



Liquidia Resubmits New Drug Application for LIQ861 (treprostinil) Inhalation Powder for the Treatment of Pulmonary Arterial Hypertension

May 10, 2021

MORRISVILLE, N.C., May 10, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) announced today that on May 7, 2021, it resubmitted its New Drug Application (NDA) for LIQ861 for the treatment of pulmonary arterial hypertension (PAH). The U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the NDA in November 2020 indicating that the application was incomplete and not ready for approval in its present form. Liquidia and the FDA held a Type A meeting in January 2021 to discuss the CRL and the requirements for the NDA resubmission.

The resubmitted NDA includes 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 was required. The Company anticipates that the FDA will classify the resubmitted NDA, if accepted, as a Class 2 Resubmission, which would result in a six-month review cycle from the date of resubmission.

In addition to the items identified in the CRL, the FDA also confirmed the need to conduct on-site pre-approval inspections. The FDA noted it had been unable to conduct these inspections in 2020 during the initial review cycle due to COVID-19 related travel restrictions. The company remains prepared to conduct these inspections at any time.

Damian deGoa, Chief Executive Officer of Liquidia, said: "The team has worked hard to provide a comprehensive and rapid response to the CRL. We look forward to working with the FDA through the review process during the coming months."

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 PAH. Liquidia PAH provides the commercialization for rare disease pharmaceutical products, such as 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 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 risk that the expected benefits and synergies from the Merger Transaction are not realized, 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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