# Liquidia Corporation Provides Update on New Drug Application for YUTREPIA™ (treprostinil) inhalation powder

January 25, 2024

MORRISVILLE, N.C., Jan. 25, 2024 (GLOBE NEWSWIRE) -- Liquidia Corporation (the Company) (NASDAQ: LQDA) announced today that the U.S. Food and Drug Administration (FDA) provided an update on its review of the New Drug Application (NDA) for YUTREPIA™ (treprostinil) inhalation powder to treat pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). The FDA informed the Company that it is confirming the process for adding the PH-ILD indication as an amendment to the NDA for YUTREPIA. Accordingly, the FDA is not able to issue an action letter in time to meet the previously issued Prescription Drug User Fee Act (PDUFA) goal date of January 24, 2024, and their review remains ongoing. The FDA did not request any additional clinical data to support the NDA and did not issue a new PDUFA goal date.

Dr. Roger Jeffs, Chief Executive Officer, said: “We are in active communication with the FDA regarding the process we followed to amend our NDA to add PH-ILD to the labeled indication. Whether the NDA is amended or supplemented, we will continue to prepare for the final FDA approval of YUTREPIA to treat both PAH and PH-ILD patients following the expiration of regulatory exclusivity for Tyvaso® on March 31, 2024. As communicated by the tentative approval to treat PAH, YUTREPIA has already met the regulatory standards for quality, safety and efficacy. We remain committed to addressing the unmet needs across all patients whose lives may be improved by the unique benefits of YUTREPIA.”

On November 5, 2021, the FDA issued a tentative approval for YUTREPIA for the treatment of PAH to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms. In July 2023, Liquidia filed an amendment to its New Drug Application for YUTREPIA, seeking to add PH-ILD to the label. The FDA previously confirmed that YUTREPIA may include the treatment of PH-ILD to the proposed label for YUTREPIA without additional clinical studies.

YUTREPIA also remains subject to ongoing litigation. Liquidia filed a request for Judge Andrews of the U.S. District Court for the District of Delaware (District Court) to set aside the injunction that was instituted in August 2022 tied to litigation filed by United Therapeutics (UTHR) alleging patent infringement of U.S. Patent No. 10,716,793 (the ‘793 Patent) in Case No. 1:20-cv-00755-RGA (the Original Hatch-Waxman Litigation). On December 20, 2023, the United States Court of Appeals for the Federal Circuit (CAFC) affirmed the earlier decision by the Patent Trial and Appeal Board (PTAB), which found all claims of the ‘793 Patent to be unpatentable due to the existence of prior art cited by Liquidia in *inter partes* review proceedings.

Additionally, in September 2023, UTHR filed a second complaint for patent infringement in District Court in Case No. 1:23-cv-00975-RGA (the New Hatch-Waxman Litigation). As of January 22, 2024, the only patent at issue is U.S. Patent No. 11,826,327 (the ‘327 Patent) which issued November 30, 2023. UTHR has stipulated to the dismissal of the ‘793 Patent from the New Hatch-Waxman Litigation as a result of the CAFC decision affirming invalidity of the '793 Patent. The '327 Patent, the sole remaining patent at issue in the New Hatch-Waxman Litigation, was not issued before Liquidia submitted the NDA for YUTREPIA in January 2020 to treat PAH. Therefore, the Company believes that final FDA approval for YUTREPIA will not be subject to any statutory 30-month stay arising from the New Hatch-Waxman Litigation per Section 505(c)(3)(C) of the Federal Food, Drug and Cosmetic Act.

**About YUTREPIA™(treprostinil) inhalation powder**

YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a convenient, low-resistance, 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 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 Corporation.

**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 FDA’s authority to request new or additional information related thereto and any potential delays of regulatory approval in connection therewith, the timeline or outcome related to patent litigation in the U.S. District Court for the District of Delaware or *inter partes* review proceedings conducted at the PTAB, including appeals of decisions in any such proceedings, the timeline associated with any regulatory stay provisions, 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 lower tribunals are not determinative of the outcome of the appeals 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.

**Contact Information**

**Media & Investors:**
Jason Adair
Chief Business Officer
919.328.4400
jason.adair@liquidia.com

Source: Liquidia Corporation