# eGenesis and OrganOx Announce Successful Use of a Genetically Engineered Porcine Liver with a Human Donor

## 72-hour proof-of-concept procedure at Penn Medicine marks longest perfusion using genetically engineered porcine organ designed for liver support

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**Cambridge, Mass. (January 18, 2024) –** eGenesis, a biotechnology company developing human-compatible organs and cells for the treatment of organ failure, and OrganOx, a medical device company with a focus on the therapeutic applications of isolated organ perfusion, today announced the successful completion of an extracorporeal perfusion of a brain-dead research donor using a genetically engineered porcine liver. The donor was the first to be enrolled in the ongoing PERFUSE-2 study.

The study, made possible through the generosity of a donor family seeking to help other families through the advancement of clinical research, was carried out in collaboration with the University of Pennsylvania Transplant Institute and Gift of Life Donor Program. The perfusion was performed using the eGenesis liver, EGEN-5784, connected to the OrganOx extracorporeal liver cross-circulation (ELC) device to enable circulation of the donor's blood through the porcine liver. Stable blood flow, pressure, and pH were maintained throughout the procedure, in addition to robust bile production. No evidence of rejection was observed. The perfusion was electively stopped per-protocol at 72 hours with the liver appearing healthy.

The PERFUSE-2 study is being conducted to evaluate the feasibility of using this liver perfusion system to support patients suffering from liver failure. Annually in the US, over 300,000 patients are admitted with various forms of liver failure, requiring treatment in the acute setting. The efficacy of existing liver support options is limited, and patients in liver failure face a high risk of mortality. For some patients, utilizing a human-compatible, genetically engineered porcine whole liver to support the function of a patient's decompensated liver may provide time for the recovery of the patient's native liver or time to obtain a liver transplant. eGenesis and OrganOx are co-developing this technology and anticipate submitting an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) in 2024 to initiate a first-in-human clinical study.

The genetically engineered porcine liver used in this study carried the same genetics as the porcine kidneys used in the landmark preclinical study recently published in Nature. These edits include (1) knock out of three genes involved in the synthesis of glycan antigens implicated in hyperacute rejection, (2) insertion of seven human transgenes involved in the regulation of several pathways that modulate rejection: inflammation, innate immunity, coagulation, and complement, and (3) inactivation of the endogenous retroviruses in the porcine genome.

“We extend our deepest gratitude to the donor and their family for enabling this important medical achievement and for paving the way for future work toward a potential solution for the many patients in need of life-saving liver support,” said Michael Curtis, Ph.D., President and Chief Executive Officer of eGenesis. “In addition to being a first in the field of xenotransplantation, this study provides important information to help advance our IND application.”

Abraham Shaked, M.D., Ph.D. of the University of Pennsylvania Transplant Institute said, “The success of this study provides support for further exploration of organ products developed using advanced genome engineering to provide novel, high-quality therapeutic options for individuals experiencing organ failure.”

“This marks a key milestone in our journey towards an effective treatment for acute liver decompensation. The OrganOx ELC system combined with a genetically engineered liver from eGenesis links modern organ perfusion technology with the functions of a whole liver, with the goal of providing a treatment that offers a lifeline to the critically ill patient – time for their own liver to recover or time to receive a transplant,” said Prof Peter Friend, Chief Medical Officer, OrganOx.

“Gift of Life Donor Program, one of the nation’s leading organ procurement organizations, is proud to have collaborated on this pioneering study that has the potential to bring new hope to waitlist patients by providing a bridge to transplant or time for healing,” said Richard D. Hasz, Jr., MFS, CPTC, President and CEO, Gift of Life Donor Program. “This unique study was only possible thanks to the generosity of a donor family willing to help alleviate the suffering of others despite their own personal loss. Every day, we are inspired by the kindness of families who choose donation. We look forward to partnering with Penn Medicine, eGenesis and OrganOx on future trials to advance this evolving field of medicine.”

“Our family is very proud to support this medical advancement and see our loved one’s legacy benefit countless others,” said a member of the donor family. “It is a testament to our loved one’s selflessness and compassion to know this donation offers such hope for people suffering serious disease in the future.”

**About OrganOx**

OrganOx is a commercial stage UK-based medical device company with a focus on the therapeutic applications of isolated organ perfusion. Its first product, the OrganOx metra normothermic liver machine perfusion system, has been used to support more than 3000 liver transplant operations globally, optimizing the use of donated organs by enabling assessment of the quality of livers as well as longer preservation durations. Other therapeutic applications, including in kidney transplantation, are in development. Learn more at www.organox.com.

**About eGenesis**

eGenesis is pioneering a genome engineering-based approach in the development of safe and effective transplantable organs. The eGenesis Genome Engineering and Production (EGEN™) Platform is the only technology of its kind to comprehensively address cross-species molecular incompatibilities and viral risk via genetic engineering. eGenesis has demonstrated durable preclinical success to date and is advancing development programs for

acute liver failure, kidney transplant, and pediatric as well as adult heart transplant. Learn more at www.egenesisbio.com.