, including the receipt or timing of regulatory approvals; 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.

ⁱ https://www.pptaglobal.org/images/Data/Plasma_Collection/Total_Yearly_Collections_2008-2019.pdf

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