Liquidia Schedules First Commercial Shipment of YUTREPIA™ (treprostinil) Inhalation Powder for Patients with PAH and PH-ILD

June 2, 2025

- YUTREPIA now available to be prescribed to patients via specialty pharmacies
- FDA approved YUTREPIA on May 23, 2025
- Court denies United Therapeutics' request for preliminary injunction and a temporary restraining order, clearing the path for full commercial launch

MORRISVILLE, N.C., June 02, 2025 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease, today announced that Liquidia is scheduled to make its first commercial shipment of YUTREPIA™ (treprostinil) inhalation powder, marking the first time YUTREPIA will be available to be prescribed to patients at specialty pharmacies. This milestone was achieved only five business days following the U.S. Food and Drug Administration (FDA) approval of YUTREPIA on May 23, 2025, for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD).

Dr. Roger Jeffs, CEO, Liquidia said: "We have moved with exceptional speed to provide a new and differentiated therapeutic alternative to the marketplace. In just over one week, our sales force hit the ground running with the promotion of YUTREPIA, the product was listed with compendia, and commercial product was shipped to specialty pharmacies. This extraordinary pace is a direct result of our rigorous preparation and the strategic urgency driving our desire to provide patients immediate access to the unique attributes of YUTREPIA as we look to position it as the prostacyclin of first choice for patients with PAH and PH-ILD."

On May 30, 2025, the U.S. District Court for the Middle District of North Carolina denied United Therapeutics' (UTHR) request for a preliminary injunction and a temporary restraining order in its complaint filed against Liquidia (Case No. 1:25-cv-00368) alleging infringement of U.S. Patent No. 11,357,782 (the '782 patent). UTHR sought to enjoin Liquidia from commercializing YUTREPIA for the treatment of patients with PAH and PH-ILD. The Court denied the request, in part, based on its conclusion that UTHR is not likely to succeed on the merits of its claims. Liquidia has also filed a motion to dismiss, stay or transfer UTHR's claims regarding the '782 patent. That motion remains pending with the Court. With this denial, UTHR no longer has any motions pending that seek emergency relief to enjoin the launch of YUTREPIA.

About Pulmonary Arterial Hypertension (PAH)
Pulmonary arterial hypertension (PAH) is a rare, chronic, progressive disease caused by narrowing, thickening or stiffening of the pulmonary arteries that can lead to right heart failure and eventually death. Currently, an estimated 45,000 patients are diagnosed and treated in the United States. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression, and improve quality of life.

About Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD)
Pulmonary hypertension (PH) associated with interstitial lung disease (ILD) includes a diverse collection of up to 200 different pulmonary diseases, including interstitial pulmonary fibrosis, chronic hypersensitivity pneumonitis, connective tissue disease-related ILD, and chronic pulmonary fibrosis with emphysema (CPFE) among others. Any level of PH in ILD patients is associated with poor 3-year survival. A current estimate of PH-ILD prevalence in the United States is greater than 60,000 patients, though population size in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until March 2021, when inhaled treprostinil was first approved for this indication.

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. Liquidia has completed the INSPIRE trial (NCT03399604), or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, an open-label, multi-center phase 3 clinical study of YUTREPIA in patients diagnosed with PAH who are naïve to inhaled treprostinil or who are transitioning from Tyvaso® (nebulized treprostinil). YUTREPIA is currently being studied in the ASCENT trial (NCT06129240), or An Open-Label ProSpective MultiCENTer Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in PH, with the objective of informing YUTREPIA's dosing and tolerability profile in patients with PH-ILD. YUTREPIA was previously referred to as LIQ861 in investigational studies.

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 Cmax 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 YUTREPIA.com.

About Liquidia Corporation
Liquidia Corporation is a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease. 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 that has been approved for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PHILD). The company is also developing L606, an investigational sustained-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.

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; our ability to successfully commercialize our products, including YUTREPIA, for which we obtain FDA or other regulatory authority approval; the acceptance by the market of our products, including YUTREPIA, and their potential pricing and/or reimbursement by third-party payors, if approved (in the case of our product candidates) and whether such acceptance is sufficient to support continued commercialization or development of our products; the successful development or commercialization of our products, including YUTREPIA; our revenue from product sales and whether or not we may become profitable in the near term, or at all; future competitive or other market factors that may adversely affect the commercial potential for YUTREPIA; and our ability to execute on our strategic or financial initiatives, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Despite the approval of YUTREPIA by the FDA, it is possible that commercialization of YUTREPIA may be blocked or delayed in connection with legal proceedings that have been initiated or that may in the future be initiated, or we may be required to pay damages, including royalties, in connection with our commercial launch, as a result of these legal proceedings. The denial of the motion for temporary restraining order and preliminary injunction in United Therapeutics' lawsuit against Liquidia in the U.S. District Court for the Middle District of North Carolina does not conclude the lawsuit and is not determinative of the final outcome of the lawsuit. 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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