NEWS RELEASE

WhiteSwell Announces Successful Treatment of Acute Decompensated Heart Failure Patients in its Early Feasibility DELTA-HF Study

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GALWAY, Ireland--(BUSINESS WIRE)-- WhiteSwell, a company pioneering a new paradigm in the treatment of acute decompensated heart failure (ADHF), announced today positive initial results from its ongoing DELTA-HF trial evaluating the WhiteSwell eLym™ System. The data were presented at the Heart Failure Society of America (HFSA) Annual Scientific Meeting 2023 in Cleveland, Ohio.

In DELTA-HF, a minimally invasive catheter-based system is introduced to facilitate the removal of excess fluid from the body's tissues and organs concurrent with diuretic removal of excess vascular fluid. The eLym System targets the body's largest lymphatic vessel and creates pressure conditions that support the tissue drainage capabilities of the overwhelmed lymphatic system.

Nine hospitalized patients received eLym therapy in conjunction with diuretic therapy, while six patients received standard of care treatment with loop diuretics alone.

Summary of key findings:

- Treatment with the eLym System was performed safely and successfully.
  - Deployed and activated in nine patients with a mean treatment time of 24 hours.
  - No patient experienced a serious procedure-, device-, or therapy-related adverse event.
- Early clinical results are promising and support further clinical investigation.
  - Patients who underwent therapy with the eLym System plus loop diuretic lost a mean of 6.0±4.6 kg from

baseline to hospital discharge while maintaining kidney function, as measured by a stable or improved creatinine (mean Δ -0.10±0.12 mg/dL).

- The loop diuretic-only group lost a mean of 3.3±3.7 kg.
- One treated patient (1/9, 11%) was hospitalized within 30 days of discharge.

"It cannot be overemphasized how significant and challenging it is to fully decongest patients hospitalized with decompensated heart failure. Patients with persistent congestion at discharge are more likely to be rehospitalized, are less likely to be treated with optimal medical therapy and are at greater risk of poor outcomes. Most of the fluid accumulates in the tissues, and we have not previously had a way to actively target that fluid," said William Abraham, M.D., Professor of Medicine, Physiology, and Cell Biology at The Ohio State University Wexner Medical Center. "WhiteSwell's ingenious approach of reducing thoracic duct pressure to facilitate lymphatic drainage of the tissues enables us to actively address both interstitial tissue and intravascular decongestion simultaneously. I'm particularly encouraged by the amount of decongestion achieved with stable or improved creatinine, an indicator of kidney function."

"This is a new approach, and we are excited to investigate WhiteSwell's catheter-based system," said Zviad Kereselidze, M.D., Head of the ICCU at Tbilisi Heart Center. "We have treated some of our most challenging patients who are frequently hospitalized with congestion, and we have been pleasantly surprised with how well they have decongested at the time of discharge and how the benefit was sustained at 30-day follow-up."

WhiteSwell continues to evaluate this unique approach to treating ADHF patients with continued enrollment and follow-up in The Safety and Feasibility of the eLym™ System for the Decongestion of Excess Lymphatic Fluid via the Thoracic Duct in Acute Decompensated Heart Failure (DELTA-HF) Trial. The company looks forward to sharing additional data in the future.

About the DELTA-HF Trial

The DELTA-HF trial is a non-randomized early feasibility trial evaluating the safety and performance of the eLym System in the treatment of fluid overload or congestion in patients with ADHF.

About the eLym™ System

The eLym System is a minimally invasive catheter-based system designed to facilitate the removal of excess fluid from tissues and organs (interstitial fluid) in patients with ADHF by supporting the overwhelmed lymphatic system's ability to actively drain fluid. The eLym System is deployed in the left internal jugular and innominate veins near where the lymphatic system's major highway, the thoracic duct, connects. It creates a low-pressure zone to facilitate fluid drainage in conjunction with intravenous diuretics.

About Acute Decompensated Heart Failure (ADHF)

ADHF is an episode of worsening heart failure symptoms that results in millions of hospitalizations worldwide each year, including three million in the U.S. alone.1 Patients with ADHF experience difficulty breathing, fatigue, and edema (swelling) due to fluid back-up in the lungs and other parts of the body (congestion). The condition requires hospital-based treatment to remove excess fluid in a process called decongestion. Complete decongestion is the goal of ADHF treatment since residual congestion at hospital discharge is the strongest predictor of rehospitalization and death.2 As many as half of ADHF patients are discharged from the hospital not fully decongested, and one out of four ADHF patients is readmitted to the hospital within one month.3,4,5

About the Lymphatic System and ADHF

In healthy individuals, the lymphatic system continuously captures fluid from tissues throughout the body and pumps it back into the vascular system to maintain homeostasis. In ADHF, excess fluid collects in the tissues of the body (the interstitial compartment), causing edema and an increase in venous blood pressure. Excess tissue fluid and high venous blood pressure interfere with the lymphatic system's ability to move fluid back to the vascular system, which can further exacerbate congestion.

About WhiteSwell

WhiteSwell is a patient-focused company dedicated to improving treatment of acute decompensated heart failure (ADHF), a primary cause of repeat hospitalization and emergency room visits. A privately held company, WhiteSwell is headquartered in Galway, Ireland. For more information, visit **www.whiteswell.com**.

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1 Hollenberg et al., J Am Coll Cardiol 2019;74:1966–2011. (1M annual hospital discharges with HF as primary diagnosis and 2M hospital discharges with HF as secondary contributing diagnosis.)
2 Martens & Mullens, How to tackle congestion in acute heart failure, Korean J Intern Med 2018;33:462-473
3 Girerd et al, Integrative Assessment of Congestion in Heart Failure Throughout the Patient Journey, J Am Coll Cardiol HF 2018;6:273–85
4 Arrigo et al, **Nature Reviews Disease Primers** volume 6, Article number: 16 (2020)
5 Rubio-Gracia, J. et al. (2018). International Journal of Cardiology, 258, pp. 185-191.

Dunia Cristan
Email: **dunia@healthandcommerce.com**

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