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Capricor Announces FDA Approval To Initiate ALLSTAR Trial of Allogeneic Stem Cell Therapy In Patients Following Heart Attack

LOS ANGELES--(BUSINESS WIRE)-- Capricor, Inc., a privately held biotechnology company focused on regenerative medicine, today announced that the U.S. Food and Drug Administration has approved initiation of its Investigational New Drug (IND) application for the ALLSTAR study, which will use allogeneic cardiac-derived stem cells (CDCs) to treat patients following large myocardial infarctions (MI).

ALLSTAR will study the use of CAP-1002 delivered directly into a coronary artery from thirty days to one year following a heart attack. The trial will have a 14 patient lead in phase and is planned as a 260 patient, twenty center randomized controlled trial. ALLSTAR will study a variety of safety and effectiveness endpoints with the goal of demonstrating sufficiently strong data to permit an eventual Phase III trial as a path to commercialization of CAP-1002.

ALLSTAR is predicated on the positive results of the landmark CADUCEUS trial that showed approximately 50 percent reduction of scar size and 50 percent more viable muscle in the infarction zones of patients studied one year after a heart attack. ALLSTAR will use donor cells whereas CADUCEUS used each patient's own CDCs. The shift from autologous to allogeneic cells is supported by extensive pre-clinical evidence of safety and effectiveness and is expected to expand the market opportunity as well as to reduce the costs for treatment.

"IND approval for ALLSTAR is another major milestone for Capricor as we continue to develop cardiac-derived stem cells for the treatment of heart disease," said Linda Marbán, Ph.D., CEO of Capricor. "There are greater than 6 million people in the US living with heart failure, and that number continues to rise as heart disease remains the number one killer. Capricor's CDCs represent a novel treatment to repair the heart after muscle loss following large heart attacks through the regeneration of heart muscle and the shrinking of scar tissue. Our ultimate goal will be to demonstrate that muscle regeneration in these patients will result in clinically meaningful improvements to their lives."

"This is terrific news," says Ellen Feigal, M.D., Senior Vice President for Research and Development at California's stem cell agency, CIRM. "This is the first time a Disease Team funded by CIRM has been given an Investigational New Drug (IND) approval from the FDA, a critical step in testing promising therapies in patients. It's a reflection of the progress being made in turning promising therapies into real-world treatments."

Capricor has asked CIRM to assist in the funding of a portion of ALLSTAR. "Capricor was founded Baltimore and moved to California almost five years ago in part because of the environment that CIRM has created to foster stem cell research in this state. We are grateful to have received the seed support from CIRM that has funded a portion of our research. Our mission is to develop meaningful treatments for patients suffering from heart disease and to grow Capricor into a major California biotechnology company," said Linda Marbán.

About CAP-1002

CAP-1002, Capricor's lead candidate, is a proprietary allogeneic adult stem cell product for the treatment of myocardial infarction. The product contains multiple progenitor cells and is derived from donor heart tissue. The cells are multiplied in the laboratory using a specialized process, and then introduced directly into a patient's heart via infusion in a coronary artery at the time of standard cardiac catherization.

About Capricor, Inc.

Los Angeles-based Capricor is a privately held biotechnology company that aims to create powerful, yet easy-to-administer cardiac stem cell treatments to regenerate damaged heart muscle and improve heart function for patients suffering from an MI or heart failure. Using proprietary technology, Capricor is the only stem cell company working to develop and commercialize cardiac stem cell therapies that are based on Cardiospheres™, its unique mixture of cells from the heart itself. Where most other organizations derive stem cells from a range of pre-cursor and non-cardiac tissues and then attempt to differentiate those cells to become and support heart tissue, Capricor's work begins and ends with the heart.

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