FDA Grants Tentative Approval for Liquidia's YUTREPIA™ (Treprostinil) Inhalation Powder

November 8, 2021

- First dry-powder formulation of treprostinil to meet criteria required for FDA approval
- Final FDA approval may occur in October 2022 or earlier upon resolution of on-going litigation
- Conference call and webcast scheduled for today at 9:00 a.m. Eastern Standard Time

MORRISVILLE, N.C., Nov. 08, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) announced today that the U.S. Food and Drug Administration (FDA) granted tentative approval for YUTREPIA™ (treprostinil) inhalation powder, previously referred to as LIQ861. YUTREPIA is indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms. Tentative approval indicates that YUTREPIA has met all regulatory standards for quality, safety and efficacy required for approval in the United States.

Dr. Tushar Shah, Chief Medical Officer of Liquidia, said: "We would like to take the opportunity to thank the patients and investigators who participated in the clinical development of YUTREPIA. The tentative approval for YUTREPIA is another step toward providing an important option for patients with PAH in the U.S. We believe YUTREPIA can improve the limitations of current nebulized therapies by allowing the administration of an expanded dose range of inhaled treprostinil using a proven, convenient, palm-sized device."

The addressable market for inhaled treprostinil is significant and expected to grow. In 2020, United Therapeutics reported that its nebulized formulation of treprostinil indicated for PAH achieved sales of more than $480 million. The attributes of YUTREPIA including ease-of-use, convenience, direct lung delivery, and higher dosage range may not only make YUTREPIA a preference to nebulized therapy, but also an alternative to oral treatments, and possibly a treatment option to delay the use of parenteral therapies in PAH. There may also be future expansion opportunities for inhaled treprostinil into additional indications.

Damian deGoa, Chief Executive Officer of Liquidia added: "This is a significant milestone for Liquidia. We are really proud of our team. Not only does the tentative approval establish the safety and efficacy of YUTREPIA for PAH patients but, in the process, we have validated our proprietary PRINT® technology to engineer discrete drug particles with uniform composition, size, and shape. There is more work to be done. We will now focus our efforts on pre-commercial launch activities and the growing market opportunity for YUTREPIA in PAH and potential new indications."

Due to a regulatory stay pursuant to the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), YUTREPIA cannot yet be marketed in the United States. In June 2020, United Therapeutics filed a lawsuit against Liquidia for alleged infringement of three patents related to Tyvaso®. As a result, the FDA cannot give final approval of YUTREPIA until the expiration of the regulatory stay on October 27, 2022, or earlier resolution or settlement of the ongoing litigation.

Webcast and Conference Call
Liquidia will host a webcast and conference call Monday, November 8, 2021, at 9:00 a.m. EST to discuss this regulatory update for YUTREPIA™ (treprostinil) inhalation powder. The live call may be accessed by dialing 1-877-707-8711 (domestic) or 1-857-270-6219 (international) and entering the conference code: 8254404. A live and archived webcast of the webcast will also be available on the Events & Presentations page of the Liquidia website at https://liquidia.com/index.php/investors/events-and-presentations.

Tyvaso® is a registered trademark of United Therapeutics.

About YUTREPIA™(treprostinil) inhalation powder
YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a proven, convenient, palm-sized device. On November 5, 2021, the FDA issued a tentative approval for YUTREPIA, which is indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms. 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 optimal 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 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. and Liquidia PAH, LLC. Liquidia Technologies has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH). Liquidia PAH provides the commercialization for rare disease pharmaceutical products, such as generic Treprostinil Injection. For more information, 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 future results of operations and financial position, strategic and financial initiatives, business strategy and plans and 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 Liquidia's patent litigation pending in the U.S. District Court for the District of Delaware or its inter partes review with the PTAB or any related appeals, the issuance of

patents by the USPTO and Liquidia's ability to execute on its strategic or financial initiatives, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. 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. Liquidia has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that it believes may affect its 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 Liquidia's filings with the SEC, including the impact of the coronavirus (COVID-19) outbreak on the company and its financial condition and results of operations, as well as a number of uncertainties and assumptions. Moreover, Liquidia operates in a very competitive and rapidly changing environment and its industry has inherent risks. New risks emerge from time to time. It is not possible for Liquidia's management to predict all risks, nor can Liquidia assess the impact of all factors on its 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 Liquidia 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 Liquidia undertakes no duty to update its 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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