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Hiroshima University and SCREEN Complete Clinical Trial of "OrganPocket," a Medical Device for Kidney Transplantation

To Develop a Medical Device That Supports More Reliable Kidney Transplantation

Kyoto, Japan – August 9, 2022 – Hiroshima University and SCREEN Holdings Co., Ltd. (hereinafter, SCREEN) have recently completed a clinical trial to examine the safety and usefulness of "OrganPocket," a medical device for kidney transplantation developed by SCREEN. SCREEN will place the medical device on the market and continue research and development, aiming to expand the intended for use to organs other than kidneys.

During vascular anastomosis*¹ in kidney transplantation procedures, kidneys removed from donors and stored after cooling are exposed to the risk of second warm ischemic injury*² due to heating by contact with a surgeon or donor's tissues. To counteract such temperature rise in kidneys, measures that have been taken included spraying of physiological saline solution. However, since the effect of doing so is only temporary and it is difficult to set conditions on the amount of spraying and timing, there has been a need for an effective and standardized way to control temperature.

To address such issues, SCREEN has developed "OrganPocket," a medical device to cover organs temporarily and keep them cool, through joint research with Prof. Eiji Kobayashi, M.D., Ph.D., Department of Organ Fabrication, Keio University School of Medicine (currently Project Professor, Department of Kidney Regenerative Medicine, Jikei University School of Medicine). Made of a special gel material, this thermal isolation bag is an instrument shaped like a drawstring pouch bag and wraps an organ to be transplanted during kidney transplantation to properly hold it, blocking contact heat and physical stimuli from the surgeons or patient. A special material, which is transparent and extremely soft, adheres closely to the kidney to protect it while allowing vascular anastomosis of the blood vessels or the ureter exposed through the product opening. Once reperfusion of blood to the kidney is complete, OrganPocket is easily removed from the organ. A product performance test has demonstrated that when a porcine kidney isolated and cooled to 4°C is placed in a pseudo-abdominal environment set at 37°C, its surface temperature normally increases to near body temperature after 10 minutes. With OrganPocket, in contrast, the surface temperature remains 20°C or less even after 30 minutes.

Hiroshima University has conducted a clinical trial under the direction of Prof. Hideki Ohdan, Professor of the Department of Gastroenterological and Transplant Surgery,

Graduate School of Biomedical and Health Sciences, Hiroshima University, to evaluate the safety, usefulness, and procedural validity of OrganPocket in kidney transplantation. An open-label, uncontrolled, single-arm study*³ in 10 patients has revealed that the surface temperature of renal grafts (transplanted kidneys) using OrganPocket was controlled to a median of 16.1 [12.8–18.7]°C. The results indicate that using OrganPocket enables more reliable control of temperature rises. The clinical trial results will be presented at an academic conference by the end of this year.

The clinical trial is expected to confirm that OrganPocket provides greater reliability in organ protection during transplantation procedures. This product has been notified to the authority as a medical device, and SCREEN will manufacture and market the product, and is planning to conduct research and development aiming to expand the product's application to organs other than kidneys.

Hiroshima University and SCREEN will continue to strengthen industrial-academic cooperation through joint research to contribute to the development of transplantation medicine.

*1 Vascular anastomosis: To connect the artery, vein, or the ureter of a donor organ to the recipient side in transplant surgery.

*2 Warm ischemic injury: If biological tissues are exposed to body temperature without blood flow (warm ischemia), cellular homeostasis is not maintained due to the lack of oxygen and nutrients, and so disabling substances are released outside the cell. Upon blood reperfusion, circulation of disabling substances causes organ dysfunction.

*3 Open-label, uncontrolled, single-arm study: A clinical trial conducted only in a study group using the product, without setting a control group

■ Comments by Prof. Hideki Ohdan, Professor of the Department of Gastroenterological and Transplant Surgery, Graduate School of Biomedical and Health Sciences, Hiroshima University

Transplanted organs should be maintained at as low a temperature as possible until reperfusion in order to suppress cellular metabolism and reduce organ dysfunction. OrganPocket is a unique new product for thermal isolation of organs that can maintain transplanted organs at a low temperature during procedures. This product is expected to contribute to stable transplant performance.

■ Comments by Prof. Eiji Kobayashi, Project Professor of the Department of Kidney Regenerative Medicine, Department of Industrial-Academic Cooperation, Jikei University School of Medicine

Joint development of SCREEN's first medical device up to its clinical application is a significant achievement in industrial-academic cooperation. OrganPocket was inspired by a need in the field of transplant surgery. I would like to show my highest respect for corporate researchers in other fields who have passionately commercialized the product, and that Hiroshima University has achieved a successful clinical trial.

■ Comments by Dr. Kazunari Tanabe, Department of Urology, Tokyo Women's Medical University School of Medicine

In organ transplantation, it is extremely important to maintain transplanted organs at an appropriate temperature for preserving the functions of transplanted organs. OrganPocket, which is a newly developed product and can keep organs at a low temperature, is expected to help preserve the functions of transplanted organs.

■ Comments by Mr. Junji Otsuka, Corporate Executive Officer of SCREEN Holdings Co., Ltd.

OrganPocket has been developed with Dr. Kobayashi of Keio University (then), and its usefulness has been demonstrated through a clinical trial conducted by Dr. Ohdan and Dr. Ide of Hiroshima University thanks to their significant efforts. Our company will continue to provide products and services as a “solution creator” for medical issues through industrial-academic cooperation.