For Immediate Release

United Therapeutics Receives FDA Regenerative Medicine Advanced Therapy Designation for miroliver*ELAP*® for Treatment of Acute Liver Failure

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., April 8, 2026: United Therapeutics Corporation (Nasdaq: **UTHR**), a public benefit corporation, today announced that the U.S. Food and Drug Administration (**FDA**) has granted Regenerative Medicine Advanced Therapy (**RMAT**) designation to the company's investigational miroliver*ELAP*®, an external liver assist product.

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 human endothelial 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.

In January, United Therapeutics announced positive results from its phase 1 study of miroliver*ELAP* in patients with acute forms of liver failure, acute-on-chronic liver failure, and severe acute alcoholic hepatitis, collectively called acute liver failure (**ALF**). Full study results will be published in the second half of 2026. miroliver*ELAP* is investigational and is not approved for any use in any country. In addition to miroliver*ELAP*, United Therapeutics and Miromatrix are developing mirokidney®, a fully transplantable bioengineered kidney, utilizing the same decellularization and seeding technology used in miroliver*ELAP*.

The FDA's RMAT designation is a specialized program created to accelerate the development and regulatory review of promising regenerative medicine therapies that target serious or life-threatening diseases with unmet medical needs while maintaining rigorous safety and efficacy standards. To receive RMAT designation, a therapy must demonstrate preliminary clinical evidence of potential efficacy in treating, modifying, reversing, or curing such conditions. Once designated, sponsors receive intensive FDA guidance throughout the development process, including advice on efficient study design, surrogate endpoints, and pathways to accelerated approval. The designation also provides significant regulatory advantages, such as eligibility for priority review, rolling review of Biologics License Application materials, and enhanced organizational commitment from the FDA to expedite the overall development and approval timeline.

"Receiving this designation from the FDA highlights both the critical unmet need we are addressing and the promising potential of miroliver*ELAP* as a novel therapeutic option," said **Jeff Ross, Ph.D.**, President of Miromatrix. "We look forward to continuing our collaborative exchange with the FDA as we advance the clinical development of miroliver*ELAP* for patients with acute liver failure."

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.[1]

United Therapeutics' organ and organ alternative manufacturing efforts consist of three platforms — xenotransplantation, allogeneic regenerative medicine, and autologous 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.

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 concerning: the promising potential of miroliver*ELAP* as a novel therapeutic option; the timing of our regulatory efforts with respect to miroliver*ELAP*, including the potential acceleration of such efforts afforded by RMAT designation; our clinical development plans for miroliver*ELAP*; our plans to publish the results of our phase 1 study of miroliver*ELAP*; United Therapeutics' broader organ and organ alternative manufacturing program; and our goals of expanding the supply of transplantable organs, developing practical technologies that can save lives, creating long-term shareholder value, and operating with sustainable practices. 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 April 8, 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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[1] 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