Liquidia Corporation Announces FDA Acceptance of New Drug Application Resubmission for YUTREPIA™ (treprostinil) Inhalation Powder

March 28, 2025

- *FDA sets PDUFA goal date of May 24, 2025*

MORRISVILLE, N.C., March 28, 2025 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease, today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) resubmission for YUTREPIA™ (treprostinil) inhalation powder to treat pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). The FDA confirmed that the resubmission was a complete, Class 1 response to the previous action letter issued on August 16, 2024, which granted tentative approval of YUTREPIA for both PAH and PH-ILD. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of May 24, 2025.

Dr. Roger Jeffs, Ph.D., Chief Executive Officer of Liquidia, said: “We are pleased that the FDA has responded promptly to the resubmission that we filed on Monday. We look forward to working with the FDA over the coming months as we seek final approval for YUTREPIA and, in the meantime, will continue preparations to support a launch of YUTREPIA as soon as possible.”

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 Liquidia’s lead candidate, YUTREPIA™ (treprostinil) inhalation powder, an investigational drug for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). 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, including the potential for final FDA approval of the NDA for YUTREPIA, which may occur after the expiration of the exclusivity period of TYVASO DPI, if at all, the timelines or outcomes related to patent litigation with United Therapeutics in the U.S. District Court for the District of Delaware, litigation with United Therapeutics and FDA in the U.S. District Court for the District of Columbia or other litigation instituted by United Therapeutics or others, including rehearings or appeals of decisions in any such proceedings, the issuance of patents by the USPTO and our ability to execute on our strategic or financial initiatives, our estimates regarding future expenses, capital requirements and needs for additional financing, and potential revenue and profitability of YUTREPIA, if approved, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The FDA’s final action of the NDA for YUTREPIA could be delayed beyond the assigned PDUFA date. 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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