



For Immediate Release

United Therapeutics Corporation to Feature Clinical Data Across its Commercial and Development Portfolio at the Pulmonary Vascular Research Institute 2025 Annual Congress

Posters include real-world dosing of Tyvaso DPI® in pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease, and data from the BREEZE open-label extension study of Tyvaso DPI detailing its long-term outcomes and dosing in patients with pulmonary arterial hypertension

United Therapeutics is sponsoring the *Women in PH Luncheon* and the *Career Catalyst Luncheon: Speed Mentoring for Early Career PH Professionals*

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., January 21, 2025: United Therapeutics Corporation (Nasdaq: **UTHR**), a public benefit corporation, today announced that five posters across its commercial and development portfolio in pulmonary hypertension (**PH**) will be presented at the Pulmonary Vascular Research Institute (**PVRI**) 2025 Annual Congress taking place January 29 through February 1, 2025 in Rio de Janeiro. In addition, professionals from United Therapeutics will participate in two speaking events associated with the congress.

United Therapeutics is also proud to sponsor the *Women in PH Luncheon* and the *Career Catalyst Luncheon: Speed Mentoring for Early Career PH Professionals*.

"At this year's annual congress, we are delighted to share further findings that support long-term outcomes and dosing of Tyvaso DPI, as well as interim data from our *PHINDER* study that is beginning to reveal clues that could help to efficiently detect pulmonary hypertension associated with interstitial lung disease," said **Andrew Nelsen, PharmD**, Vice President, Global Medical Affairs at United Therapeutics. "PVRI is a cornerstone event for the field of pulmonary vascular disease and provides an invaluable platform for collaboration and scientific exchange. We look forward to engaging with the scientific and medical communities about these latest developments."

Posters include:

Burger, C., El-Kersh, K., Parikh, R., Wu, B., Thrasher, C., & Broderick, M. **Real-World Dosing of Tyvaso DPI in Pulmonary Arterial Hypertension and Pulmonary Hypertension Associated with Interstitial Lung Disease.**

Spikes, L., Bajwa, A., Burger, C., Ramani, G., Palevsky, H., Mehta, J., Joly, J., El-Kersh, K., Fisher, M., Eggert, M., Restrepo-Jaramillo, R., Sahay, S., Desai, S., Johri, S., Shah, T., Shapiro, S., Thrasher, C., Deng, C.Q., Smith, P., & Broderick, M. **BREEZE Optional Extension Phase: Long-Term Outcomes with Tyvaso DPI in Patients with Pulmonary Arterial Hypertension.**

Beck, E., Broderick, M., Chavarria, M.C., DerSarkissian, M., Kiely, D.G., Lee, D., Maher, K., Paxton, K., Sahay, S., Scholand, M.B., Shen, E., Shlobin, O., & Zisman, D. **Interim Results from PHINDER: Pulmonary Hypertension Screening in Patients with Interstitial Lung Disease for Earlier Detection.**

Argula, R., El-Kersh, K., Estrada, R., McLaughlin, V., Hong, T., Thrasher, C., & Broderick, M. **Inhaled treprostinil for the treatment of pulmonary arterial hypertension in intermediate-high risk patients: a sub-group analysis of the TRIUMPH study.**

Tomson, M.L., Gunzenhauser, D., Dackowski, N., McGovern, A., Orozco, L., Clark, K., Mintz, A., O'Toole, B., Derma, A., Sista, P., & Rahaghi, F. **Patient Reported Experience of Participants in the ARTISAN study for PAH.**

Speaking events include:

Session 3: Real World Evidence/Real World Data, Wednesday, January 29, 10:40 to 11:15: 2nd Floor, Oceania IX. Co-chaired by Kellie Morland, PharmD, United Therapeutics.

Session 6: Challenges of Clinical Trial Design, Conduct & Endpoints, Wednesday, January 29, 12:22 to 12:30: 2nd Floor, Oceania IX - **Insights on clinical trial design from the perspective of industry.** Presented by C.Q. Deng, M.D., Ph.D., MPH, United Therapeutics.

Sponsored events include:

The Women in PH Luncheon, Friday, January 31, 11:15 to 13:00. *Women in PH* began as a way to support educational opportunities for women in PH and strengthen their professional network, aimed at building an inclusive, diverse community.

The Career Catalyst Luncheon: Speed Mentoring for Early Career PH Professionals, Thursday, January 30, 11:10 to 13:00. This event will offer micro-mentoring opportunities to early-career PH professionals and trainees, facilitating networking and connection-building between early-career PH professionals and providing opportunities to connect with renowned senior and mid-career PH researchers in a welcoming and informal setting.

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 ≥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 ≥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 ≥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 or call 1 844 UNITHER (1-844-864-8437).

TYVISIhpcSEP2024

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, 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 January 21, 2025, 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.

For Further Information Contact:

Dewey Steadman at (202) 919-4097 (media/investors)

Harry Silvers at (301) 578-1401 (investors)

<https://ir.unither.com/contact-uthr/>