District Court Dismisses Dispute Filed by United Therapeutics Against Liquidia

May 2, 2025

- Court will not hear cross-claim that challenges the PH-ILD indication in the tentatively approved NDA for YUTREPIA
- FDA can grant final approval of YUTREPIA after blocking regulatory exclusivity expires on May 23, 2025

MORRISVILLE, N.C., May 02, 2025 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease, today announced that Judge Kelly of the U.S. District Court for the District of Columbia (District Court) dismissed, without prejudice, the cross-claim filed by United Therapeutics (UTHR) that sought to challenge Liquidia's amendment to its New Drug Application (NDA) for YUTREPIA™ (treprostinil) inhalation powder, which added the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD) to the proposed label for YUTREPIA. In its ruling, the District Court determined that UTHR's claim was unripe and that UTHR had failed to plausibly allege that it has standing.

Dr. Roger Jeffs, CEO, Liquidia said: "We are pleased with the court's decision to dismiss this cross-claim, specifically holding that UTHR failed to establish standing. We also continue to believe that the FDA was correct to accept, and subsequently tentatively approve, our amended NDA for YUTREPIA to include the PH-ILD indication. We remain laser focused on the potential final approval of YUTREPIA following the expiration of gating regulatory exclusivity on May 23, 2025, and look forward to delivering what we believe will become the prostacyclin of first choice for patients with PAH and PH-ILD and the physicians who treat them."

UTHR has the right to appeal the Court's ruling.

The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date for the YUTREPIA NDA of May 24, 2025.

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, the timeline or outcome of the cross-claims that United Therapeutics has brought against the FDA, the timeline or outcome related to patent litigation in the U.S. District Court for the District of Delaware, 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, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The decisions of courts or other tribunals are not determinative of the outcome of the appeals or rehearings of the decisions. 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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