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Press Release – Science

Leuven, Belgium – 9 January 2006

Administering stem cells to patients with myocardial infarction leads to a reduction of the size of the infarct

Leuven, Belgium – This week, doctors at the Catholic University of Leuven, connected with the University Hospital - Gasthuisberg, the Stem Cell Institute Leuven (SCIL), and the Flanders Interuniversity Institute for Biotechnology (VIB), are publishing a major breakthrough in the treatment of patients with acute myocardial infarction. Their research shows that the administration of a patient's own stem cells has a significant positive effect on the heart's recovery: in the patients studied, the size of the infarct was clearly reduced. The use of stem cells appears to be safe, and to date no side effects have occurred that can be attributed to the stem cells. This study is a world-first – its exciting results are being published in the prominent medical journal *The Lancet*.

In an acute myocardial infarction, the flow of blood from a blood vessel in the heart is blocked, whereby the cardiac muscle receives insufficient oxygen and heart tissue dies. In many cases, the supply of blood in the deadened portion of the heart can be restored via the so-called balloon technique. But the heart suffers permanent damage, primarily to the left ventricle.

The researchers in Leuven have tested the administration of bone marrow stem cells on patients stricken with acute myocardial infarction. In the 67 patients of the study, the supply of blood in the heart was restored optimally via the balloon technique. Then, within 24 hours, some patients received an injection of stem cells from their own bone marrow and some received an aqueous (placebo) solution (the patients in each group were selected by drawing lots). Such a double-blind, placebo-controlled study has never before been conducted.

Collaboration among the cardiology, hematology, radiology and nuclear medicine services yielded an unparalleled study in which state-of-the-art technology was used to investigate changes in the left ventricle, blood supply and heart metabolism.

Improvement in the global functioning of the left ventricle was comparable in both the control group (injected with the placebo) and the group that received the stem cells. But a clear global improvement in function was found in the sub-group of patients who had been afflicted with the most serious infarctions. Moreover, the reduction of the size of infarct was significantly greater in all patients in the 'stem cell group' and correlates with a better preserved regional left ventricle function. It is still much too early to conclude that every patient with a myocardial infarction should be treated with stem cells. Indeed, there is still a long road to travel in the development of a medication, and no risks must be taken along the way.

One of the major scientific merits of this study is that it has investigated – in a rigorously controlled manner – the possible role as well as the limitations of the administration of stem cells. The findings are thus an important driving force for further targeted clinical and pre-clinical research. This study is the initial impetus for VIB and the Catholic University of Leuven and the newly established SCIL to quickly combine fundamental research on stem cells with clinical applications for the benefit of patients.



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Note to the editor:

We wish to point out that you must mention the University Hospital - Gasthuisberg / Catholic University of Leuven and the Stem Cell Institute Leuven (SCIL) as well as VIB in your reportage or article.

This research has been conducted and financed by the University Hospital - Gasthuisberg and its physicians. This is the first success of the collaboration between scientists and doctors in the new Stem Cell Institute Leuven.

The **Cardiology Department of the University Hospital - Gasthuisberg** plays an active role in the clinical area of the European Stem Cell Task Force, which has been established within the European cardiology society with the purpose of directing the clinical development of these promising new methods of treatment and reinforcing Europe's pioneering role.

VIB, the Flanders Interuniversity Institute for Biotechnology, is a research institute where 800 scientists conduct gene technological research in a number of life-science domains, such as human health care and plant systems biology. Through a joint venture with four Flemish universities (Ghent University, the Catholic University of Leuven, the University of Antwerp, and the Free University of Brussels) and a solid funding program for strategic basic research, VIB unites the forces of nine university science departments in a single institute. Through its technology transfer activities, VIB strives to convert the research results into products for the benefit of consumers and patients. VIB also distributes scientifically substantiated information about all aspects of biotechnology to a broad public.

The **Stem Cell Institute Leuven (SCIL)** is a multidisciplinary fundamental and clinical research institute under the direction of Professors Catherine Verfaillie and Marc Boogaerts, who are engaged in the elucidation of the biology and pathophysiology of adult and embryonal stem cells and their current and future clinical applications.

For more information (referral for readers):

Given that this research can raise a lot of questions for patients, we ask you to please refer questions in your report or article to the email addresses that the University Hospital -Gasthuisberg and VIB make available for this purpose: cardiologie@uz.kuleuven.ac.be and patienteninfo@vib.be. Everyone can submit questions concerning this and other medically-oriented research directly to the University Hospital - Gasthuisberg or VIB via these addresses.

For more information concerning this press release, please contact VIB's Communication department:

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Reference article:

Stefan Janssens, Christophe Dubois, Jan Bogaert, Koen Theunissen, Christophe Deroose, Walter Desmet, Maria Kalantzi, Lieven Herbots, Peter Sinnaeve, Joseph Dens, Johan Maertens, Frank Rademakers, Steven Dymarkowski, Olivier Gheysens, Johan Van Cleemput, Guy Bormans, Johan Nuyts, Ann Belmans, Luc Mortelmans, Marc Boogaerts, and Frans Van de Werf.

"Autologous Bone Marrow-Derived Stem Cell Transfer in Patients with ST-Segment Elevation Myocardial Infarction. A double-blind, randomised, controlled study."

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