



## **FDA Grants Fast Track Designation to YUTREPIA® for the Treatment of Raynaud's Phenomenon Associated with Systemic Sclerosis**

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- Fast Track designation underscores the significant unmet need for patients with systemic sclerosis-associated Raynaud's phenomenon (SSc-RP), a debilitating manifestation affecting up to 90% of SSc patients
- No therapy is currently approved in the U.S. to treat SSc-RP and management options are limited and often inadequate for patients with more severe disease
- Liquidia plans to initiate RE-WARM, a Phase 2a dose-finding study of YUTREPIA in SSc-RP, in the fourth quarter of 2026

MORRISVILLE, N.C., Sept. 03, 2026 (GLOBE NEWSWIRE) -- Liquidia Corporation (Nasdaq: LQDA), a biopharmaceutical company driven by science and compassion to revolutionize care for patients with challenging respiratory and vascular diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to YUTREPIA® (treprostinil) inhalation powder for the treatment of Raynaud's phenomenon associated with systemic sclerosis (SSc-RP). The potential use of YUTREPIA in SSc-RP is currently under clinical development, and its safety and efficacy for this indication have not been evaluated by any regulatory authority.

Systemic sclerosis (SSc) is a rare, chronic autoimmune disease marked by widespread vasculopathy and fibrosis of the skin and internal organs, and it carries the highest mortality of any systemic rheumatic disease. Raynaud's phenomenon (RP) consists of recurrent, often severe vasospastic episodes that cause pain, numbness and color change in the fingers and toes. Affecting up to 90% of SSc patients, these attacks are more frequent, prolonged and severe than primary Raynaud's, often progressing to digital ischemic ulcers in an estimated 40% to 60% of patients and, in recurrent cases, digital amputation. At a 2020 FDA Patient-Focused Drug Development meeting, SSc patients identified Raynaud's attacks as among the disease's most bothersome and impactful symptoms, citing pain, functional limitation and considerable emotional distress tied to fear of ulceration and tissue loss. A central driver of SSc-RP is deficient endogenous prostacyclin production, which contributes to the vasospasm, platelet activation and vascular remodeling underlying the disease. Liquidia estimates the addressable population of SSc-RP patients with moderate to severe symptoms to be approximately 30,000 patients in the United States.

Dr. Rajeev Saggarr, Chief Medical Officer, said: "Fast Track designation reflects the seriousness of this condition and the need for new options. No therapy is currently approved by the FDA specifically for SSc-RP. We are encouraged by the opportunity to evaluate whether YUTREPIA can reduce the complications of moderate to severe Raynaud's that most affect patients' quality of life, and we are committed to advancing this program with urgency, starting with the RE-WARM study later this year."

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs intended to treat serious conditions and fill an unmet medical need. Fast Track designation provides Liquidia with the opportunity for more frequent interactions with the FDA throughout development, the potential for rolling review of a New Drug Application, and, if relevant criteria are met, potential eligibility for Priority Review and/or Accelerated Approval.

### **About RE-WARM**

Liquidia plans to initiate RE-WARM (NCT07748000), a Phase 2a, randomized, open-label, dose-finding study of YUTREPIA in approximately 75 adults with SSc experiencing symptomatic Raynaud's phenomenon attacks, at up to approximately 30 sites in the United States. RE-WARM is designed to characterize the safety and pharmacodynamics of YUTREPIA in this population. The study also explores whether treatment reduces the number, severity and impact of RP attacks. The study is expected to begin in October 2026, with primary completion targeted for February 2027.

### **About YUTREPIA® (treprostinil) Inhalation Powder**

YUTREPIA is an inhaled dry-powder formulation of treprostinil delivered through a convenient, low-effort, palm-sized device. YUTREPIA was designed using Liquidia's PRINT® technology, which enables the development of drug particles that are precise and uniform in size, shape and composition, and that are engineered for enhanced deposition in the lung following oral inhalation. YUTREPIA is approved for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). YUTREPIA is not approved for the treatment of Raynaud's phenomenon associated with systemic sclerosis, and there is no guarantee that the FDA will ultimately approve YUTREPIA for this use, even with Fast Track designation.

### **INDICATION**

YUTREPIA (treprostinil) inhalation powder is a prostacyclin analog indicated for the treatment of:

- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies 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%).
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study 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%).

## **SELECTED SAFETY INFORMATION: WARNINGS AND PRECAUTIONS**

- Treprostinil is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, treatment with treprostinil may produce symptomatic hypotension.
- Treprostinil inhibits platelet aggregation and increases the risk of bleeding.
- Co-administration of a cytochrome P450 (CYP) 2C8 enzyme inhibitor (e.g., gemfibrozil) may increase exposure (both C<sub>max</sub> 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, YUTREPIA 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.
- Most common adverse reactions with YUTREPIA (≥10%) are cough, headache, throat irritation and dizziness.

Prescribing Information and Instructions for Use for YUTREPIA (treprostinil) inhalation powder are available at <https://www.yutrepia.com/full-prescribing-information.pdf>.

## **About Liquidia Corporation**

Liquidia Corporation is a biopharmaceutical company driven by science and compassion to revolutionize care for patients with challenging respiratory and vascular diseases. The company's current focus spans the development and commercialization of products in pulmonary hypertension and other applications of its proprietary PRINT® Technology. PRINT enabled the creation of YUTREPIA® (treprostinil) inhalation powder, a drug approved for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). YUTREPIA is currently under development for other indications, including SSc-RP. The company is also developing L606, an investigational extended-release formulation of treprostinil administered twice daily with a next-generation nebulizer, and currently markets generic Treprostinil Injection for the treatment of PAH. To learn more about Liquidia, please visit [www.liquidia.com](http://www.liquidia.com).

## **Cautionary Statements Regarding Forward-Looking Statements**

This press release may include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical facts, including statements regarding our future results of operations and financial position, our strategic and financial initiatives, our business strategy and plans and our objectives for future operations, are forward-looking statements. Such forward-looking statements, including statements regarding clinical trials, clinical studies and other clinical work (including the funding therefor, anticipated patient enrollment, safety data, study data, trial outcomes, timing or associated costs), regulatory applications and related submission contents and timelines, the receipt, timing and continuation of Fast Track designation and any benefits thereof, and our ability to successfully develop and, if approved, commercialize YUTREPIA for SSc-RP or any other product candidate, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Fast Track designation does not guarantee that YUTREPIA will receive FDA approval for the treatment of SSc-RP, that development will proceed on the anticipated timeline, or that RE-WARM or any future study will produce favorable results. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks discussed in our filings with the SEC, as well as a number of uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment and our industry has inherent risks. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Nothing in this press release should be regarded as a representation by any person that these goals will be achieved, and we undertake no duty to update our goals or to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

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