



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

July 19, 2022

MORRISVILLE, N.C., July 19, 2022 (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. 10,716,793 ('793 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, based on the preponderance of the evidence, all the claims of the '793 patent have been shown to be unpatentable.

Roger Jeffs, Chief Executive Officer of Liquidia said: "We are very pleased with this decision by the PTAB. Today's decision is another step down the path towards YUTREPIA's potential final regulatory approval. We will continue to vigorously defend our right to commercialize YUTREPIA as soon as possible and look forward to hearing the final decision from the district court in the Hatch-Waxman litigation."

The PTAB's decision with respect to the '793 patent does not resolve the on-going district court litigation brought by UTC related to YUTREPIA. In June 2020, UTC filed a lawsuit against Liquidia under Hatch-Waxman for infringement of Patents No. 9,604,901 ('901 patent) and 9,593,066 ('066 patents). Upon initiation of the lawsuit, the U.S. Food and Drug Administration (FDA) triggered a statutory regulatory stay on the final approval of YUTREPIA until October 27, 2022, or earlier resolution or settlement of the ongoing litigation. UTC later amended the lawsuit to include the '793 patent when it was granted in July 2020.

In December 2021, UTC agreed to the entry of judgment of Liquidia's non-infringement of the '901 patent based on the Court's construction of certain terms in the patent. Thus, only the '066 and '793 patents remain at issue in the Hatch-Waxman proceedings in district court. In the event that the Court finds any of the asserted claims of the '066 patent or '793 patent are valid and infringed, then the Court is expected to issue an order that the effective date of final YUTREPIA approval will not be earlier than the date of expiration of the patent that has been found to be valid and infringed, which would be in the year 2027 in the case of the '793 patent and in the year 2028 in the case of the '066 patent.

Today's decision by the PTAB would not override an order of the Court in the Hatch-Waxman litigation that YUTREPIA may not be approved due to infringement of the '793 patent unless and until the decision of the PTAB is affirmed on appeal.

### About YUTREPIA™ (treprostinil) inhalation powder

YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a proven, convenient, palm-sized device. On November 5, 2021, the FDA issued a tentative approval for YUTREPIA, which is indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms. YUTREPIA was designed using Liquidia's PRINT® technology, which 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 has completed INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, an open-label, multi-center phase 3 clinical study of YUTREPIA in patients diagnosed with PAH who are naïve to inhaled treprostinil or who are transitioning from Tyvaso (nebulized treprostinil). YUTREPIA was previously referred to as LIQ861 in investigational studies.

### 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 has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH). Liquidia PAH provides the commercialization for pharmaceutical products to treat pulmonary disease, such as generic Treprostinil Injection. For more information, please visit [www.liquidia.com](http://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 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 appeals of PTAB decisions, 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 '793 patent is not determinative of the outcome of any appeal of that decision 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.

## Contact Information

### Media & Investors:

Jason Adair

Vice President, Corporate Development and Strategy

919.328.4400

[jason.adair@liquidia.com](mailto:jason.adair@liquidia.com)



Source: Liquidia Corporation