United Therapeutics Announces Positive Results from Phase 1 Study of miroliver*ELAP*® in Patients with Acute Liver Failure

This study was the world's first FDA-cleared clinical trial using a bioengineered liver. Based on these positive results, United Therapeutics will initiate a phase 2 study

Approximately 30% of acute liver failure patients die because they are ineligible for a liver transplant or a donated liver is not available[1], demonstrating the critical need for organ alternatives

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., January 26, 2026 – United Therapeutics Corporation (Nasdaq: **UTHR**) today announced positive results from its phase 1 study of miroliver*ELAP*®, an external liver assist product, in patients with acute forms of liver failure, acute-on-chronic liver failure, and severe acute alcoholic hepatitis, collectively called acute liver failure (**ALF**).[2]

Developed by Miromatrix Medical Inc., a wholly owned subsidiary of United Therapeutics, miroliver*ELAP* consists of an external blood circuit and a single-use bioengineered liver sustained outside of the human body to provide temporary liver support to ALF patients. The bioengineered liver is manufactured by seeding a decellularized porcine liver scaffold with allogeneic[3] human endothelial[4] cells and human liver cells isolated from donated human livers. The donated human livers are not suitable for transplantation and are provided by organ procurement organizations (**OPOs**).

In the study, five ALF patients who were not candidates for a liver transplant were continuously treated with miroliver*ELAP* for at least 44 hours. The single-arm, open label, safety study met the primary endpoint of survival during miroliver*ELAP* treatment and there were no reports of unexpected serious adverse events attributable to the miroliver*ELAP* over a subsequent 32-day follow-up period. Full study results will be presented and published in the second half of 2026.

"This study provides early evidence that miroliver*ELAP*, an innovative bioengineered organ alternative product, has the potential to provide liver support for patients experiencing ALF, giving their native livers more time to recover. Achieving this important milestone allows us to continue advancing miroliver*ELAP* to help save and improve the lives of ALF patients, who face poor outcomes and a desperate need for therapies," said **Jeff Ross, Ph.D.**, President of Miromatrix.

"United Therapeutics is committed to developing technologies that expand the availability of transplantable organs, and the completion of this clinical trial represents yet another historic achievement for our company. We are thrilled to see positive results from this groundbreaking study of miroliver*ELAP* in ALF patients for whom liver transplantation was not an option. We sincerely thank the patients, physicians, and OPOs who made this trial possible," said **Martine Rothblatt, Ph.D.**, Chairperson and Chief Executive Officer of United Therapeutics.

ALF, a devastating condition that affects thousands of patients each year, is characterized by a rapid loss of liver function in a matter of days or weeks. Approximately 45% of ALF patients will experience spontaneous recovery, while 25% will receive a liver transplant, the only effective ALF treatment. Approximately 30% of ALF patients will die because they are ineligible for a liver transplant or are unable to receive one in time due to the rapid onset of the disease and the drastic shortage of transplantable organs.[5]

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[1] Mendizabal M, Silva MO. Liver transplantation in acute liver failure: A challenging scenario. World J Gastroenterol. 2016 Jan 28;22(4):1523-31. DOI: 10.3748/wjg.v22.i4.1523. PMID: 26819519; PMCID: PMC4721985. https://pmc.ncbi.nlm.nih.gov/articles/PMC4721985/

[2] More information on the study is available at https://clinicaltrials.gov/study/NCT06285253.

[3] **Allogeneic** cells come from a donor who is genetically different from the recipient.

[4] **Endothelial** cells form the inner lining of blood vessels.

[5] Lee, W. M., Squires, R. H., Jr, Nyberg, S. L., Doo, E., & Hoofnagle, J. H. (2008). Acute liver failure: Summary of a workshop. *Hepatology (Baltimore, Md.)*, *47*(4), 1401–1415. https://doi.org/10.1002/hep.22177

United Therapeutics' organ and organ alternative manufacturing efforts consist of three platforms – xenotransplantation,[6] allogeneic regenerative medicine, and autologous[7] regenerative medicine – encompassing four different organs: hearts, kidneys, livers, and lungs. These programs are intended to address the ongoing shortage of transplantable organs for patients with end-stage organ disease.

Miromatrix received clearance from the United States Food and Drug Administration for its Investigational New Drug application for the phase 1 clinical trial of miroliver*ELAP* in 2024. miroliver*ELAP* is investigational and is not approved for any use in any country. In addition to miroliver*ELAP*, Miromatrix is developing mirokidney, a fully transplantable bioengineered kidney, utilizing the same decellularization and seeding technology used in miroliver*ELAP*.

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 (**PBC**). Our public benefit purpose is to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) 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 the future development of our miroliver*ELAP* product, including our expectation that we will commence a phase 2 study; the potential for miroliver*ELAP* to offer a new treatment to improve and save lives of ALF patients; 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. 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 January 26, 2026, 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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[6] **Xenotransplantation** is the process of transplanting living cells, tissues, or organs from one species into another—most commonly from animals into humans. United Therapeutics is conducting research involving transplantation of whole organs from gene-edited pigs into humans.
[7] **Autologous** cells are cells collected from and then used in the same individual.