For Immediate Release

UNITED THERAPEUTICS ANNOUNCES AGREEMENT TO ACQUIRE PRIORITY REVIEW VOUCHER

Voucher expected to be applied to the forthcoming NDA for Tyvaso DPI™

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., Monday, December 28, 2020: United Therapeutics Corporation (Nasdaq: UTHR) announced today an agreement to acquire a Rare Pediatric Disease Priority Review Voucher (PRV), which it plans to use with a forthcoming New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA). The PRV entitles the holder to designate an NDA for priority review and provides for an expedited eight-month review, instead of the standard twelve-month review period. Following the close of the transaction, United Therapeutics intends to apply the PRV to its NDA for Tyvaso DPI, expected in the first half of 2021.

"This acquisition affirms our commitment to bring a new generation of treatments to patients with pulmonary hypertension as quickly as possible," said Michael Benkowitz, President and Chief Operating Officer of United Therapeutics. "Once approved, Tyvaso DPI with the innovative Dreamboat® device is expected to be a major advancement in the delivery of inhaled treprostinil therapy, offering substantial convenience compared to the existing Tyvaso nebulizer."

United Therapeutics has entered into a definitive agreement to purchase the PRV for $105 million. The closing of the transaction is subject to customary closing conditions, including obtaining expiration or early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvement Act of 1976.

About Tyvaso DPI™

Tyvaso DPI, previously referred to as Treprostinil Technosphere®, is an investigational drug-device combination product comprised of a dry powder formulation of treprostinil and a small, portable, dry powder inhaler. If approved, Tyvaso DPI is expected to provide a more convenient method of administration as compared with traditional nebulized Tyvaso therapy. United Therapeutics is developing Tyvaso DPI under a collaboration and license agreement with MannKind Corporation. Tyvaso DPI incorporates the dry powder formulation technology and Dreamboat® inhalation device technology used in MannKind's Afrezza® (insulin human) Inhalation Powder product, approved by the FDA in 2014.

United Therapeutics plans to submit the Tyvaso DPI NDA to include an indication to treat pulmonary arterial hypertension (PAH), as well as pulmonary hypertension associated with interstitial lung disease (PH-ILD). Tyvaso is indicated to treat WHO Group 1 PAH, and the FDA is currently reviewing a supplement to the Tyvaso NDA to expand its labelling to include PH-ILD.

Tyvaso DPI is an investigational combination product that is not approved for any use in any country, and the Tyvaso DPI tradename is pending FDA review.

About TYVASO® (treprostinil) Inhalation Solution

INDICATION

TYVASO (treprostinil) is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately 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 controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

IMPORTANT SAFETY INFORMATION FOR TYVASO

WARNINGS AND PRECAUTIONS

- The efficacy of TYVASO has not been established in patients with significant underlying lung disease (such as asthma or chronic obstructive pulmonary disease). Patients with acute pulmonary infections should be carefully monitored to detect any worsening of lung disease and loss of drug effect
- TYVASO is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, TYVASO may cause symptomatic hypotension
- Titrate slowly in patients with hepatic or renal insufficiency, as exposure to treprostinil may be increased in these patients
- TYVASO inhibits platelet aggregation and increases the risk of bleeding
- Co-administration of the cytochrome P450 (CYP) 2C8 enzyme inhibitor gemfibrozil may increase exposure to treprostinil. Co-administration of the CYP2C8 enzyme inducer rifampin may decrease exposure to treprostinil. Increased exposure is likely to increase adverse events, whereas decreased exposure is likely to reduce clinical effectiveness

DRUG INTERACTIONS/SPECIFIC POPULATIONS

- The concomitant use of TYVASO with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension
- Co-administration of the CYP2C8 enzyme inhibitor gemfibrozil increases exposure to oral treprostinil. Co-administration of the CYP2C8 enzyme inducer rifampin decreases exposure to oral 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
- It is unknown if geriatric patients respond differently than younger patients. Caution should be used when selecting a dose for geriatric patients

ADVERSE REACTIONS

- The most common adverse reactions seen with TYVASO in ≥4% of PAH patients and more than 3% greater than placebo in the placebo-controlled clinical study 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 ≥10% of patients were dizziness and diarrhea

Please see the Full Prescribing Information, Patient Product Information, and the TD-100 and TD-300 TYVASO® Inhalation System Instructions for Use manuals. For additional information about TYVASO, visit www.tyvaso.com or call 1-877-UNITHER (1-877-864-8437).

For Consumer Important Safety Information, please see https://www.tyvaso.com/dtc/important-safety-information/

About United Therapeutics

United Therapeutics Corporation focuses on the strength of a balanced, value-creating biotechnology model. We are confident in our future thanks to our fundamental attributes, namely our obsession with quality and innovation, the power of our brands, our entrepreneurial culture, and our bioinformatics leadership. We also believe that our determination to be responsible citizens – having a positive impact on patients, the environment, and society – will sustain our success in the long term.

Through our wholly owned subsidiary, Lung Biotechnology PBC, we are focused on addressing the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply. Lung Biotechnology is the first public benefit corporation subsidiary of a public biotechnology or pharmaceutical company.

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 relating to the anticipated timing and outcome of the New Drug Application for Tyvaso DPI, the potential indications for Tyvaso DPI, the expected benefits of Tyvaso DPI to patients, the pending supplemental New Drug Application for Tyvaso to expand its label to include PH-ILD, our commitment to bring a new generation of treatments to patients with PAH, and the timing thereof, our ability to create value and sustain our success in the long term, as well as our efforts to develop technologies that either delay the need for transplantable organs or expand the supply 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 December 28, 2020 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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