Liquidia Receives Complete Response Letter from FDA for LIQ861 (treprostinil) Inhalation Powder for the Treatment of Pulmonary Arterial Hypertension

November 25, 2020

CRL does not cite need for additional clinical studies

CRL focuses on drug CMC and device biocompatibility information

Conference Call Scheduled for Today at 9:00a.m. ET

RESEARCH TRIANGLE PARK, N.C., Nov. 25, 2020 (GLOBE NEWSWIRE) -- Liquidia Technologies, Inc., a wholly owned subsidiary of Liquidia Corporation (NASDAQ: LQDA), today announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) for the company's New Drug Application (NDA) for LIQ861 (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH).

In the CRL, the FDA stated that it is unable to approve the NDA at this time. The CRL identified the need for additional information and clarification on chemistry, manufacturing and controls (CMC) data pertaining to the drug product and device biocompatibility. Liquidia does not believe that the items raised in the CRL will be a barrier to the ultimate approval of LIQ861.

The FDA also reconfirmed the need to conduct on-site pre-approval inspections (PAIs) of two of Liquidia's U.S. manufacturing facilities before the application can be approved. The FDA noted it had been unable to conduct these inspections during the initial review cycle due to COVID-19 related travel restrictions.

The CRL did not cite the need to conduct further clinical studies, nor did the FDA require additional studies related to toxicology or clinical pharmacology. Of note, Liquidia believes that it can address the items raised in the CRL without delaying the otherwise projected launch timing of LIQ861 in the second half of 2022, subject to FDA approval.

"We remain very confident in LIQ861 and are committed to working closely with the FDA to address these items to support its approval," said Neal Fowler, Chief Executive Officer at Liquidia. "With more than 70 patients now having received LIQ861 for more than two years in our clinical trials, Liquidia remains committed to PAH patients who we believe are underserved with currently available treatment options."

Webcast and Conference Call
Liquidia will host a webcast and conference call Wednesday, November 25, 2020 at 9:00 a.m. ET to discuss this regulatory update for LIQ861. The live call may be accessed by dialing 1-877-707-8711 (domestic) or 1-857-270-6219 (international) and entering the conference code: 3295968. A live and archived webcast of the call will also be available on the Events & Presentations page of the Liquidia website.

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 ("DPI") for the treatment of pulmonary arterial hypertension (PAH). PRINT ® technology enables development of drug particles that are precise and uniform in size, shape, weight and composition 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 PAH
PAH is a chronic, progressive disease caused by the hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death. Treprostinil is a synthetic analog of prostacyclin, a vasoactive mediator essential to normal lung function that is deficient in patients with PAH. PAH is a rare disease, with an estimated prevalence in the United States of approximately 30,000 patients. The exact cause of PAH is often unknown and, although the symptoms are treatable, there is no known cure for the disease.

About Liquidia
Liquidia Technologies, Inc., a wholly owned subsidiary of Liquidia Corporation, is a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products using its proprietary PRINT® technology to transform the lives of patients. PRINT is a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. Currently, Liquidia is focused on the development of two product candidates for which it holds worldwide commercial rights: LIQ861 for the treatment of pulmonary arterial hypertension (PAH) and LIQ865 for the treatment of local post-operative pain. Liquidia is headquartered in Research Triangle Park, NC. 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 anticipated submission contents and timelines, including potential resubmission of the NDA following our receipt of a CRL 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 its *inter partes* review with the Patent Trial and Appeal Board (PTAB), the issuance of patents by the U.S. Patent and Trademark Office (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 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 Liquidia’s 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.

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