



For Immediate Release

United Therapeutics Announces Recent Milestones for its Heart and Kidney Xenotransplantation Programs

Second UHeart™ recipient recovering after a successful transplant

UThymoKidney™ demonstrates normal function during a 61-day study

Human xenotransplant clinical studies could begin in 2025

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., September 22, 2023 -- United Therapeutics Corporation (Nasdaq: **UTHR**), a public benefit corporation, today announced the achievement of two milestones for its xenotransplantation programs in September: the second transplant of a UHeart™ xenoheart into a living person, and a 61-day study of the UThymoKidney™ xenokidney and thymus in a human pre-clinical model.

United Therapeutics' organ manufacturing efforts consist of seven investigational programs: xenoheart, xenokidney, xenothymokidney, regenerative lungs, 3D-printed lungs, 3D-printed livers, and 3D-printed kidneys. These groundbreaking programs are intended to address the ongoing shortage of transplantable organs for patients with end stage organ disease.

According to the U.S. Health Resources and Services Administration, around 110,000 Americans are currently waiting for an organ transplant, and more than 6,000 patients - 17 every day - die each year before receiving one. Almost 89,000 patients are waiting for kidneys, over 10,000 for livers, over 3,300 for hearts, and almost 1,000 for lungs, with many more patients suffering from end-stage organ failure who are ineligible for the strict organ transplant waiting list who could benefit from a readily available supply of organs on demand.

United Therapeutics initiated its xenotransplantation research work in 2011 and currently employs more than 50 scientists and support staff advancing this program. The company is currently finalizing construction of a \$100 million clinical-scale designated pathogen free facility in Christiansburg, VA to support future clinical xenotransplantation studies with a capacity of approximately 125 organs per year.

To date, 10 xenotransplantation procedures using United Therapeutics' xenohearts and xenokidneys have been performed in living and brain-dead human recipients: two living human recipients of xenohearts, six brain-dead xenokidney/thymokidney recipients, and two brain-dead xenoheart recipients. United Therapeutics has built on its history of innovation in xenotransplantation with strong partnerships with top academic medical centers including the University of Maryland Medicine (**UMM**), NYU Langone Health (**NYU**), and the University of Alabama at Birmingham (**UAB**).

Second Successful Xenoheart Transplant Conducted at the University of Maryland Medical Center

In the second procedure of its kind, surgeons affiliated with UMM last Wednesday transplanted a UHeart from a 10-gene modified pig into **Mr. Lawrence Faucette**, under an emergency approval from the U.S. Food and Drug Administration (**FDA**). According to the transplant team, a xenoheart transplant was the only

option available for Mr. Faucette, who has end-stage heart disease and was deemed ineligible for a traditional transplant with a human heart due to his pre-existing peripheral vascular disease and complications with internal bleeding. Mr. Faucette was facing near-certain death from heart failure.

United Therapeutics' UHeart is a heart from a pig with 10 genetic modifications to support organ functioning in the human body. Six human genes were added to the pig genome to facilitate immune acceptance of the organ, while four genes were knocked out: three that contribute to porcine organ rejection in humans and one that can cause organ growth beyond what is normal for humans. United Therapeutics is also developing the UKidney™, a kidney from the same 10-gene modified pig.

"The second transplantation of a UHeart into a living person and the extended study of a UThymoKidney in a decedent, coupled with other ground-breaking research by our collaborators at the University of Alabama at Birmingham, University of Maryland Medicine, and NYU Langone Health, form the basis of knowledge we are sharing with the FDA ahead of commencing future human clinical studies of xeno organs in humans," said **Leigh Peterson, Ph.D.**, Executive Vice President, Product Development & Xenotransplantation at United Therapeutics. "We look forward to continuing our dialogue with the FDA with the goal of starting clinical studies in 2025."

Dr. Peterson continued: "We are grateful for the courageous contribution of Mr. Faucette and his family to the advancement of this important science. The entire United Therapeutics family is pulling for Mr. Faucette and hopeful for a smooth recovery."

United Therapeutics is preparing for clinical trials of its xenoheart and xenokidney products, following completion of ongoing preclinical studies required by the FDA.

Xenokidney Demonstrates the Longest-Documented Case of Xeno Organ Function in a Human Body at NYU Langone Medical Center

In a 61-day study that concluded September 13th, surgeons at NYU Langone Medical Center evaluated the function of a UThymoKidney in what is now the longest-documented case of a xeno organ functioning in a human body. The kidney recipient, with his family's consent, was a deceased 58-year-old man who had been on a ventilator after being declared dead by neurologic criteria before the xenotransplant.

United Therapeutics' UThymoKidney is a kidney from a one-gene modified pig along with the pig's thymus. The gene that is inactivated is responsible for the synthesis of alpha-gal, a sugar on the surface of cells that can cause the immediate rejection of the organ in a human body. The pig's thymus is intended to help teach the recipient's immune system to recognize the kidney as "self" and prevent rejection.

"We at United Therapeutics congratulate our research collaborators at University of Maryland Medicine and NYU for these two historic achievements," said **David Ayares, Ph.D.**, President and Chief Scientific Officer of United Therapeutics' Revivicor subsidiary. "We also recognize the contributions of the patients and families associated with these procedures that help us move forward with this important science. In addition, I want to recognize the decades of work and dedication by the Revivicor team to bring this technology so close to its potential to revolutionize the way we treat end stage organ disease."

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 organ manufacturing programs, including our plans to complete required preclinical studies and commence clinical trials of one or more xenotransplantation products in 2025, our planned construction of a clinical-grade xenotransplantation manufacturing facility and its anticipated 125 organ per year capacity, and 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. 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 September 22, 2023, 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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For Further Information Contact:

Dewey Steadman at (202) 919-4097

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