



For Immediate Release

## United Therapeutics to Feature Clinical Data Across its Commercial and Development Portfolio at the CHEST 2024 Annual Meeting

*Data from the BREEZE open-label extension study of Tyvaso DPI® detail its long-term outcomes and dosing in patients with pulmonary arterial hypertension*

*United Therapeutics is sponsoring the Tyvaso DPI®: Clinical Pearls and Drug-Device Characteristics Symposium*

SILVER SPRING, Md., and RESEARCH TRIANGLE PARK, N.C., September 24, 2024 -- United Therapeutics Corporation (Nasdaq: **UTHR**), a public benefit corporation, today announced that five presentations and one poster across its commercial and development portfolio will be presented at the CHEST 2024 Annual Meeting hosted by the American College of Chest Physicians taking place October 6-9, 2024, in Boston. United Therapeutics will sponsor the *Tyvaso DPI®: Clinical Pearls and Drug-Device Characteristics Symposium*. In addition, United Therapeutics is proud to sponsor the Women in Chest Medicine Annual Luncheon and the Advanced Practice Providers (**APPs**) in Chest Medicine Forum.

"The CHEST Annual Meeting remains an important event for United Therapeutics and the pulmonary hypertension community, and this year we are excited to share additional analyses, particularly from the *BREEZE* open-label extension study, that continue to expand on these important learnings," said **Andrew Nelsen, PharmD**, Vice President, Global Medical Affairs at United Therapeutics. "Equally, we are proud to sponsor a symposium entitled *Tyvaso DPI®: Clinical Pearls and Drug-Device Characteristics*, as well as a series of rapid-fire presentations showing interesting findings in health care resource utilization, patient reported outcomes, and health-related quality of life."

### Oral Presentations include:

[Rapid fire original investigation presentation](#), Tuesday, October 8, 10:20 a.m. to 10:24 a.m. ET: Rapid Area 4B/4071 - **Patient-Reported Symptom Burden and Health-Related Quality of Life in Pulmonary Arterial Hypertension: Results from a Patient's Perspective on Palliative Care Online Survey**. Presented by Denise Sese, M.D., Medical University of South Carolina.

[Rapid fire original investigation presentation](#), Tuesday, October 8, 10:32 a.m. to 10:36 a.m. ET: Rapid Area 4B/4071 - **Initial Validation of the Pulmonary Hypertension Functional Classification Self-Report (PH-FC-SR): A Patient Focused Measure for Use in Research and in the Clinic**. Presented by Kristin Highland, M.D., FCCP, Cleveland Clinic.

[Rapid fire original investigation presentation](#), Tuesday, October 8, 1:45 p.m. to 1:49 p.m. ET: Rapid Area 4A/4072 - **Real-World Hospitalization Differences in Patients with Pulmonary Hypertension due to Interstitial Lung Disease: Initiating Inhaled Treprostinil vs. Those Who Remain Untreated**. Presented by Steven Cassady, M.D., University of Maryland Medical Center.

[Rapid fire original investigation presentation](#), Tuesday, October 8, 2:03 p.m. to 2:07 p.m. ET: Rapid Area 4A/4072 - **Long-Term Outcomes and Dosing in the BREEZE Study Optional Extension Phase**. Presented by Abubakr Bajwa, MBBS, FCCP, Mayo Clinic.

[Rapid fire original investigation presentation](#), Tuesday, October 8, 2:21 p.m. to 2:25 p.m. ET: Rapid Area 4A/4072 - **Inhaled Treprostinil for the Treatment of Connective Tissue-Associated Pulmonary Arterial Hypertension**. Presented by Kristin Highland, M.D., FCCP, Cleveland Clinic.

**Posters include:**

[Poster discussion session](#), Wednesday, October 9, 10:20 a.m. to 11:05 a.m. ET: 4529/4430 - **Real-World Oral Treprostinil Initiations: Insights from Specialty Pharmacy Data**. Presented by Daniel Lachant, D.O., University of Rochester Medical Center.

**Sponsored events include:**

[The APPs in Chest Medicine Forum](#), Sunday, October 6, 12:00 to 1:30 p.m. ET. The event will include a brief presentation on navigating opportunities and challenges APPs face in clinical practice, led by Danielle McCamey, DNP, CRNP, ACNP-BC, FCCP; and Corinne Young, MSN, FNP-C, FCCP. Presenters will give practical tips for making the most of the CHEST 2024 experience. The forum will be held in the Contemporary Ballroom at the Omni Hotel.

[The Women in Chest Medicine Annual Luncheon](#), Monday, October 7, 12:00 to 1:30 p.m. ET. National negotiation expert and best-selling author, Sara Laschever, will facilitate an interactive conversation about cultivating effective negotiation skills and how to be your best self-advocate. In addition, the 2024 recipient of the CHEST Women's Lung Health grant will be honored at the luncheon. The luncheon will be held in room 156A at the Boston Convention and Exhibition Center.

[Tyvaso DPI® \(Treprostinil Inhalation Powder\): Clinical Pearls and Drug-Device Characteristics](#), Monday, October 7, 6:00 to 9:00 p.m. ET, featuring Anthony Hickey, Ph.D., Sc.D., University of North Carolina at Chapel Hill; Jennifer H Keeley, DNP, Allegheny General Hospital; and Sandeep Sahay, M.D., FCCP, Houston Methodist Hospital. The symposium will be held at the Omni Boston Hotel at the Seaport, Momentum ABC Ballroom, Level 5.

# About Tyvaso® Inhalation Solution and Tyvaso DPI® Inhalation Powder

## 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.TYVASOHCP.com](http://www.TYVASOHCP.com) or call 1-877-UNITHER (1-877-864-8437).

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## 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](https://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, our goals of innovating for the unmet medical needs of our patients and to benefit our other stakeholders, 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 September 24, 2024, 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.

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

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