United Therapeutics Corporation Announces FDA Approval of the LungFX™ Device for Centralized Ex Vivo Lung Perfusion

LungFX™ is the first device approved for centralized ex vivo lung perfusion for donor organs not otherwise used for transplant, an important step in advancing United Therapeutics' platforms

SILVER SPRING, M.D. and RESEARCH TRIANGLE PARK, N.C., JUNE 29, 2026 – United Therapeutics Corporation (Nasdaq: UTHR), a public benefit corporation, today announced that the U.S. Food and Drug Administration (**FDA**) has granted premarket approval (**PMA**) of the LungFX™ device (**LungFX**) for use in centralized ex vivo lung perfusion (**EVLP**), a procedure that enables donor lungs to be assessed outside the body after procurement and before transplantation.

The PMA, submitted by United Therapeutics' wholly owned subsidiary, Lung Bioengineering Inc., included comprehensive safety and effectiveness data supporting use of LungFX to perform EVLP in a centralized facility.

LungFX is indicated for centralized, ex vivo (outside the body) evaluation of deceased-donor lungs (single and double) that cannot be placed for transplantation by an organ procurement organization (**OPO**) with any of the matched candidates if using direct-to-recipient procurement and preservation procedures. LungFX provides normothermic perfusion and ventilation of procured donor lungs initially stored with cold static preservation solution.

LungFX is intended to allow for re-assessment, in a controlled environment, of the suitability of procured donor lungs for transplantation into male and female patients aged 18 years or older with end-stage lung disease awaiting first-time (double or single) lung transplantation. Lungs accepted for transplantation after LungFX require a second period of storage with cold static preservation solution, and cumulative preservation time of transplanted lungs is not intended to exceed 20 hours.

To date, Lung Bioengineering has performed 1,100 EVLP procedures using other approved devices, with 600 lungs accepted for transplant. Lung Bioengineering expects to add LungFX to its available services in 2027.

"Today's approval is a big step forward in reducing the large number of donor lungs – over 80% – that are unfortunately left behind instead of being transplanted," said Martine Rothblatt, Ph.D., Chairperson and Chief Executive Officer of United Therapeutics. "The FDA approval of our LungFX device also marks an important milestone on our path toward using advanced technologies to create an unlimited supply of transplantable organs."

"Too many donor lungs go unused today," said Dr. Kenneth McCurry, M.D., Director of the Cleveland Clinic Enterprise Transplant Center and investigator in the LungFX pivotal trial. "EVLP with this device provides additional clinical data to transplant teams to help determine whether donated lungs that might otherwise go unused are suitable for transplant. Our work with Lung Bioengineering over the last ten years has significantly increased the number of patients we have been able to successfully transplant."

"LungFX is the first EVLP device approved specifically for use in a fit-for-purpose centralized facility, expanding access for transplant programs without requiring them to build EVLP capabilities within their own hospitals. It also strengthens United Therapeutics' platform for advancing new technologies designed to enhance donor lung function," said Brandi Zofkie, M.P.H., Associate Vice President of Lung Bioengineering.

Lung Bioengineering Inc., a wholly owned subsidiary of United Therapeutics, is the global leader in centralized EVLP. The company owns and operates facilities in Silver Spring, Maryland, and

Jacksonville, Florida, dedicated to performing centralized EVLP procedures designed to extend preservation and enable assessment of donor lungs that might otherwise be deemed unsuitable for transplant.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
There are no known contraindications.

WARNINGS AND PRECAUTIONS
- The LungFX device is not intended for the preservation of donor lungs that could be matched and successfully placed by an OPO without utilization of the device. In the CLES Pivotal Study, the observed 12-month survival rate among recipients of LungFX lungs did not meet the pre-specified performance goal (> 95% posterior probability of 1 year survival > 81.2%); rates of 12-month overall mortality and Clinical Events Committee (CEC)-adjudicated lung graft-related mortality were higher in EVLP subjects as compared to non-EVLP contemporaneous control subjects; and two-year survival within several pre-specified subgroups were clinically less favorable among EVLP donor lungs than among non-EVLP control donor lungs. Before deciding to proceed with LungFX organ preservation, a physician should fully consider the risks and benefits of this device and those of other organ preservation modalities. Transplant physicians are advised to carefully review the available clinical data in the LungFX device labeling when considering its use for any donor lungs and recipients.
- Only qualified Lung Bioengineering personnel can operate the LungFX device.
- Only trained physicians can evaluate lung suitability for transplantation after LungFX device evaluation.
- Safety and effectiveness of the LungFX device is derived principally from clinical data collected prospectively in the CLES Pivotal Study within 1 year after organ preservation and transplantation and from 2 years of observational, post-transplantation survival. Therefore, the impact of the LungFX device on clinical outcomes such as longer-term recipient survival and graft function (e.g., chronic lung allograft dysfunction (CLAD)) is uncertain. Other approved devices allow for pre-transplant assessment of procured donor lungs under conditions of *ex vivo* normothermic perfusion and ventilation, and there are various approaches available for isolated cold static storage preservation of procured donor lungs. Each alternative has its own advantages and disadvantages. A physician should fully discuss these alternatives with transplant candidates to identify the type of donor organ and preservation method that best meets patient expectations.
- Safety and effectiveness of the LungFX device have not been studied in:

    - **Patients:** individuals under 18 years of age; patients listed for same-side lung re-transplantation, multiple-organ transplantation involving the lung and another organ, or live donor lobar lung transplantation; and patients with HIV infection or *Burkholderia cenocepacia* infection.

    - **Donors/donor lungs:** donors or donor lungs with confirmed pneumonia, persistent purulent secretions identified by bronchoscopy before donor lung excision, confirmed evidence of aspiration, significant mechanical lung injury or trauma, HIV or active hepatitis C.
- A device malfunction or User error could lead to a potential loss of a donor lung.

ADVERSE EVENTS
Patients receiving a lung evaluated with LungFX may experience adverse events (AEs) including those experienced with any lung transplant. Below is a list of some of the AEs observed during clinical studies of the device.
- Death
- Primary graft dysfunction (PGD)

- Chronic lung allograft dysfunction (CLAD)
- Respiratory failure
- Lung transplant rejection
- Pulmonary embolism
- Pneumonia
- Bronchostenosis
- Hypoxia
- Dysphagia

These AEs were also observed in transplant recipients whose lungs did not undergo evaluation with the LungFX device prior to transplantation.

PRESCRIPTION INFORMATION
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Please see the LungFX Physician Labeling and Instructions for Use for further detailed information.

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 Lung Bioengineering's expectation to add LungFX to its available services in 2027; our goal of reducing the number of donor lungs that are left behind not transplanted; our goal of using advanced technologies to create an unlimited supply of transplantable organs; 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. 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 June 29, 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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