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HELP Therapeutics Secures FDA Approval for Phase I Study of HiCM-188 in Heart Failure Treatment

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U.S. FDA clears Investigational New Drug (IND) application for HELP Therapeutics' iPSC-derived cardiomyocytes, marking the first clinical trial of its kind for end-stage heart failure, offering a new hope for millions of patients.

HELP Therapeutics Co. Ltd, a clinical-stage cell therapy company, announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for "Allogeneic Human iPSC-derived cardiomyocytes (HiCM-188) administered via intramyocardial injection during coronary artery bypass graft surgery."

Heart failure (HF) is a significant public health issue, affecting at least 7 million patients in the US and approximately 65 million globally. Due to its increasing incidence and prevalence among the elderly, heart failure is one of the leading causes of death and hospitalization in this demographic. HiCM-188, a leading pipeline program of HELP Therapeutics, consists of highly purified allogeneic cardiomyocytes (cardiac muscle cells) reprogrammed from human induced pluripotent stem (iPS) cells using proprietary serum-free, genetic vector-free, and integration-free conditions.

HiCM-188 is the first investigational iPSC-derived cell therapy to undergo clinical evaluation for the treatment of end-stage heart failure in the United States. The primary objective of the Phase I study is to evaluate the safety and tolerability of HiCM-188 cell transplantation one-year post-transplant. The study will assess various dose levels of HiCM and is anticipated to enroll participants at sites across the United States. Professor Emerson C. Perin, Medical Director at The Texas Heart Institute, one of the planned trial centers, stated, "I believe this milestone for HELP Therapeutics has the potential to advance the field of cell therapy and represents a significant step in their development program. I am eager to collaborate with them on this clinical program."

Professor Junbo Ge, Academician of Chinese Academy of Sciences, and the Chief of Cardiology at Zhongshan Hospital, Fudan University, is encouraged by this approval: "The innovative drug independently developed by HELP Therapeutics is the first IND approved by the U.S. Food and Drug Administration using iPSC technology for cardiovascular indications. This is an exciting and proud achievement, representing a significant milestone in China's cardiovascular innovative drugs and opening a new chapter in China's cell therapy innovations."

"Cardiomyocytes derived from pluripotent stem cells represent an effective means of increasing the pool of contractile cells in failing hearts and thus to improve their function. The IND released to HELP Therapeutics represents a major milestone in the landscape of cardiac regeneration as it paves the way for the first large-scale efficacy trial whose outcomes have the potential to strengthen the rationale for remuscularizing the heart with cardiac-committed cells and thus expand the clinical indications of this innovative therapy." stated Professor Philippe Menasché from University of Paris Descartes.

"The intensifying aging population has made heart failure an increasingly prominent issue. Due to the scarcity of heart transplant donors and the high economic threshold of artificial heart technologies, the clinical needs of many heart failure patients remain unmet," stated Jiaxian Wang, MD, PhD, Founder and CEO of Help Therapeutics. "Our off-the-shelf product - the Regenerative Cardiac Cell Injection (iPS-CMs: HiCM188) - has successfully obtained IND clinical trial approval in the U.S. This product innovatively shifts from whole heart transplantation to precise myocardial repair by transplanting fresh myocardial cells into damaged areas, promising a revolutionary treatment option for heart failure patients. Additionally, the company is committed to developing affordable innovative drugs, aiming to create cell therapy products that are accessible and beneficial a broad patient population."