LINK Medical contracted by Hemanext to run a study to assess the Hemanext ONE® Red Blood Cell (RBC) Processing and Storage System

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LINK Medical has signed an agreement with Hemanext, inc. that appoints LINK Medical Research to run a study to assess the Hemanext ONE® Red Blood Cell (RBC) Processing and Storage System. This is the second study that LINK Medical will perform for Hemanext and it is expected to run over a two-year period.

The study will include patients that receive transfusions of hypoxic RBC units processed with Hemanext ONE, with the purpose of evaluating the safety and efficacy of hypoxic red blood cells processed with the Hemanext ONE system.

The study is a multi-center, historical control design run initially at four sites in Norway and Sweden. The purpose is to compare the transfusion of hypoxic RBCs in phosphate-adenine-glucose-guanosine-saline-mannitol (PAGGSM) additive solution (study group) against the transfusions completed with conventional RBCs in (saline-adenine-glucose-mannitol (SAGM) additive solution (control group) that occurred during the previous 12-month period.

Each patient will be followed for up to 24 months, and it is expected that up to 50 subjects may be included across four disease specific arms: sickle cell disease (SCD), myelodysplastic syndromes (MDS), thalassemia and acute bleeding/trauma.

SCD is an inherited disease in which the red blood cells have an abnormal crescent shape or “sickle”-shape, block small blood vessels, and do not survive as long as normal red blood cells. This disease is associated with serious, life-threatening complications, including stroke and acute chest syndrome (ACS).[1,2] As a result, people with SCD often require chronic red blood cell transfusions,[2] which for some patients is a life-saving therapy.[2]

In patients with MDS, the stem cells fail to become mature RBCs, white blood cells (WBCs), or platelets in the bone marrow.[3] Myelodysplasia can cause serious conditions like anemia, frequent infections, and spontaneous bleeding. Some patients may need red blood cell transfusions and those that do may need them once every week, while others may only need a transfusion once every 6 to 12 weeks.[4]

Thalassemia is an inherited blood disorder caused by the body not making enough of a protein called hemoglobin, an important part of red blood cells.[5] Without enough hemoglobin, the RBCs in the body don’t function properly and last shorter periods of time causing there to be fewer healthy RBCs in the bloodstream. Fewer healthy RBCs in the bloodstream result in less oxygen being delivered to all other cells in the body, causing anemia. As such, blood transfusions play a vital role in the treatment and management of thalassemia and other hemoglobin disorders.[6]

LINK Medical is currently initiating the start-up activities for the study.

Martin Cannon, Co-Founder and CEO of Hemanext, said*: "We are pleased to announce our partnership with LINK Medical Research, a renowned full-service Contract Research Organization (CRO). With their extensive expertise, we are confident that this collaboration will propel us forward, helping generate clinical data showing the potential of our innovative technology to transform blood and transfusion therapy. This real-world data will bring us one step closer to delivering a solution that could benefit transfusion-dependent patients worldwide."*

Sissel Lønning Andresen, CEO of LINK Medical commented, "We are very excited to offer support from our experts which could bring solutions to transfusion-dependent patients, we look forward to another collaboration with the great team at Hemanext"

About Hemanext
Hemanext is a privately held medical technology company based in Lexington, MA that is dedicated to improving the quality, safety, efficacy, and cost of transfusion therapy. The company's research and development efforts center on the study of hypoxically stored red blood cells (RBCs). The company's aim is to significantly improve the quality of stored RBCs by limiting oxygen and carbon dioxide levels in the storage environment.

About Hemanext ONE
In the European Union, the system is CE Marked for the processing and storage of CPD/ PAGGSM Red Blood Cells, Leukocytes Reduced (LR RBC) that have been prepared and processed with the HEMANEXT ONE® system within 24-hours of collection. The HEMANEXT ONE® system limits the O_2 and CO_2 levels in the storage environment. Red Blood Cells Leukocytes Reduced, O_2 /CO_2 Reduced may be stored for up to 42 days at 1-6°C. HEMANEXT ONE® is used for volumes no greater than 350 ml of LR RBC.

The Hemanext ONE® System has not been authorized, cleared, or approved by FDA and is pending FDA de novo review.

About LINK Medical
LINK Medical is a leading life science service partner, providing experts, flexible services, and innovative technologies for the pharmaceutical and medical device industries

LINK Medical has over 25 years of experience in offering end-to-end solutions across all product development areas, from pre-to post-marketing.

Our services include CRO, Clinical Development, Project Management, Biometrics, Regulatory Affairs, Chemistry Manufacturing and Controls (CMC) development, Safety & Pharmacovigilance, Medical Monitoring, Medical Writing, Quality Assurance (QA), Market Access, and Real-World Evidence among other services.

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