



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

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RESEARCH TRIANGLE PARK, N.C., April 08, 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 the U.S. Food and Drug Administration (FDA) accepted for review the Company's New Drug Application (NDA) seeking marketing approval for LIQ861 for the treatment of pulmonary arterial hypertension (PAH). Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a goal date of November 24, 2020.

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

"FDA acceptance of this NDA is a significant milestone for our company and our PRINT technology. PRINT was the cornerstone that allowed for the precise engineering and development of LIQ861 into its current form and serves as the foundation for all of our products in development," said Neal Fowler, Chief Executive Officer of Liquidia. "If approved, LIQ861 will represent an important step forward in addressing the unmet needs of PAH patients by providing a convenient alternative to existing therapies. We look forward to working closely with the FDA through the NDA review process."

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 the filing of the New Drug Application (NDA) for LIQ861 or potential FDA approval of the NDA submission, 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, including the impact of the coronavirus (COVID-19) outbreak on the 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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