



Liquidia Releases Final LIQ861 Results from Pivotal Phase 3 INSPIRE Study in Patients with Pulmonary Arterial Hypertension

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RESEARCH TRIANGLE PARK, N.C., April 30, 2020 (GLOBE NEWSWIRE) -- Liquidia Technologies, Inc. (Nasdaq: LQDA), a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products utilizing its proprietary PRINT® technology, today announced that it has released final safety and tolerability results from the two-month endpoint of the pivotal phase 3 INSPIRE trial that evaluated LIQ861 in patients with pulmonary arterial hypertension (PAH). Details from this late-breaking abstract were provided as an ePresentation on ISHLTV, an online platform designed as an alternative to the face-to-face scientific exchange originally scheduled at the International Society for Heart & Lung Transplantation (ISHLT) Annual Meeting.

LIQ861 is an investigational, inhaled dry powder formulation of treprostinil designed and engineered using Liquidia's novel PRINT technology with the goal of enhancing deep-lung delivery of treprostinil in PAH patients by means of a convenient, palm-sized dry powder inhaler.

"This final two month analysis of LIQ861 from the INSPIRE study is consistent with earlier findings and particularly encouraging for physicians as the data show that LIQ861 can be successfully titrated to therapeutic levels across a wide range of inhaled doses and was very well tolerated," said Nicholas Hill, MD, Chief Pulmonary, Critical Care & Sleep Division and Professor of Medicine at Tufts University School of Medicine and INSPIRE Principal Investigator. "If approved, LIQ861 may provide an effective and more convenient treatment option for patients when compared with those that are currently available."

In the INSPIRE trial (which stands for Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil), LIQ861 was observed to be well-tolerated in 121 patients, with 113 patients (93 percent) completing their two-month visit. During that period, LIQ861 was evaluated at doses ranging from 26.5 mcg to 159 mcg with no study-drug related serious adverse events observed. Reported treatment-emergent adverse events ("TEAEs") were mostly mild to moderate in nature, the most common (reported in ≥4 percent) being cough (42 percent), headache (26 percent), throat irritation (16 percent), dizziness (11 percent), diarrhea (9 percent), chest discomfort (8 percent), nausea (7 percent), dyspnea (5 percent), flushing (5 percent) and oropharyngeal pain (4 percent).

"LIQ861 is a great example of how our PRINT technology allows us to take good science and make it better. Treprostinil is vital to the treatment of PAH and through the vast design capabilities of PRINT, we are able to engineer it into highly uniform, precision particles with the intention of enhancing deep-lung delivery through a convenient palm-sized, dry powder inhaler and could provide PAH patients with a much needed treatment option," said Neal Fowler, Chief Executive Officer of Liquidia. "We are encouraged by PRINT technology and our pipeline, including the recent acceptance of the LIQ861 NDA for review by the FDA. We look forward to working closely with the FDA as it continues to review our drug application."

The New Drug Application (NDA) for LIQ861 was submitted to the U.S. Food and Drug Administration (FDA) under the 505(b)(2) regulatory pathway and includes data from three clinical studies to establish the safety, tolerability and pharmacokinetic profile of LIQ861. On April 8, 2020, Liquidia announced the FDA had accepted the NDA for review and that it had been provided a Prescription Drug User Fee Act (PDUFA) goal date of November 24, 2020.

About INSPIRE Clinical Trial

Liquidia's pivotal open-label phase 3 clinical trial, known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, was designed to evaluate patients who have either been under stable treatment with nebulizer-delivered treprostinil for at least three months and are transitioned to LIQ861 under the protocol or patients who have been under stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and have their treatment regimen supplemented with LIQ861 under the protocol. The primary objective of the INSPIRE study was to evaluate the long-term safety and tolerability of LIQ861. In August 2019, Liquidia completed the INSPIRE study. For more information, please visit <https://clinicaltrials.gov/ct2/show/NCT03399604>.

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 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.

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 timelines, including potential U.S. Food and Drug Administration (FDA) approval of the New Drug Application (NDA) submission for LIQ861, 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 Securities and Exchange Commission, 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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