



United Therapeutics Announces FDA Clearance to Proceed with Clinical Trial for Treprostinil-Iloprost SMI in Pulmonary Arterial Hypertension

If successful, Treprostinil-Iloprost SMI would be the first use-as-needed combination inhaled therapy to be developed for pulmonary arterial hypertension (PAH)

This investigational therapy combines two potent prostacyclin analogues, treprostinil and iloprost, and is delivered as an inhalation spray via a soft mist inhaler for pro re nata (PRN) use

SILVER SPRING, Md. & RESEARCH TRIANGLE PARK, N.C. - October 28, 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 a clinical trial of Treprostinil-Iloprost SMI.

The phase 1, open-label, single ascending dose study will evaluate the safety, tolerability, and pharmacokinetics of Treprostinil-Iloprost SMI in healthy volunteers. Assuming a successful outcome in the study, United Therapeutics anticipates commencing a subsequent phase 2 study in patients with PAH in 2027.

Treprostinil-Iloprost SMI combines two potent prostacyclin analogues, treprostinil and iloprost. The therapy is intended to be used as needed to provide episodic symptom relief for PAH patients, who may need a bridge between doses of their ongoing prostacyclin therapy due to acute symptom flare-ups.

"Many people living with PAH experience moments when their symptoms flare despite their maintenance medication, and today they have no therapy designed specifically for those moments. Treprostinil-Iloprost SMI is intended to explore whether an as-needed, combination prostacyclin therapy could help fill that gap. FDA clearance to begin clinical testing is an important first step, and we look forward to advancing this program," said **Ravi Patel, PharmD**, Senior Vice President, Global Patient Safety and Strategic Clinical Development, United Therapeutics.

"As a company known for pioneering prostacyclin therapies, Treprostinil-Iloprost SMI represents another important advancement in United Therapeutics' PAH treatment portfolio. It also reflects continued innovation from our product development platform and our culture of running down the corridors of indifference in pulmonary medicine," said **Martine Rothblatt, Ph.D.**, Chairperson and Chief Executive Officer of United Therapeutics.

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

About Pulmonary Arterial Hypertension

PAH is a life-threatening disease that affects the blood vessels in the lungs and is characterized by increased pressure in the pulmonary arteries, due to increased pulmonary vascular resistance in the small precapillary vessels (i.e., the small blood vessels leading from the heart to lungs). The elevated pressure in the pulmonary arteries strains the right side of the heart as it pumps blood to the lungs. This eventually leads to right heart failure and, ultimately, death. PAH is characterized by structural changes in blood vessel walls, aggregation of platelets, and alteration of smooth muscle cell proliferation. PAH affects about 500,000 individuals worldwide, with around 50,000 people affected in the United States. Increases in the number of people diagnosed with the disease have been observed, but due to the rarity of the disease and the complexity of diagnosing it, only a fraction of patients with PAH are treated.



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 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: the timing and design of our planned studies of Treprostinil-Iloprost SMI, including our upcoming phase 1 study in healthy volunteers and our plan to commence a phase 2 study in PAH patients in 2027; the potential benefits of Treprostinil-Iloprost SMI for PAH patients; 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 28, 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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