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Large European Trial to Investigate Patient Outcomes from Machine-perfused versus Static-stored Cadaveric Donor Kidneys

Geneva, 16 October 2005 – On behalf of leading transplant centers in The Netherlands, Germany, and Belgium, the Scientific Steering Committee and Eurotransplant today announced the pending commencement of the “Machine Preservation Trial,” the first large, prospective, randomized, controlled, multicenter trial to investigate the relative efficacy and cost-effectiveness of continuous hypothermic machine perfusion versus the prevailing alternative of static cold storage preservation in cadaveric donor kidneys before transplantation. This clinical trial will compare outcomes in pairs of patients who receive contralateral pairs of donor kidneys, one preserved by machine perfusion and the other by static storage, with left or right kidneys randomly assigned. Investigators will furthermore assess the practical feasibility of total ex vivo machine perfusion, from recovery to transplant, across an international organ sharing system.

The Machine Preservation Trial aims to fill a longstanding gap in the medical literature. Smaller clinical investigations over the past three decades have consistently demonstrated the efficacy of machine preservation, but many have lacked the scale and/or statistical power to guide routine practice. Many transplant professionals today seek a much stronger base of clinical evidence.

“I am convinced that this is a one-time and unique chance to finally resolve a historical question, revisiting the concepts of Drs. Belzer and Collins using evidence-based medicine, and currently highly relevant with increasing numbers of older and more marginal donor organs that are more susceptible to delayed graft function or graft nonfunction,” said coordinating principal investigator Professor Rutger Ploeg (University Medical Center Groningen, Netherlands), who leads the trial with principal investigators Professor Jacques Pirenne (Universitaire Ziekenhuizen, Leuven, Belgium) and Professor Andreas Paul (Universitätsklinikum, Essen, Germany). The trial is being conducted in collaboration with Eurotransplant International Foundation, who will coordinate organ allocation, randomization, and transportation and facilitate data accrual together with the Deutsche Stiftung für Organtransplantation (DSO) in Germany.

“This watershed study could end 30 years of debate about which preservation method is best. The aim of the study is to reduce delayed graft function, which is difficult for the patient, increases costs, and negatively impacts long-term graft survival,” said Arie Oosterlee, MD, MBA, director Eurotransplant



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International Foundation. “The trial is about Eurotransplant’s primary objective: the optimal allocation of organs. It is in keeping with our history of advancing the science of transplantation.”

Beginning 1 November 2005, all cadaveric kidney donors over 16 years old from Belgium, The Netherlands, and the DSO Region Nordrhein-Westfalen Germany will be considered for enrollment in the Machine Preservation Trial. Upon acceptance for donation, one kidney will be randomized to machine preservation. The contralateral kidney serving as a control will be preserved by cold static storage in a traditional ice cooler. Transplant nephrologists and surgeons will be blinded as to preservation method at the time of allocation. Either preservation method will endure from the time of recovery to the time of transplantation.

The structure of the trial features an independent scientific steering committee with principal investigators, central trial assistance by Eurotransplant, and sponsorship by Organ Recovery Systems, Chicago, IL, USA, employing its LifePort® Kidney Transporter. “The Machine Preservation Trial will demonstrate the ideal application of our technology,” said Organ Recovery Systems CEO David Kravitz. “We are pleased to be working with such eminent physician-scientists to guide evidence-based transplant medicine in Europe and the world.”

The Principal Investigators as well as Eurotransplant International Foundation and Organ Recovery Systems executives will be available to discuss the Machine Preservation Trial at the 12th Congress of the European Society of Transplantation in Geneva, 16 – 19 October 2005.

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About the Machine Preservation Trial Scientific Steering Committee

The Scientific Steering Committee is responsible for the coordination, conduct and presentation of the outcome of the randomized controlled trial of machine perfusion versus static cold storage. It includes the principal investigators of the Universities of Groningen (Coordinating Center), Leuven and Essen who will closely collaborate in their respective regions with the individual professionals involved in organ donation and kidney transplantation.

About Eurotransplant International Foundation

The Eurotransplant International Foundation is responsible for the mediation and allocation of organ donation procedures in Austria, Belgium, Germany, Luxemburg, The Netherlands, and Slovenia. In this international collaborative framework, the participants include all transplant hospitals, tissue-typing laboratories, and hospitals where organ donations take place. The Eurotransplant region numbers well over 118 million. Eurotransplant is based in Leiden, The Netherlands.

About Organ Recovery Systems



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Organ Recovery Systems is a privately held company developing technologies and services to improve the quality and quantity of organs, tissues, and cells for transplantation. The Machine Preservation Trial is part of the company's worldwide O:PAIRS initiative, a group of landmark clinical studies being launched in 2005 in Europe, the United Kingdom, and Brazil, and soon in the United States. Founded in 1998, Organ Recovery Systems is based in Chicago, IL, USA, with European activities headquartered in Brussels.

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