



## United Therapeutics Corporation Prevails in Patent Litigation against Liquidia

**SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C. - September 30, 2026** - United Therapeutics Corporation (Nasdaq: **UTHR**), a public benefit corporation, today announced that the United States District Court for the District of Delaware issued an opinion that finds Liquidia Technologies, Inc. (**Liquidia**) infringes two claims of United Therapeutics' patent covering the use of inhaled treprostinil to treat pulmonary hypertension associated with interstitial lung disease (**PH-ILD**).

"We are pleased with the Court's decision, which reinforces our significant research and commitment to bring innovative therapies to the patients we serve. Our immediate priority is ensuring that no patient goes without the therapy they need, and we are ready to support a seamless transition to Tyvaso or Tyvaso DPI should PH-ILD be removed from the Yutrepia label. We look forward to working closely with patients, prescribers, and all other stakeholders throughout this process," said **Michael Benkowitz**, President and Chief Operating Officer of United Therapeutics.

The opinion was rendered in litigation concerning United Therapeutics' U.S. Patent No. 11,826,327 (the '**327 patent**'), which relates to a method of improving exercise capacity in patients with PH-ILD by inhaling treprostinil at specific dosages. Specifically, the Court determined that Liquidia induces infringement of claims 1 and 14 of the '327 patent by marketing Yutrepia for PH-ILD. The Court also concluded that Liquidia failed to prove that those claims are invalid.

As a result of the Court's decision, United Therapeutics believes that it is entitled to an order instructing the U.S. Food and Drug Administration (**FDA**) to withdraw approval of Liquidia's new drug application (**NDA**) for Yutrepia as required by 35 U.S.C. § 271(e)(4)(A). If such an order is granted, it may result in Yutrepia being removed from the U.S. market until such time as FDA can approve labeling omitting the PH-ILD indication. United Therapeutics also intends to seek monetary damages for past infringement, which could include a royalty on past sales of Yutrepia. The Court set a deadline of one week for the parties to submit "an agreed upon form of final judgment" including any such order. If the parties cannot agree on the scope of the final judgment, the Court will need to rule on the issue.

United Therapeutics markets and sells Tyvaso DPI® (treprostinil) and nebulized Tyvaso® (treprostinil) Inhalation Solution, both of which are approved for PH-ILD. United Therapeutics has programs available to assist PH-ILD patients in accessing Tyvaso DPI (treprostinil) and nebulized Tyvaso (treprostinil) Inhalation Solution as prescribed by their healthcare provider.

### 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](http://www.unither.com) and follow us on [LinkedIn](#), [Facebook](#), and [Instagram](#).

## INDICATION

TYVASO (treprostinil) Inhalation Solution and TYVASO DPI (treprostinil) Inhalation Powder are prostacyclin mimetics indicated for the treatment of:

- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies with TYVASO establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%).

The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities.

While there are long-term data on use of treprostinil by other routes of administration, nearly all clinical experience with inhaled treprostinil has been on a background of an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor. The controlled clinical experience with TYVASO was limited to 12 weeks in duration.

- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study with TYVASO establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

- TYVASO and TYVASO DPI are pulmonary and systemic vasodilators. In patients with low systemic arterial pressure, either product may produce symptomatic hypotension.
- Both products inhibit platelet aggregation and increase the risk of bleeding.
- Co-administration of a cytochrome P450 (CYP) 2C8 enzyme inhibitor (e.g., gemfibrozil) may increase exposure (both  $C_{max}$  and AUC) to treprostinil. Co-administration of a CYP2C8 enzyme inducer (e.g., rifampin) may decrease exposure to treprostinil. Increased exposure is likely to increase adverse events associated with treprostinil administration, whereas decreased exposure is likely to reduce clinical effectiveness.
- Like other inhaled prostaglandins, TYVASO and TYVASO DPI may cause acute bronchospasm. Patients with asthma or chronic obstructive pulmonary disease (COPD), or other bronchial hyperreactivity, are at increased risk for bronchospasm. Ensure that such patients are treated optimally for reactive airway disease prior to and during treatment with TYVASO and TYVASO DPI.

### DRUG INTERACTIONS/SPECIFIC POPULATIONS

- The concomitant use of either product with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension.
- Human pharmacokinetic studies with an oral formulation of treprostinil (treprostinil diolamine) indicated that co-administration of the cytochrome P450 (CYP) 2C8 enzyme inhibitor, gemfibrozil, increases exposure (both  $C_{max}$  and AUC) to treprostinil. Co-administration of the CYP2C8 enzyme inducer, rifampin, decreases exposure to treprostinil. It is unclear if the safety and efficacy of treprostinil by the inhalation route are altered by inhibitors or inducers of CYP2C8.
- Limited case reports of treprostinil use in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. However, pulmonary arterial hypertension is associated with an increased risk of maternal and fetal mortality. There are no data on the presence of treprostinil in human milk, the effects on the breastfed infant, or the effects on milk production.
- Safety and effectiveness in pediatric patients have not been established.

- Across clinical studies used to establish the effectiveness of TYVASO in patients with PAH and PH-ILD, 268 (47.8%) patients aged 65 years and over were enrolled. The treatment effects and safety profile observed in geriatric patients were similar to younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant diseases or other drug therapy.

## ADVERSE REACTIONS

- Pulmonary Arterial Hypertension (WHO Group 1)  
In a 12-week, placebo-controlled study (TRIUMPH I) of 235 patients with PAH (WHO Group 1 and nearly all NYHA Functional Class III), the most common adverse reactions seen with TYVASO in  $\geq 4\%$  of PAH patients and more than 3% greater than placebo were cough (54% vs 29%), headache (41% vs 23%), throat irritation/pharyngolaryngeal pain (25% vs 14%), nausea (19% vs 11%), flushing (15% vs  $<1\%$ ), and syncope (6% vs  $<1\%$ ). In addition, adverse reactions occurring in  $\geq 4\%$  of patients were dizziness and diarrhea.

In a 3-week, open-label, single-sequence, safety and tolerability study (BREEZE) conducted in 51 patients on stable doses of TYVASO who switched to a corresponding dose of TYVASO DPI, the most commonly reported adverse events seen with TYVASO DPI in  $\geq 4\%$  of PAH patients during the 3-week treatment phase included cough (35.3%), headache (15.7%), dyspnea (7.8%), and nausea (5.9%).

- Pulmonary Hypertension Associated with ILD (WHO Group 3)  
In a 16-week, placebo-controlled study (INCREASE) of 326 patients with PH-ILD (WHO Group 3), adverse reactions with TYVASO were similar to the experience in studies of PAH.

Please see Full Prescribing Information for [TYVASO](#) or [TYVASO DPI](#), Instructions for Use manuals for [TD-100](#) and [TD-300](#) TYVASO® Inhalation System and [TYVASO DPI® Inhalation Powder](#), and additional information at [www.TYVASOHCPC.com](http://www.TYVASOHCPC.com) or call 1-844-UNITHER (1-844-864-8437).

## 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: our efforts to bring innovative therapies to the patients we serve; our goal of ensuring that no patient goes without the therapy they need; our readiness to support a seamless transition to Tyvaso or Tyvaso DPI; any remedies and potential outcomes stemming from the Court’s ruling, including the potential withdrawal of FDA’s approval of the Yutrepia NDA, the removal of Yutrepia from the market, the eventual removal of the PH-ILD indication from Yutrepia’s labeling, and the potential award of monetary damages, including a royalty on past sales of Yutrepia; 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 September 30, 2026, and assume no obligation to update or revise the information contained in this press release whether because of new information, future events, or any other reason.

TYVASO and TYVASO DPI are registered trademarks of United Therapeutics Corporation.

YUTREPIA is a registered trademark of Liquidia Technologies, Inc.

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