

TRANSPLANT BIOMEDICALS ANNOUNCES POSITIVE INTERIM RESULTS OF THE FIRST IN HUMAN CLINICAL STUDY OF VIVIAN® DEVICE IN KIDNEY TRANSPLANTATION (THE EMERGE STUDY)

Barcelona, Spain, June 21th, 2019– TRANSPLANT BIOMEDICALS, a company specializing in the research and development of medical devices for organ, tissue and cell preservation, today announces the positive interim results at 30-days post-transplantation of the first-in-human clinical trial of VIVIAN® KIDNEY, a medical device used for the transportation and preservation of kidneys in patients undergoing kidney transplantation.

The EMERGE study enrolled 32 patients requiring kidney transplantation and was aimed to evaluate the safety and performance of VIVIAN® KIDNEY in this setting. The results show an excellent safety profile with no events directly related with the use of VIVIAN® KIDNEY device and no organs being discarded before implantation. Furthermore, VIVIAN® KIDNEY was associated with a low rate of delayed graft function (DGF) at 30-days with a short duration of DGF and length of hospitalization.

The EMERGE trial is an ongoing multicenter, prospective, open, single-arm study designed to evaluate the safety and performance of VIVIAN® KIDNEY. A total of 32 patients undergoing kidney transplantation and receiving a graft from either brain death standard and extended criteria donors (DBD; SCD+ECD) or cardiac arrest donors (DCD MIII) were included in three hospitals of the Barcelona area: Hospital Clínic de Barcelona, Hospital de la Vall d'Hebron and Hospital de Bellvitge.

The primary safety endpoint of the study was the rate of events directly related with the use of the device, the primary performance endpoint evaluated the rate of DGF at 30-d after kidney transplantation. The secondary parameters of safety and performance included in the 30-days interim analysis were: rate of organ discarded prior to implantation, duration of DGF, rate of functional delayed function (fDGF), rate of primary non-function, glomerular filtration rate (GFR) and length of hospital stay. Graft and patient survival will be evaluated at 1-y post-transplantation.

In the primary safety analysis at 30-days post-transplantation, no events directly related with the use of VIVIAN® KIDNEY occurred. Moreover, no organ was discarded prior or during the surgical procedure. Serious adverse events (SAE) were reported in 10 recipients, all SAE were unrelated to VIVIAN® KIDNEY and commonly observed in other studies of kidney transplantation and routine clinical practice.

In the primary performance endpoint, the proportion of recipients with DGF in the ITT population was 0.19. In the DBD and DCD subgroups, the rate of DGF was 0.25 and 0.16, respectively. Similar results were observed in the PP population. No recipient suffered from a graft primary non-function (PNF).

Based on these results, Fritz Diekmann, MD, Head of Renal Transplant Unit at Hospital Clinic de Barcelona and principal investigator of the EMERGE study commented: "A 19% rate of DGF, is a remarkable achievement, in particular if we take into consideration the high proportion of DCD (61%) and the mean age (over 60-years) of the donor/recipient population included in the EMERGE study. These results are very encouraging for patients undergoing kidney transplantation and surpasses our clinical daily experience and those reported in the literature in comparison to static cold storage".

“We are delighted with the interim results at 30-days of this first-in-human study with VIVIAN® KIDNEY. These results are in full alignment with our pre-clinical experience and fully support the idea that our disrupting platform can play a relevant role in addressing the current unmet medical needs not covered by the standard-of-care in solid organ preservation, static cold storage” said Dr. Carmen Peralta, Co-founder and Chief Scientific Officer of TRANSPLANT BIOMEDICALS.

“We believe that VIVIAN® is a platform with the profile of a true game changer in organ, tissue and cells preservation market. These interim results in kidney transplantation represent a boost to our mission of improving the outcomes in solid organ transplantation and to continue and accelerate further our development activities in cell and tissue preservation” said Dr. Joan Salgado, Chief Executive Officer of TRANSPLANT BIOMEDICALS.

More information on the trial:

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

About VIVIAN®

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. VIVIAN® is able to activate new intrinsic protective signalling pathways in the preservation of organs, tissue and cells of great scientific and clinical relevance.

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 extended criteria donors, are most susceptible to the consequences of preservation related injury (early allograft dysfunction, primary non-function, acute rejection) and thus, impacting negatively the post-operative outcomes after transplantation and the quality of life of the patients.

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, enhance the poor post-operative outcomes after organ transplantation from standard and extended criteria donors, and maximize the usage of the available organ pool reducing thus the waiting list for transplant

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.

www.transplantbiomed.com

Contact

Joan Salgado

CEO

jsalgado@transplantbiomed.com

+ 34 655 694 452