

Heart Donor Shortage Solution, HeartGenesis eHL Stem Cells Acheive Long-Term Survival of End-Stage Heart Failure Patient

Potential Heart Donor Shortage Solution as HeartGenesis EHL Cells Achieved World's First Long-Term Survival (>14 yrs) of Severe/End Stage Heart Failure Patient

TOKYO, JAPAN, May 22, 2024 /EINPresswire.com/ -- <u>HeartGenesis, a</u> <u>clinical-stage cardiac regenerative</u> <u>therapeutics</u> and medical device biotech company, announced that the extended long-term survival follow-up data from the surgical implantation of eHL-1 (HFDSC) stem cells for patients with severe/end-stage heart failure (NYHA class IIIb–IV) was presented by the Company's co-founding cardiac surgeon, Federico Benetti M.D., PhD., at the 2nd Asia-Pacific Congress on Medicine Today (APCMT 2024) Tokyo, Japan on May 13, 2024.

The data presented was based on clinical trials performed on 10 highrisk, no-option, patients (avg age 64.8) with severe/end-stage heart failure (HF) due to non-ischemic dilated



HeartGenesis + HoloEye AI + Augmented/Mixed Reality Smart Glasses, AI-Powered Ecosystem for Less invasive Advanced Surgical Procedures

cardiomyopathy that was previously published in peer review, authored by F Benetti et al., to determine the safety and efficacy of direct myocardial transplantation of eHL-1 (HFDSC) stem cells by open-chest surgical procedure.

HeartGenesis's eHL-1 (HFDSC) consists of allogeneic primitive hematopoietic-like stem cells and progenitor cell (HPCs) populations that express proteins, including vascular growth factors, signaling factors that play a role in angiogenesis, homeostasis, and regeneration process that, in

addition, could promote cardiomyogenesis and vasculogenesis.

Data presented showed: six of the severe/end-stage heart failure (NYHA class IIIb–IV) patients survived after 40 months. Statistically significant improvement in ejection fraction (EF) and left ventricular end diastolic dimension (LVEDD), myocardial function and cellular activity, improved NYHA class. Heart tissue was regenerated with "extremely good results". No rejection reaction or malignancy at 48 months. 50% of



patients had complete reverse remodeling of the left ventricle within 3 months of implantation. One patient that did not have complete reverse remodeling of the left ventricle died of arrhythmia 3.6 years after treatment. The second patient died after 5.4 years from an infection. The third patient died at 5.10 years of unknown cause. The fourth patient died at 7.4 years of heart failure. The fifth patient died at 8.4 years of Heart Failure. The six Patient died at 14.4 years after treatment at 83 yrs-old from Heart Failure.

"Conclusion of >14 year extended long-term survival follow-up of the world's first clinical experience of direct surgical injection of primitive hematopoietic-like stem cells and progenitor cells (HFDSC) in severe/end-stage heart failure patients showed: excellent long term results with near 60% average survival of the group of patients that had complete reverse remodeling of the left ventricle at 3 months after just one cell implantation had an average survival rate K/M at 6 years. Clear evidence of sustained effect of (eHL-1) cell therapy offers the possibility for a new approach and new hope for patients with terminal heart failure. The evidence strongly suggests additional IV treatment of stem cells and progenitor cells could maintain the positive effect, and improve the quality of life and longevity in these types of patients" said Dr. F. Benetti

"These long-term follow-up results demonstrate that eHL-1 stem cells are effective and safe as an off-the-shelf evidence-based therapeutic option for advanced or end-stage heart failure patients who are unable to undergo heart transplantation due to a shortage of heart donors. This is epoch-making evidence that offers hope for Heart Failure patients." Said James Ryan, Executive chairman of HeartGenesis, and Director of HoloEye AI.

"Over the past 14 years, many patients with advanced stage heart failure have died because a heart donor could not be found. HeartGenesis plans to begin additional clinical trials based on these results. HeartGenesis's regenerative therapy opens the possibility of heart failure treatment that does not require a heart donor." Said James Ryan "Our proprietary OculiDeus -now being embedded into HoloEye AI AR/MR smart glasses ecosystem with a patient specific AIpowered digital therapeutics assistant- aims to dramatically improve our therapeutics platform with less invasive precision procedures that afford multiple medical interventions."

Heart failure (HF) is a global pandemic that affects more than 64 million people worldwide and its prevalence is steadily growing. About 10-15% of patients currently with heart failure meet the requirements for a heart transplant (HT). However, less than half of these obtain a referral for transplant evaluation.

Prognosis in advanced HF is grave, with a 1-year mortality in class III–IV patients exceeding 25% and 50% 1-year mortality in end-stage HF patients. Published data suggests 250,000–300,000 patients younger than 75 yrs. old suffer from advanced HF (NYHA class IIIb–IV) in the USA.

"in advanced HF patients older than 75 years old is another epidemic. Based in our long term results, older patients may benefit significantly by combining our primitive stem cells HF treatment with our regenerative therapeutics for age-related biological frailty and digital therapeutics management to sustain and improve the quality of life for these patients" said Federico Benetti M.D., PhD., founder of HeartGenesis and Holoeye AI.

"OculiDeus provides patient-specific deciphering of the best timing for subsequent implants following an initial cell therapy intervention. OculiDeus is therefore a unique intelligent Assistant for a kind of precision regenerative medicine that is both fitting the unmet single patient's needs and suited for large-cohort subjects' treatment. These issues are particularly relevant when assessing the dynamics of failing hearts in light of regenerative medicine interventions. To this end, OculiDeus will be essential in affording a patient-specific characterization of regional end diastolic and end systolic wall thickness nearby an infarcted area, or regions or contractile failure as those arising in dilating cardiomyopathies. Under these circumstances a thorough identification of the metabolic surviving border regions, distinguishing them from the healthier remote myocardium will provide crucial information on where cellular regenerative treatments should be applied. Similar strategies could also be envisioned for the identification of the true boundaries of the scarred myocardium." Said Prof. Carlo Ventura, founder and CSO of HoloEye-Al and HeartGenesis

About: HeartGenesis, established by a world-class team with decades of deep expertise in developing regenerative therapeutics, is accelerating a proprietary multifaceted platform that combines state-of-the-art stem cell technologies, best-in-class surgical techniques, instruments, (HOLOEYE-AI + OculiDeus) and devices for life-threatening and age-related conditions such as advanced/end-stage heart failure, cardiovascular and age-related diseases.

Visit: www.heartgenesis.me

OculiDeusTM -by ElpisEremo- accelerates diagnostic accuracy and precision assessment of human cells, oocytes, tissues and organs, molecular signature insights, powered by Proprietary

Biological Artifactual Intelligence Model (BAiM) to significantly boosts performance.

James Ryan HeartGenesis Inc. & HoloEye Al email us here

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