

World's first genetically engineered pig kidney transplant into living patient is major step towards addressing global organ shortage



Genesis, a biotechnology company developing human-compatible engineered organs to address the global organ shortage, [on March 21, 2024] announced the first ever transplantation of a genetically engineered porcine kidney into a living human recipient.

The transplant was authorized by the U.S. Food & Drug Administration (FDA) under the Expanded Access pathway and performed by a surgical team at Massachusetts General Hospital (MGH) led by Tatsuo Kawai, MD, PhD and Nahel Elias, MD. The patient suffers from end-stage renal disease and lacked other therapeutic options following the loss of vascular access to support continued use of dialysis. Following the procedure, the patient is in good condition and recovering well at MGH.

More than 800,000 people in the U.S., and millions globally, suffer from end-stage renal disease or kidney failure, a life-threatening condition for which transplantation is considered the gold standard treatment option to improve quality of life and outcomes. Yet the demand for organs far outpaces supply, with more than 90,000 individuals on the kidney waitlist and approximately 25,000 kidney transplants performed each year. Human compatible donor organs developed by eGenesis offer a potentially viable alternative to end waitlist mortality and alleviate the shortage of transplantable organs.

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The eGenesis donor kidney (EGEN-2784) used for this procedure is the company's lead candidate for kidney transplant and carries three classes of edits: (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 pathways that modulate rejection: inflammation, innate immunity, coagulation, and complement, and (3) inactivation of the endogenous retroviruses in the porcine genome. eGenesis is the only company in the industry developing organs that carry all three classes of edits to address organ safety and efficacy. Without genetic modification, a porcine kidney would be immediately rejected by a human recipient.

"This successful procedure heralds a new era in medicine in which we have the potential to eliminate organ supply as a barrier to transplantation and realize our vision that no patient dies waiting for an organ," said Michael Curtis, Ph.D., Chief Executive Officer of eGenesis. "We are humbled by the courage and generosity of this patient, who is a true pioneer, enabling this major break-through in science and transplant medicine. The large body of preclinical evidence of long-term recipient survival with EGEN-2784 that we have generated gives us the confidence to evaluate our product in the clinical setting. We are thrilled to collaborate with the team at MGH on this historic procedure given their preeminence in clinical care and research as well as their long-term experience with our technology."

The immunosuppression regimen used includes approved agents as well as a novel, investigational

monoclonal antibody, tegoprubart, targeting the co-stimulatory CD40L pathway. Tegoprubart is supplied by Eledon Pharmaceuticals and is currently being evaluated in two clinical trials for kidney allotransplantation.

“This procedure marks a pivotal milestone in the field of transplantation, illustrating the power of collaboration within our community and with leading organizations like eGenesis to address the critical issue of global organ shortage. MGH and eGenesis rigorously worked side by side to take this transplant from concept to reality. We are also grateful to the FDA team for their support and guidance during this process. Lastly, we commend the courage of our patient. The success of this procedure shines a beacon of hope for individuals worldwide grappling with organ failure,” stated Leonardo V. Riella, MD, PhD, Medical Director for Kidney Transplantation at Massachusetts General Hospital.

Decades of progress in cross-species transplantation, accelerated by the advancement of modern genome editing tools and next-generation sequencing, have enabled eGenesis to progress genetically engineered organs to the clinical setting.

[Read the original post here](#)