

Regenerative Therapy for heart failure enters Ph III Trial

24 April 2013 | News | By BioSpectrum Bureau

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Singapore: Belgian biotechnology company Cardio3 BioSciences (C3BS) has received authorization from the Belgian Federal Agency for Medicines and Health Products (FAMHP) to begin its Congestive Heart failure Cardiopoietic Regenerative Therapy (CHART-1) European Phase III trial for C3BS-CQR-1 in Belgium. This represents a world premiere for a regenerative medicine product targeting heart failure to be tested in the context of a Phase III trial. C3BS-CQR-1 is an autologous stem cell therapy for heart failure.

The Phase III trial is a prospective, multi-centre, randomized, sham-controlled, patient-and evaluator-blinded study comparing treatment with C3BS-CQR-1 to a sham treatment. The trial will recruit a minimum of 240 patients with chronic advanced symptomatic heart failure. The primary endpoint of the trial is a composite endpoint including mortality, morbidity, quality of life, Six Minute Walk Test and left ventricular structure and function at 9 months post-procedure.

The Cardio3 BioSciences therapy, called C3BS-CQR-1, involves taking stem cells from a patient's own bone marrow and through a proprietary process called Cardiopoiesis, re-programming those cells so that they go onto becoming heart cells. The cells, known as cardiopoietic cells, are then injected back into the patient's heart through a minimally invasive procedure using a catheter called C-Cathez, with the aim of repairing damaged tissue and improving heart function and patient clinical outcomes. C3BS-CQR-1 is the outcome of multiple years of research conducted at Mayo Clinic (Rochester, Minnesota, USA), Cardio3 BioSciences (Mont-Saint-Guibert, Belgium) and Cardiovascular Centre in Aalst (Aalst, Belgium). This Phase

III trial builds on the successful outcome of the Phase II trial conducted between 2009 and 2010 in multiple clinical sites in Belgium, Serbia and Switzerland.

Dr Christian Homsy, CEO of Cardio3 BioSciences, said, "Heart failure remains a significant unmet clinical need associated with high morbidity, mortality and escalating healthcare costs. We believe C3BS-CQR-1 has a potential to become an alternative to heart transplantation which is the only curative treatment for heart failure available today. Our Phase III trial is the first to begin anywhere in the world for a regenerative therapy for this indication. We look forward to confirming the promising results we have already seen in our Phase II study."

Dr Jozef Bartunek, principal investigator, added, "Regenerative therapies have the potential to revolutionize the treatment of heart disease and other conditions and we are excited to be working with Cardio3 BioSciences on what is a ground breaking study. The results seen in the earlier trials were encouraging and if repeated in this larger study would bring nearer a potentially disruptive treatment for the expanding epidemic of heart failure."

Cardio3 BioSciences has completed a Phase II trial with C3BS-CQR-1, which demonstrated that heart failure patients improved heart function and exercise capacity following treatment compared to patients receiving current standard of care. Moreover, feasibility and safety of the C3BS-CQR-1 treatment regimen were established.