Liquidia Submits New Drug Application for LIQ861 (treprostinil) inhalation powder to U.S. Food and Drug Administration for the Treatment of Pulmonary Arterial Hypertension (PAH)

January 27, 2020 08:00 ET | **Source:** Liquidia Technologies, Inc.

RESEARCH TRIANGLE PARK, N.C., Jan. 27, 2020 (GLOBE NEWSWIRE) -- Liquidia Technologies, Inc. (Nasdaq:**LQDA**) ("Liquidia"), a late-stage clinical biopharmaceutical company focused on the development of products using its proprietary PRINT® technology, today announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for 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).

The NDA has been submitted under the 505(b)(2) regulatory pathway and includes data from three clinical studies to establish the safety, tolerability and pharmacokinetic profile of LIQ861. The open-label Phase 3 study, known as INSPIRE (Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil) (**NCT03399604**), included 121 PAH patients who transitioned from stable doses of the reference listed drug or added LIQ861 to no more than two approved non-prostacyclin oral PAH therapies. The company also completed pharmacokinetic studies to establish the bioavailability of LIQ861 relative to the bioavailability of the reference listed drug.

Neal Fowler, Chief Executive Officer of Liquidia, said, "The submission of the NDA for LIQ861 in the U.S. is a significant milestone for our company and our goal to address

an important unmet need in the delivery of inhaled therapy for PAH patients. We would like to sincerely thank the patients, their families and the clinical investigators for their participation in the LIQ861 clinical program, and we look forward to working closely with the FDA during the review process."

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 Liquidia

Liquidia is a late-stage clinical biopharmaceutical company focused on the development and commercialization of therapeutics using its **proprietary PRINT® technology** to transform the lives of patients. Currently, Liquidia is focused on the development of two product candidates using its PRINT particle engineering platform: **LIQ861** for the treatment of pulmonary arterial hypertension and **LIQ865** for the treatment of local post-operative pain. Having been evaluated in a phase 3 clinical trial (INSPIRE), LIQ861 is designed to improve the therapeutic profile of treprostinil with the goal of enhancing deep-lung delivery and achieving higher dose levels than current inhaled therapies by using a convenient, palm-sized dry powder inhaler. LIQ865, for which Liquidia has completed two phase 1 clinical trials, is designed to deliver sustained-release particles of bupivacaine, a non-opioid anesthetic, to treat local post-operative pain for three to five days through a single administration.

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 the filing of the New Drug Application (NDA) for LIQ861 or FDA acceptance of the NDA submission and potential approval thereof, 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, including but not limited to whether the conditions for the closing of the private placement will be satisfied. These forward-looking statements are subject to a number of risks discussed in our filings with the Securities and Exchange Commission, 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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