Liquidia Receives Favorable Ruling in Inter Partes Review against United Therapeutics Patent

October 8, 2021

MORRISVILLE, N.C., Oct. 08, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) announced today that the U.S. Patent Trial and Appeal Board (PTAB) ruled in its favor in the *Inter Partes* Review (IPR) proceeding against U.S. Patent No. 9,604,901 ('901 patent) owned by United Therapeutics Corporation (UTC) and listed in the Orange Book for Tyvaso® (treprostinil inhalation solution).

In its ruling, the PTAB found that seven of the nine claims were unpatentable. Only the narrower dependent claims 6 and 7 remain, both of which require actual storage at ambient temperature of treprostinil sodium. The PTAB's decision primarily relates to the issue of patentability based on a review of prior art. This decision does not preclude the invalidation of the remaining claims on other grounds as part of the ongoing Hatch Waxman litigation, nor does it mean that Liquidia infringes either of the surviving claims.

Damian deGoa, President and Chief Executive Officer of Liquidia said: "We are very pleased with this decision by the PTAB. This is a clear win in our on-going patent dispute with United Therapeutics, and we remain confident that we will ultimately prevail on all patent claims they have asserted against us. We will continue to vigorously defend our right to commercialize LIQ861 as soon as possible."

The PTAB's decision with respect to the '901 patent does not resolve the on-going litigation brought by UTC related to LIQ861. In June 2020, UTC filed a lawsuit against Liquidia under the Hatch-Waxman Act for infringement of three Tyvaso® patents, including the '901 patent, referenced in the 505(b)(2) regulatory filing for the LIQ861 New Drug Application (NDA). The lawsuit triggered a 30-month stay on an FDA regulatory approval of LIQ861, which expires on the earlier of October 24, 2022, or resolution of the litigation.

Tyvaso® is a registered trademark of United Therapeutics.

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.

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 favorable decision of the PTAB in the IPR for the '901 patent is not determinative of the outcome of any appeal of that decision, any IPRs that have been instituted by the PTAB with respect to any other patents of UTC or the Hatch-Waxman litigation between Liquidia and UTC. 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 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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