



## **United Therapeutics Announces FDA Clearance to Proceed with *SUMMIT* Clinical Trial for Treprostinil SMI in PH-COPD**

*The development of a soft mist inhaler (SMI) represents a further advancement of treprostinil delivery devices to potentially address a wider range of patient tolerability profiles*

*A soft mist formulation may be beneficial for patients with pulmonary hypertension associated with chronic obstructive pulmonary disease (PH-COPD), who are susceptible to cough and bronchospasm from inhaled therapies*

*Treprostinil SMI has the potential to be the first FDA-approved therapy specifically indicated for PH-COPD*

**SILVER SPRING, Md. & RESEARCH TRIANGLE PARK, N.C. - October 19, 2026** - United Therapeutics Corporation (Nasdaq: **UTHR**), a public benefit corporation, today announced that the U.S. Food and Drug Administration (**FDA**) has granted clearance under the company's investigational new drug application to proceed with the *SUMMIT* clinical trial of treprostinil SMI in PH-COPD.

The phase 2, 16-week, double blind *SUMMIT* study will evaluate the safety and tolerability of treprostinil SMI in approximately 40 patients with PH-COPD. The study's secondary endpoints will evaluate the efficacy of treprostinil SMI on exercise capacity and N-terminal pro-B-type natriuretic peptide (**NT-proBNP**), a critical biomarker for heart failure. Eligible patients in the *SUMMIT* study will be able to enroll in an open-label extension study to evaluate the long-term safety, tolerability, and efficacy of treprostinil SMI.

Assuming a successful outcome in the *SUMMIT* study, United Therapeutics anticipates commencing a subsequent phase 3 registration study for treprostinil SMI in PH-COPD in 2028.

"PH-COPD is a serious, life-threatening condition with no approved treatments. We believe that inhaled treprostinil, delivered via a soft mist inhaler, may benefit the carefully defined *SUMMIT* PH-COPD patient population by directly targeting the pulmonary vasculature. Our hope is that treprostinil SMI will offer meaningful benefit and reduce disease burden for PH-COPD patients who deserve a treatment option that addresses their significant unmet needs," said **Leigh Peterson, Ph.D.**, head of pharmaceutical and xenograft development at United Therapeutics."

"I believe this development will lead to an exponential inflection point for United Therapeutics," said **Martine Rothblatt, Ph.D.**, its Chairperson and Chief Executive Officer. "We estimate PH-COPD could impact five to ten times the number of patients than the conditions all of our current therapies are approved to treat today. Upon successful completion of the *SUMMIT* program and approval by the FDA, we expect United Therapeutics will become a several times larger company than it is today."

Treprostinil SMI includes a portable, handheld soft mist inhaler designed to deliver a preserved formulation of inhaled treprostinil solution in a single breath. The product will be available for the clinical study in multiple dose strengths to support individualized titration and long-term maintenance dosing, administered four times daily. Each single-load cartridge is designed to support up to two weeks of use, and the product can be stored at room temperature, offering patients a convenient, easy-to-carry delivery option.

United Therapeutics also plans to develop treprostinil SMI for pulmonary arterial hypertension, pulmonary hypertension associated with interstitial lung disease, idiopathic pulmonary fibrosis, and progressive pulmonary fibrosis.

Treprostinil SMI is an investigational-stage product, and is not yet approved in any jurisdiction for any indication.



### **About PH-COPD**

COPD, a group of serious, progressive lung diseases for which there is no cure, is the fifth leading cause of death in the U.S.<sup>1</sup> Pulmonary hypertension (**PH**) is a common complication of COPD, leading to poorer outcomes and further increasing the risk of death.<sup>2</sup> United Therapeutics estimates that 400,000 to 800,000 people are living with PH-COPD in the U.S. Because PH symptoms are difficult to differentiate from COPD symptoms, and right heart catheterization is not recommended in stable COPD patients, PH often goes undiagnosed in COPD.<sup>2</sup> Earlier diagnosis of PH in COPD patients and improved methods for identifying COPD patients at risk for severe PH are needed to ensure appropriate treatment and better outcomes for this patient population.

### **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](#).

### **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 planned *SUMMIT* study of treprostinil SMI in PH-COPD, including its enrollment of 40 patients; our plans to begin a phase 3 study of treprostinil SMI in PH-COPD in 2028; our expectation that treprostinil SMI could become the first FDA-approved therapy for PH-COPD; our expectation that a soft mist formulation of treprostinil may benefit PH-COPD patients; our plan to develop treprostinil SMI for additional indications; the potential for our *SUMMIT* program to lead to an exponential inflection point for United Therapeutics; our expectation that upon successful completion of the *SUMMIT* program and approval by the FDA, United Therapeutics will become a several times larger company than it is today; 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 October 19, 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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## REFERENCES

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2. Vitulo P, Piccari L, Wort SJ, et al. Screening and diagnosis of pulmonary hypertension associated with chronic lung disease (PH-CLD): A consensus statement from the pulmonary vascular research institute's innovative drug development initiative—group 3 pulmonary hypertension. Pulm Circ. 2024;14:e70005. <https://doi.org/10.1002/pul2.70005>.