Cardiorentis

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Cardiorentis initiates first-ever acute heart failure Phase III clinical trial designed to assess early treatment on cardiovascular mortality and symptoms

Switzerland (ots/PRNewswire) -

Cardiorentis has initiated the first-ever acute heart failure (AHF) Phase III trial to be specifically designed to assess the effect of early treatment on cardiovascular mortality. TRUE-AHF (TRial of Ularitide's Efficacy and safety in patients with Acute Heart Failure) aims to show that early treatment with intravenous (IV) ularitide may reduce AHF symptoms in the short-term and cardiovascular mortality in the long-term. Health authorities have agreed with the designation of cardiovascular mortality as a primary efficacy endpoint, and patient enrolment is already underway in the US and Europe.

Heart failure is a significant public healthcare concern, with an overall population prevalence of approximately one to three per cent, rising to approximately 10 per cent in the very elderly. AHF is one of the most common reasons for unscheduled hospitalisation of people over the age of 65 years.[i] AHF patients are at a markedly increased risk of rehospitalisation within three months of their first episode and experience mortality rates five-times greater than that of patients following a heart attack.[ii],[iii]

"The TRUE-AHF is a landmark study. We believe that early decompression of the dilated heart can reduce myocardial injury in patients with acutely decompensated heart failure," commented Milton Packer, M.D., chair of the trial, Professor and Chair, Department of Clinical Sciences, University of Texas Southwestern Medical Center. He continued, "If decompression produced by a 48-hour infusion of ularitide can prevent significant myocardial damage during this vulnerable period, then we are likely to see a reduction in cardiovascular mortality over the following months and years."

TRUE-AHF is designed to build on the growing body of evidence that suggests patients suffering from AHF should be treated as early as possible. Heart failure experts, cardiologists and emergency physicians are working hand-in-hand to ensure an early enrolment of patients into the trial (within the first hours after presentation to the hospital). The trial is evaluating the following endpoints:

- A composite score that assesses the symptoms and clinical course of patients during the 48-hour infusion of ularitide. - Cardiovascular mortality following randomisation for the entire duration of the trial

"We have been in close discussions with the health authorities to achieve the most robust study design for TRUE-AHF. We wanted the study design to reflect our belief that ularitide could provide symptom improvement and a reduction in cardiovascular mortality, which are both crucial measures for new therapies being investigated for the treatment of AHF. Following promising results in previous clinical trials SIRIUS I and II, we are confident ularitide will provide clinicians with a much-needed addition to their AHF treatment armamentarium," said Elmar Schnee, CEO Chairman at Cardiorentis Ltd. "We are also encouraged that such a highly regarded group of cardiologists and emergency physicians are working in partnership with us on the clinical programme," he added.

Approximately 190 centres across the US, Europe, Canada and Latin America will be involved in the TRUE-AHF trial, and approximately 2,152 patients with AHF will be randomised to receive placebo or ularitide for 48 hours in addition to standard care.

Notes to editors

About Ularitide

Ularitide is an advanced natriuretic peptide in Phase III development as an intravenous (IV) infusion treatment for acute heart failure (AHF). Ularitide is the chemically synthesized form of urodilatin - a human, natriuretic peptide that is produced in the kidneys and induces excretion of sodium into the urine (natriuresis) and increased urine production (diuresis) to regulate fluid balance and sodium haemostasis. Ularitide induces natriuresis and diuresis by binding to specific natriuretic peptide receptors (NPR-A, NPR-B and other natriuretic peptide receptors), thereby increasing intracellular cyclic guanosine monophosphate (cGMP) helping to relax smooth muscle tissues, leading to vasodilation and increased blood flow.

About AHF

Heart failure is a growing problem worldwide. More than 23 million people around the world are affected.[iv],[v] AHF can be defined as the sudden or gradual onset of the signs or symptoms of heart failure resulting in a need for urgent therapy or hospitalisation.[vi] It is a life-threatening condition which requires immediate medical attention. Signs and symptoms of AHF include extreme fatigue and shortness of breath, worsening kidney function, severe swelling, sudden weight gain and a distended jugular vein along the side of the neck.

About Cardiorentis Ltd.

Cardiorentis is a private biopharmaceutical company headquartered in Zug, Switzerland. Cardiorentis is committed to bringing novel therapies to the treatment of heart failure and related cardiovascular diseases. The company's disease-based technology platform integrates expertise in protein biology to identify novel targets and rationally design small molecule compounds and peptides for markets with unmet medical needs. For more information, visit http://www.cardiorentis.com

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