Liquidia Announces FDA Acceptance of New Drug Application Resubmission for LIQ861 (treprostinil) Inhalation Powder

June 2, 2021

MORRISVILLE, N.C., June 02, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) announced today that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) resubmission for LIQ861 (treprostinil) inhalation powder to treat pulmonary arterial hypertension (PAH). The FDA confirmed that the resubmission was a complete, class 2 response to the previous action letter issued on November 24, 2020. The FDA set a PDUFA goal date of November 7, 2021.

If the FDA determines, following its substantive review of the NDA, that all requirements for approval have been met, the FDA may issue tentative approval on a timeline generally informed by the PDUFA goal date. Any final FDA approval of the NDA for LIQ861 would be subject to the resolution of the pending Hatch-Waxman litigation commenced by United Therapeutics, and also subject to the FDA's consideration of developments that may have occurred since the time of the tentative approval. The FDA may not issue a final approval until the expiration of a 30-month regulatory stay in October 2022 or an earlier judgment unfavorable to United Therapeutics by the court. A new drug product may not be marketed until the date of final approval which is confirmed by the FDA at the time of final submission.

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 for the treatment of pulmonary arterial hypertension (PAH). PRINT® technology enables the development of drug particles that are precise and uniform in size, shape and composition, and 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 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 pulmonary arterial hypertension (PAH). Liquidia PAH provides the commercialization for rare disease pharmaceutical products, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

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