



Cardio3 BioSciences receives its accreditation number from the Belgian Federal Agency for Medicines and Health Products for the manufacture of C-Cure™ for human use.

Mont-Saint-Guibert – Belgium, November 18, 2008 - Cardio3 BioSciences, announces that it has received its Good Manufacturing Practices (GMP) accreditation number for the manufacture of clinical batches of C-Cure, the only advanced therapy medicinal product of its kind.

Cardio3 BioSciences is the first Belgian company active in the field of cardiac regenerative therapies to receive such an accreditation. This means that its manufacturing processes and the quality systems in place have reached the internationally recognized standards of quality for the manufacture of clinical batches of human medicinal products. This accreditation number has been obtained through constructive and permanent interactions with the inspectors of the **Belgian Federal Agency for Medicines and Health Products**.

Christian Homsy, CEO Cardio3 BioSciences: « Receiving this accreditation number will allow us soon to initiate the first C-CURE clinical trial process over the coming weeks. Administrative steps at the Agency are still required prior to the delivery of the GMP certificate itself, but this should be completed in the coming weeks. Once this certificate is issued, we will be able to file a full request to the Competent Authorities in each country to obtain the authorization to start the C-CURE trial. The C-CURE trial is divided in two phases: The first phase will enroll 45 patients in up to 10 internationally renowned clinical sites, while the second phase will enroll an additional 195 patients in 15 more clinical sites. The principal investigators of the C-CURE protocol are Dr Jozef Bartunek from the cardiovascular center Aalst, and Prof André Terzic from the Mayo Clinic®, Rochester, USA. The C-CURE trial has already been approved by Ethics Committees of 10 sites in Belgium, Germany, Switzerland and India. The submissions to the Competent Authorities was awaiting this GMP certificate, therefore, receiving the accreditation number is a key milestone for the company. »

Jozef Bartunek, MD: «Cardiac regenerative therapy aims to address the unmet needs of growing number of patients suffering from heart failure caused by heart attacks or chronic coronary artery disease. The concept that stem cells taken from the same patient may improve the heart function and quality of life of such patients is studied in several clinical trials. The C-CURE trial will study a unique product that was meticulously developed by applying the cutting edge bio-technology. The C-CURE product of guided cardiopoietic stem cells demonstrated superior biological and functional efficacy in preclinical testing and the trial holds the promise of the very innovative approach to cure human ischemic heart failure»

Cardio3 BioSciences is a leading edge company, founded in 2007 and active in the field of regenerative therapies for the treatment of heart failure. C-Cure™ is a cell therapy based on the usage of autologous stem cells differentiated into cardiac precursors called cardiopoietic cells. This second generation cell therapy was developed based on leading edge research conducted with the Cardiovascular Center of Aalst, Belgium, and the Mayo Clinic® Rochester, USA. For more information, please visit www.c3bs.com

Contacts

Cardio3 BioSciences
Christian Homsy
CEO
+32 10 39 41 00
chomsy@c3bs.com

CARDIO3 BIOSCIENCES S.A.