Liquidia Provides Update on U.S. Patent Trial and Appeal Board Decision on Inter Partes Review of Two United Therapeutics' Tyvaso® Patents

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PTAB Institutes Inter Partes Review Proceeding Against United Therapeutics' '901 Patent and Denies Institution on '066 Patent for Tyvaso®

RESEARCH TRIANGLE PARK, N.C., Oct. 14, 2020 (GLOBE NEWSWIRE) -- Liquidia Technologies, Inc. (NASDAQ: LQDA), a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products using its proprietary PRINT® technology, today announced that the U.S. Patent Trial and Appeal Board (PTAB) has instituted *inter partes* review (IPR) against U.S. Patent No. 9,604,901 ('901) and concurrently denied institution on 9,593,066 ('066), both owned by United Therapeutics Corporation (UTC) and listed in the Orange Book for Tyvaso® (treprostinil).

For '901, the PTAB Institution Decision states that "based on the information presented, we institute an *inter partes* review of claims 1–9 of the '901 patent."

Conversely, for '066, the PTAB denied institution of IPR stating that the petition "has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable."

"The PTAB's decision to institute an IPR proceeding against the '901 patent for Tyvaso is another important step forward for Liquidia's ongoing effort to bring LIQ861, a convenient and well tolerated treatment option, to the PAH community," stated Neal Fowler, Chief Executive Officer at Liquidia. "We believe PTAB's decision on '066 to be in error and while there are options for reconsideration, we remain confident in the arguments of non-infringement and invalidity to be made in district court."

Mr. Fowler added, "The Liquidia management team and our board are committed to providing PAH patients with alternative treatment options, like LIQ861, that we believe they need and deserve. We will not be deterred by any effort to limit our ability to deliver on this goal for patients and are confident in our options to bring LIQ861 to commercialization."

Liquidia's 505(b)(2) New Drug Application (NDA) for LIQ861, a dry powder inhalation of treprostinil, is currently under active review by the U.S. Food and Drug Administration (FDA) for the treatment of pulmonary arterial hypertension (PAH). Tyvaso®, a nebulized treprostinil solution, is the Reference Listed Drug for the LIQ861 NDA.

On June 4th, UTC filed a lawsuit against Liquidia under the Hatch-Waxman Act, based on the LIQ861 NDA, for infringement of Tyvaso patents that triggered a 30-month stay on an FDA regulatory approval. The 30-month stay expires on the earlier of October 24, 2022 or resolution of the litigation, whichever occurs first.

In July, UTC filed an amended complaint asserting infringement of an additional recently issued U.S. Patent No. 10,716,793 ('793). Although UTC's amended complaint brings the '793 patent into the pending lawsuit, the statutory 30-month stay on regulatory approval, is not associated with the allegations of infringement of the '793 patent and the allegations of infringement of this patent should have no effect on the FDA's review of the LIQ861 NDA.

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.

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 timelines, including potential U.S. Food and Drug Administration (FDA) approval of the New Drug Application (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 two petitions for *inter partes* review with the Patent Trial and Appeal Board, 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 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 and Liquidia Corporation's filings with the Securities and Exchange Commission, including the risk that our proposed acquisition of RareGen, LLC is not consummated or that the expected benefits and synergies from the proposed acquisition are not realized, 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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