Update on Favorable Legal and Regulatory Outcomes Clearing Path for Potential FDA approval of YUTREPIA™ (treprostinil) inhalation powder

April 1, 2024

- On March 28, Judge Andrews removed the injunction issued in the Original Hatch Waxman Litigation
- On March 29, Judge Bates denied United Therapeutics' motion for temporary restraining order and preliminary injunction in separate litigation filed by United Therapeutics against the FDA
- On March 31, regulatory exclusivity expired for Tyvaso® in treating PH-ILD

MORRISVILLE, N.C., April 01, 2024 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) announced today that on March 28, Judge Andrews of the U.S. District Court for the District of Delaware (District Court) has set aside the injunction that was issued in August 2022 in the lawsuit filed by United Therapeutics (UTHR) in Case No. 1:20-cv-00755-RGA (the Original Hatch-Waxman Litigation). As a result, the U.S. Food and Drug Administration (FDA) is no longer enjoined from issuing final approval of Liquidia's New Drug Application (NDA) for YUTREPIA™ (treprostinil) inhalation powder.

Dr. Roger Jeffs, Chief Executive Officer of Liquidia, said: "With the recent decision by Judge Andrews, the path is cleared for us to seek final approval for YUTREPIA. We have submitted the judge's order to the FDA and look forward to a decision from the FDA in the near future. Our commercial team is fully prepared to launch YUTREPIA in both PAH and PH-ILD should the FDA grant final approval. Once launched, we are confident that YUTREPIA's convenient, low-effort delivery and wide dosing range will propel the therapy towards our goal of establishing YUTREPIA as the prostacyclin of first choice."

The FDA tentatively approved YUTREPIA to treat pulmonary arterial hypertension (PAH) in November 2021. In July 2023, the Company amended its NDA to add the indication to treat pulmonary hypertension associated with interstitial lung disease (PH-ILD). On March 31, 2024, the new clinical investigation exclusivity granted to Tyvaso® to treat PH-ILD expired. The FDA is now able to take final action on YUTREPIA's amended NDA that seeks approval for both indications.

United Therapeutics has filed a notice of appeal with respect to Judge Andrews' decision to set aside the injunction. In addition, United Therapeutics has filed two separate lawsuits in which it is seeking to obtain new injunctions to prevent launch of YUTREPIA for the treatment of PH-ILD. For both of these actions, UTHR bears the burden of demonstrating, among other things, that it is substantially likely to succeed on the merits and that UTHR will be irreparably harmed if the injunctions are not granted. None of these appeals or actions will impede the Company's launch of YUTREPIA unless UTHR is successful in obtaining the relief it is seeking.

In the first action, UTHR filed a lawsuit against FDA in the U.S. District Court for the District of Columbia (Case No. 24-484), and a motion for a temporary restraining order and preliminary injunction, seeking to prevent FDA from approving Liquidia's amended NDA. After a hearing on March 29, Judge Bates, who is presiding over this lawsuit, denied UTHR's motion. Specifically, the Court held that the subject of UTHR's case, FDA's acceptance of Liquidia's amended NDA for substantive review, is not a final agency action that UTHR can challenge in court. The Court has scheduled a status conference for April 2 to establish a process for UTHR's claims to be reevaluated after the FDA acts on the Company's amended NDA.

In the second action, UTHR filed a lawsuit against the Company in Delaware District Court (Case No. 23-975) alleging that YUTREPIA would infringe U.S. Patent No. 11,826,327 ('327 patent), which issued in November 2023. UTHR has filed a motion for preliminary injunction to block Liquidia from launching YUTREPIA for PH-ILD. Briefing on UTHR's motion remains in process.

About YUTREPIA™(treprostinil) inhalation powder

YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a convenient, low-effort, palm-sized device. The FDA previously issued tentative approval of YUTREPIA for the PAH indication in November 2021. 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 INSPIRE, 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, an Open-Label Prospective Multicenter Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in Pulmonary Hypertension, 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.

About Liquidia Corporation

Liquidia Corporation is a biopharmaceutical company focused on the development and commercialization of products in pulmonary hypertension and other applications of its PRINT® Technology. The Company operates through its two wholly owned subsidiaries, Liquidia Technologies, Inc. (Liquidia Technologies) and Liquidia PAH, LLC (Liquidia PAH). Liquidia Technologies has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of PAH and PH-ILD. Liquidia Technologies is also developing L606, an investigational liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer, for use in North America. Liquidia PAH provides for the commercialization of pharmaceutical products to treat pulmonary disease, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

Tyvaso® is a registered trademark of United Therapeutics.

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 related to patent litigation in the U.S. District Court for the District of Delaware, inter partes review proceedings conducted at the PTAB 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, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The favorable 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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