

TRANSPLANT BIOMEDICALS ANNOUNCES COMPLETION OF PATIENT ENROLMENT IN THE EMERGE TRIAL: A FIRST IN HUMAN CLINICAL STUDY OF VIVIAN® DEVICE IN KIDNEY TRANSPLANTATION

Barcelona, Spain, April 15, 2019– TRANSPLANT BIOMEDICALS, a company specializing in the research and development of medical devices for organ, tissue and cell preservation, today announces that it has completed patient enrolment of its first-in-human clinical trial of VIVIAN® kidney device for the transport and preservation of organs for transplantation. The trial enrolled 32 patients undergoing kidney transplantation for the first time, and receiving a graft from either, brain death donors (DBD; SCD+ECD) or cardiac arrest donors (DCD MIII).

The EMERGE trial is multicenter, prospective, open, single-arm study designed to evaluate the safety and performance of VIVIAN® kidney device for organ preservation in donor kidneys for transplantation. The primary objectives of the clinical trial are to evaluate the safety on the rate of events related to the use of the VIVIAN® device and the efficacy on the rate of delayed graft function (DGF). Thirty-day planned interim results are expected to be available by end of May 2019 and complete 1-year results in 1Q2020.

A total of 32 patients were included in three university hospitals of Barcelona’s area: Hospital Clínic de Barcelona, Hospital de la Vall d’Hebron and Hospital de Bellvitge. A high-risk donor and recipient population were included in the study with a high proportion of controlled donors from cardiac arrest (DCD MIII) and aged donor and recipients.

“The high proportion of DCD and very old donor and recipient population is a trademark of the evolution of transplantation that has resulted in an increased organ use from extended criteria donors. This has created new unmet medical needs not currently addressed by the standard-of-care in organ preservation,” said Dr. Carmen Peralta, Co-founder and Chief Scientific Officer of TRANSPLANT BIOMEDICALS.

“On behalf of the company, I would like to take this opportunity to thank the families involved in the donation process, the patients, the transplantation units, and the caregivers and their staff for completing the enrolment of EMERGE study,” said Dr. Joan Salgado, Chief Executive Officer of TRANSPLANT BIOMEDICALS. “We look forward to the first interim results of the EMERGE study, we believe that VIVIAN® has the profile of a true game changer in organ, tissue and cells preservation market, and our development plan is poised to explore all these opportunities”.

VIVIAN® is a medical device for organ ex-vivo treatment with Hypothermic Ultrasound Preservation Technology (HUPT), a unique patented technology combining controlled hypothermia and low frequency/energy ultrasound. Previous functional preclinical trials have shown a significant improvement in graft function in liver and kidney models and a relevant increase in recipient survival. Mechanism of action studies in preclinical models confirmed that VIVIAN® is able to activate intrinsic protective mechanisms to injury (cell survival and tissue regeneration pathways) as well as preservation energy metabolism and inflammatory response reduction.

More information on the trial:

<https://clinicaltrials.gov/ct2/show/NCT03600285>

About TRANSPLANT BIOMEDICALS

TRANSPLANT BIOMEDICALS operates in the medical device sector, we aim to develop and commercialize a new generation of medical technologies that advance organ, tissue and cellular preservation with the purpose of improving patient outcomes and the care provided by their caregivers.

The company is initially focused on the development and commercialization of an organ preservation platform envisaged for the solid organ transplantation market (kidney, liver and heart). Thereafter, the company will expand its activities with the development and commercialization of applications concentrated on the tissue and cellular preservation market.

Despite advances in medicine and an increased social awareness of organ donation and the benefits of solid organ transplantation, the gap between supply and demand continues to widen. The discrepancy between the donor supply and demand has led to an increased use of organs from extended criteria donors and donation after cardiac death donors, as an attempt to close the gap. As a result, the extension of the available deceased donor pool also reflects current societal trends, with donors presenting as significantly older and in poorer health as prior.

The paradox is that these organs from expanded criteria, are most susceptible to the consequences of preservation related injury (early allograft dysfunction, primary non-function, acute rejection) and thus, negatively impacting the effectiveness of transplantation.

TRANSPLANT BIOMEDICALS has the opportunity to become a game changer in organ transplantation by offering a new generation of medical technologies aimed to improve organ preservation. VIVIAN® is expected to address current unmet medical needs and the shortcomings of the standard-of-care in organ preservation by offering a new generation, disposable and cost-effective organ preservation device able to increase preservation efficacy, improve early graft dysfunction, maximize the usage of the available organ pool and enhance the effectiveness of organ transplantation.

TRANSPLANT BIOMEDICALS pursues a total target market of €1.1 billion and now is seeking €13.6M in order to complete the clinical development, final product and market launch of VIVIAN® in kidney transplantation and further pursue early pipeline development activities.

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