FDA Completes On-site Pre-Approval Inspection of Liquidia's Morrisville, North Carolina Facility

August 18, 2021

No Form 483 observations were issued during 5-day inspection

MORRISVILLE, N.C., Aug. 18, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) announced today that the U.S. Food and Drug Administration (FDA) has completed an on-site Pre-Approval Inspection (PAI) of its Morrisville, North Carolina facility in connection with the on-going review of the New Drug Application (NDA) for LIQ861 (treprostinil) inhalation powder. The 5-day PAI concluded on August 13 and no Form 483 Inspectional Observations were issued. This was Liquidia's first inspection of the Morrisville site by the FDA.

Robert Lippe, Chief Operations Officer at Liquidia, stated: "This is a very important element in our advancement of LIQ861 through the NDA process. In addition, we believe this favorable outcome from the first FDA inspection of our proprietary PRINT® technology helps demonstrate the potential for future applications of our precise, uniform drug particles across different types of molecules, therapeutic areas and routes of administration."

Damian deGoa, Chief Executive Officer at Liquidia, added: "We are pleased that it was possible to complete this inspection despite the challenges presented by the on-going COVID-19 pandemic. As a company, we will continue to build on the momentum of the completion of the PAI, alongside our successes in on-going litigation against United Therapeutics and the strong launch of our subcutaneous administration of Treprostinil Injection."

On June 2, 2021, the FDA accepted for review the NDA resubmission for LIQ861 (treprostinil) inhalation powder and under the Prescription Drug User Fee Act (PDUFA) set a goal date of November 7, 2021. The resubmitted NDA included additional information and clarification on chemistry, manufacturing, and controls (CMC) pertaining to the drug product as well as data on device biocompatibility. No additional data from clinical trials or studies related to toxicology or clinical pharmacology were required. The NDA has been submitted under the 505(b)(2) regulatory pathway and Tyvaso®, a nebulized treprostinil solution, is the Reference Listed Drug for the LIQ861 NDA.

In July 2021, the Company received a notice from the FDA that, due to restrictions on travel related to COVID-19, the FDA may be unable to conduct pre-approval inspections prior to the PDUFA goal date. On August 6, 2021, the FDA notified Liquidia of the planned PAI of the Morrisville site beginning on August 9, 2021, which was concluded on August 13, 2021. In addition to the completed inspection of Liquidia's Morrisville site, the FDA has notified Liquidia that a PAI will also be required for the third-party provider of encapsulation and packaging services for LIQ861. At this time, the Company has not been notified of when this additional PAI may be completed.

About LIQ861

LIQ861 is an investigational inhaled dry powder formulation of treprostinil designed using Liquidia's PRINT ® technology with the goal of enhancing deep-lung delivery using a convenient, palm-sized dry powder inhaler for the treatment of pulmonary arterial hypertension (PAH). PRINT® technology 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 believes LIQ861 can overcome the limitations of current inhaled therapies and has the potential to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs. Liquidia has completed an open-label, multi-center phase 3 clinical study of LIQ861 in patients diagnosed with PAH known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil.

About Treprostinil Injection

Treprostinil Injection is the first-to-file, fully substitutable generic treprostinil for parenteral administration. Treprostinil Injection contains the same active ingredient, same strengths, same dosage form and same inactive ingredients as Remodulin® (treprostinil), and is offered to patients and physicians with the same level of service and support, but at a lower price than the branded drug. Liquidia PAH promotes the appropriate use of Treprostinil Injection for the treatment of PAH in the United States in partnership with its commercial partner, who holds the Abbreviated New Drug Application (ANDA) with the FDA.

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 is developing LIQ861, an inhaled dry powder formulation of treprostinil 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 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 our response to the Complete Response Letter received in November 2020, the potential for eventual FDA approval of the NDA for LIQ861, the timeline or outcome related to our patent litigation pending in the U.S. District Court for the District of Delaware or our *inter partes* review with the PTAB, 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 completion and outcome of the PAI are not determinative of the ultimate decision by the FDA whether to approve or not approve the NDA for LIQ861. 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, including the impact of the coronavirus (COVID-19) outbreak on our Company and our financial condition and results of operations, 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
Vice President, Corporate Development and Strategy
919.328.4400
jason.adair@liquidia.com

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