For Immediate Release

United Therapeutics Announces Successful World's First UKidney Transplant

The first living recipient of a UKidney™ is recovering after a successful transplant

This transplant builds on two successful UHeart™ transplants completed in 2022 and 2023 and a successful UThymoKidney™ transplant in 2024

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., December 17, 2024 -- United Therapeutics Corporation (Nasdaq: **UTHR**), a public benefit corporation, today announced the world's first transplant of a UKidney, which it produced, into a living person on November 25, 2024.

The transplant is the fourth xenotransplant using United Therapeutics' xeno organs into living humans, following two successful UHeart transplants at the University of Maryland Medicine in 2022 and 2023 and a successful UThymoKidney transplant at NYU Langone Health earlier this year.

The transplant was authorized by the U.S. Food and Drug Administration (**FDA**) under the expanded access pathway, also known as "compassionate use", and performed by surgeons at NYU Langone Health led by **Robert Montgomery, M.D., DPhil**. The patient was initially identified and evaluated at the University of Alabama at Birmingham by **Jayme Locke, M.D., M.P.H., F.A.C.S., F.A.S.T.** Dr. Locke also assisted in the transplant surgery.

The patient, 53-year-old **Towana Looney** from Alabama, previously donated one of her kidneys to her mother but developed kidney failure several years later after a complication during pregnancy caused damaging high blood pressure. She was placed on the transplant waiting list and started dialysis. However, after several years, she was unable to find a suitable kidney from a donor due to unusually high levels of antibodies that make transplant rejection more likely.

United Therapeutics' xenokidney, known by the proposed trade name UKidney, is an investigational xenokidney from a pig with 10 gene edits. Six human genes are added to the pig genome to facilitate immune acceptance of the organ, while four genes are inactivated: three that contribute to porcine organ rejection in humans and one that can cause organ growth beyond what is normal for humans.

The 10-gene edit pig was developed by Revivicor, Inc., a subsidiary of United Therapeutics.

"Each successful xenotransplantation brings us closer to a future where organ shortages no longer cost lives," said **Martine Rothblatt, Ph.D.**, Chairperson and Chief Executive Officer of United Therapeutics. "The latest transplant of our UKidney is the culmination of decades of dedicated research and demonstrates the significant progress we are making in this revolutionary field. I am deeply grateful to Ms. Looney and her family and the exceptional team of scientists and surgeons who continue to advance this vital effort. While we still have more work to do as we advance toward human clinical trials, today's milestone reinforces that we are on track to fulfill our ultimate mission to create an unlimited supply of transplantable organs and organ alternatives so that patients worldwide have a second chance at life."

According to United States Renal Data System (USRDS) Annual Data Report, over 550,000 patients with end-stage renal disease were being kept alive with dialysis in 2021[1]. Of those, approximately 73,000 patients were on the U.S. kidney transplant waiting list with only around 20,000 deceased donor renal transplants occurring in 2021[2]. Based on 2018 data, after one year of treatment, those on dialysis have a 15-20% mortality rate, with a five-year survival rate of under 50%[3].

"This milestone transplant adds to the considerable body of evidence amassed over more than 20 years, in collaboration with our many research partners, that supports the potential of xenotransplantation to shape the future of treating end-stage organ disease," said **Leigh Peterson, Ph.D.**, Executive Vice President, Product Development and Xenotransplantation at United Therapeutics. "We are working diligently with our collaborators and regulators to initiate the first-ever human clinical study of a xenokidney, and we look forward to sharing more details upon filing and clearance of our clinical study protocol."

United Therapeutics' organ and organ alternative manufacturing efforts consist of four platforms – xenotransplantation, regenerative medicine, 3D organ bioprinting, and bio-artificial organs – encompassing four different organs: hearts, kidneys, livers, and lungs. These groundbreaking programs are intended to address the ongoing shortage of transplantable organs for patients with end-stage organ disease.

United Therapeutics initiated xenotransplantation research in 2011 and currently employs more than 50 scientists and support staff advancing xenotransplant science with three different organ programs: the UKidney xenokidney, the UThymoKidney, a kidney and thymus from a pig with a single-gene edit, and the UHeart, a heart from a pig with 10 gene edits. Earlier this year, United Therapeutics inaugurated the world's first clinical-scale designated pathogen-free facility in Christiansburg, Virginia to support future clinical xenotransplantation studies with a capacity of approximately 125 organs per year. An additional clinical-scale facility is under construction in Stewartville, Minnesota with a similar capacity, and more clinical-scale facilities in North America are planned to support the company's clinical and commercial efforts.

To date, 12 xenotransplantation procedures using United Therapeutics' UHearts, UThymoKidneys, and UKidneys have been performed in both living and decedent[4] recipients: two living human recipients of UHearts, one living recipient of a UThymoKidney, one living recipient of a UKidney, six UKidney and UThymoKidney decedent recipients, and two UHeart decedent recipients. United Therapeutics has built on its history of innovation in xenotransplantation with strong research collaborations with top academic medical centers including NYU Langone Health, the University of Maryland Medicine, Johns Hopkins Medicine, and the University of Alabama at Birmingham.

Preclinical work to support an upcoming investigational new drug application (**IND**) for the UKidney was conducted by **Kazuhiko Yamada, M.D., Ph.D.** and **Andrew M. Cameron, M.D., Ph.D.** at Johns Hopkins University School of Medicine. This work, along with additional data collected by Revivicor and United Therapeutics, will form the basis of the UKidney IND, which United Therapeutics anticipates submitting shortly. If cleared by the FDA, United Therapeutics plans to start a human clinical study in 2025. Alongside the UKidney, United Therapeutics is preparing for clinical trials of its UThymoKidney and UHeart products, following completion of ongoing preclinical studies required by the FDA.

[1] United States Renal Data System. ESRD Prevalent Count, year 2021. https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/usrds/data-query-tools/esrd-prevalent-count
[2] United States Renal Data System. 2023 Annual Data Report, year 2021. https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/7-transplantation
[3] The Kidney Project, University of California San Francisco, 2018
[4] A decedent recipient is a human who has been declared dead by neurologic criteria and is maintained on artificial support.

United Therapeutics: Enabling Inspiration

At United Therapeutics, our vision and mission are one. We use our enthusiasm, creativity, and persistence to innovate for the unmet medical needs of our patients and to benefit our other stakeholders. We are bold and unconventional. We have fun; we do good. We are the first publicly traded biotech or pharmaceutical company to take the form of a public benefit corporation. Our public benefit purpose is *to provide a brighter future for patients through the development of novel pharmaceutical therapies; and technologies that expand the availability of transplantable organs*.

You can learn more about what it means to be a PBC here: unither.com/PBC.

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 progress toward developing our manufactured organ and organ alternative products toward a goal of creating an unlimited supply of transplantable organs and organ alternatives, including our plan to submit an IND for a UKidney clinical trial and anticipated clearance of the IND by the FDA, our plan to commence a UKidney clinical trial in 2025, our plan to complete preclinical studies necessary to support UHeart and UThymoKidney clinical trials, our plan to construct and operate DPF facilities to produce xeno organs, our goals of innovating for the unmet medical needs of our patients and to benefit our other stakeholders and furthering our public benefit purpose of developing novel pharmaceutical therapies and technologies that expand the availability of transplantable organs, and our expectations for a future where organ shortages no longer cost lives. 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. In particular, our plans to commence clinical studies of one or more xenotransplantation products in 2025 are subject to regulatory clearance, including the completion of preclinical studies to the satisfaction of the FDA, and many other factors that we cannot control. 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 December 17, 2024, and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events, or any other reason.

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