United Therapeutics Corporation Announces First Transplant in *EXTEND* Clinical Trial of UThymoKidney™ in Patients with End-Stage Renal Disease

The EXTEND *study is the first clinical trial to evaluate xenotransplantation of a porcine thymokidney in a patient with end-stage renal disease (**ESRD**)*

EXTEND *is the second clinical trial in United Therapeutics' xeno-organ manufacturing program*

SILVER SPRING, Md., and RESEARCH TRIANGLE PARK, N.C., Nov. 20, 2026 – United Therapeutics Corporation (Nasdaq: **UTHR**), a public benefit corporation, today announced the first clinical xenotransplant in its *EXTEND* study of the UThymoKidney™ in patients with ESRD. The transplant operation was performed at NYU Langone Health.

The ongoing *EXTEND* study will evaluate the safety and efficacy of the UThymoKidney in ESRD patients who are not eligible for conventional allogeneic kidney transplantation or who are on an Organ Procurement and Transplantation Network (**OPTN**) kidney transplant waitlist, but are more likely to die or go untransplanted within five years than receive a kidney transplant.

United Therapeutics' investigational UThymoKidney is a xenokidney that contains porcine thymic tissue and is derived from a pig with a single gene edit. The pig's thymus tissue is intended to condition the recipient's immune system to recognize the UThymoKidney as "self" and reduce the likelihood of organ rejection. The single gene responsible for the synthesis of alpha-gal, a sugar on the surface of cells that can cause immediate rejection of a porcine organ when transplanted into the human body, has been inactivated in the pig's genome.

"Today marks an exciting moment for United Therapeutics and for the field of xenotransplantation. *EXTEND* is the second clinical trial in our xeno-organ manufacturing program, and it reflects years of investment in the science, facilities, and regulatory groundwork needed to bring this technology from possibility to clinical reality," said **Jayme Locke, M.D.**, Ph.D., Chief Medical Officer, Xenotransplantation at United Therapeutics

"We are demonstrating that an investigational manufactured organ program can move methodically from the laboratory to patients, always with patient safety first. We are deeply grateful to the participant, their family, and the NYU Langone team," said **Leigh Peterson, Ph.D.**, Executive Vice President, Product Development & Xenotransplantation at United Therapeutics.

"Every day, people with kidney failure die waiting for an organ that never comes. The need for new sources of organs is urgent. UThymoKidney is designed with the intention to help a recipient's immune system accept the organ and reduce the risk of organ rejection. The *EXTEND* study provides a carefully designed, scientifically rigorous way to determine whether another approach to xenotransplantation can deliver real benefit to patients who have few other options," said **Robert Montgomery, M.D.**, D.Phil., the H. Leon Pachter, M.D., Professor of Surgery; Chair of the Department of Surgery at NYU Grossman School of Medicine; and Director of the NYU Langone Transplant Institute, who led the transplant team that performed the first xenotransplant in the *EXTEND* study.

About United Therapeutics' Xenotransplantation Program
United Therapeutics is advancing clinical trials called *EXTEND*, *EXPAND*, and *EXPRESS*, which are intended to support Biologics License Applications (**BLA**) with the U.S. Food and Drug Administration (**FDA**) for each of its three investigational xenotransplantation products:

EXTEND (NCT07224763) is a multicenter, open-label, combination phase 1/2/3 clinical trial designed to evaluate the safety and efficacy of UThymoKidney. This phaseless trial will progress without separate phase 1, 2, and 3 studies typically associated with conventional drug approvals.

Study participants will receive a UThymoKidney transplant followed by a 24-week post-transplant follow-up period, including the evaluation of all study endpoints and safety assessments. After the 24-week post-transplant follow-up period, participants who receive a UThymoKidney will continue to be followed for the rest of their lives, including monitoring for UThymoKidney function and zoonotic infections.

Efficacy endpoints include participant survival rate, UThymoKidney survival rate, change in measured glomerular filtration rate[1], donor specific hyporesponsiveness[2], and change in quality of life[3] in participants at 24 weeks post-transplant, as well as overall survival time of participants receiving a UThymoKidney and overall survival time of the UThymoKidney post-transplant. Safety endpoints include the incidence of adverse events and serious adverse events, all-cause mortality, and the incidence of proteinuria[4], zoonotic infections, and opportunistic infections[5].

The first six transplants will take place at two centers, with a 12-week waiting period between the first and second transplants. After all six participants reach at least 12 weeks post-transplant, safety and efficacy data will be reviewed by an Independent Data Monitoring Committee to determine if the study should continue. United Therapeutics intends to present the data from the first six transplants to the FDA for review prior to including additional transplant centers and increasing the study sample size to support a BLA. Additional details on the *EXTEND* study, including full inclusion and exclusion criteria, are available at ClinicalTrials.gov.

EXPAND (NCT06878560) is a multicenter, open-label, safety and efficacy study of United Therapeutics' UKidney™ in patients with ESRD. The *EXPAND* study is currently being conducted at NYU Langone Health and Northwestern Medicine, with the potential to include other centers if initial data are supportive. *EXPAND* is the world's first clinical trial designed specifically to generate the definitive safety and efficacy data needed to support an application for regulatory approval (i.e., a registration study).

EXPRESS is an open-label, safety and efficacy study of United Therapeutics' UHeart™ in patients with advanced heart failure. It will start at a single center with potential to include other centers if initial data are supportive.

The UThymoKidney is a xenokidney that contains porcine thymic tissue and is derived from a pig with a single gene edit.

The UKidney and UHeart are derived from a pig with 10 gene edits. Six human genes are added to the pig genome to facilitate immunological acceptance and compatibility of the organ in the human recipient. Four porcine genes are inactivated or "knocked out" to reduce the risk of organ rejection and to moderate organ growth.

United Therapeutics' xeno-organs are all investigational-stage products which have not been approved in any jurisdiction for any indication.

The Organ Shortage Crisis and ESRD

Demand for organ transplants far exceeds the supply of available organs, and alternative organ sources are needed. In the United States alone, there are approximately 830,000 patients with kidney failure, over 550,000 patients on dialysis, and more than 90,000 patients on the kidney transplant waiting list. Only about 22,000 deceased donor kidney transplants occurred in 2025[6]. The 2024 US Renal Data System Annual Report found that, three years after starting dialysis, only 12% of patients had been placed on an OPTN kidney transplant waitlist and more than 40% had died without receiving a kidney transplant[7]. Xenotransplantation offers the potential to mitigate, and perhaps even solve, the organ shortage crisis.

About United Therapeutics

Founded by CEO Martine Rothblatt to discover a cure for her daughter's life-threatening rare disease, pulmonary arterial hypertension, United Therapeutics transforms the treatment of rare diseases and pioneers alternatives to expand the supply of transplantable organs. From our innovative therapies to our groundbreaking manufactured organs, we are bold and unconventional. We move quickly from scientific theory to practical technologies that can save lives. As a public benefit corporation, even our legal structure reflects our commitments. We serve patients, act with integrity, create long-term shareholder value, and operate with sustainable practices that protect the future we are working to build. Visit us at www.unither.com and follow us on LinkedIn, Facebook, and Instagram.

Forward-Looking Statements

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements regarding: our plans to develop our xenotransplantation products, including the *EXTEND* study of the UThymoKidney, the *EXPAND* study of the UKidnty, and the *EXPRESS* study of the UHeart; the potential that these studies will support a BLA for each of these products; and our efforts to innovate for the unmet medical needs of our patients, to benefit our other stakeholders, and to pursue our public benefit purpose of developing novel pharmaceutical therapies and technologies that expand the availability of transplantable organs. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic reports filed with the Securities and Exchange Commission, that could cause actual results to differ materially from anticipated results. Consequently, such forward-looking statements are qualified by the cautionary statements, cautionary language, and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We are providing this information as of November 20, 2026, and assume no obligation to update or revise the information contained in this press release whether because of new information, future events or any other reason.

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[1] The glomerular filtration rate, or GFR, measures how much blood passes each minute through the glomeruli, the tiny filters in the kidneys.

[2] Donor specific hyporesponsiveness will be measured using the Mixed Lymphocyte Reaction assay and will determine tolerance of the recipient's immune system to the transplanted UThymoKidney.

[3] Quality of life will be measured using the following four surveys: the EuroQol 5-Dimension 5-Level, the Standardized Outcomes in Nephrology Life Participant, the Kidney Transplant Questionnaire, and the Patient Global Impression of Change.

[4] Proteinuria is a condition where an excessive amount of protein is present in the urine. This can be caused by multiple factors, including kidney damage.

[5] Opportunistic infections are infections from pathogens that would not normally impact healthy people. Transplant patients, receiving either xenotransplants or allogeneic transplants, must use immunosuppressive medications to prevent rejection of transplanted organs. Opportunistic infections can occur in people with suppressed immune activity.

[6] American Kidney Fund. Quick Kidney Disease Facts and Stats 2026. Available at: https://www.kidneyfund.org/all-about-kidneys/quick-kidney-disease-facts-and-stats.

[7] United States Renal Data System. 2024 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024. Available at: https://usrds-adr.niddk.nih.gov/2024.