United States Supreme Court Declines to Review Rulings that Invalidate United Therapeutics' Patent

October 7, 2024

- U.S. Supreme Court denied United Therapeutics' petition to appeal rulings that found all claims of U.S. Patent No. 10,716,793 ('793 Patent) were invalid
- Decisions that Liquidia does not infringe any valid claims of the three patents originally asserted by United Therapeutics are now final and not subject to further appeal

MORRISVILLE, N.C., Oct. 07, 2024 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary diseases, today announced that the United States Supreme Court has rejected United Therapeutics' (UTHR) petition for a writ of certiorari, which requested permission to appeal prior decisions which found that all claims of U.S. Patent No. 10,716,793 ('793 Patent) are unpatentable due to prior art. As a result, the decision by the Patent Trial and Appeal Board (PTAB) in July 2022, which was affirmed by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) in December 2023, is now final and not subject to further appeal.

Dr. Roger Jeffs, Chief Executive Officer of Liquidia, said: "We are pleased that the Supreme Court has denied the petition by United Therapeutics and affirmed previous rulings that every claim of the '793 patent is invalid. We are grateful that this specific chapter has come to a close and that the '793 patent will now be forever unenforceable. We will continue to fight for the earliest possible launch of YUTREPIA so that patients and physicians have access to the unique benefits that YUTREPIA can provide."

On August 16, 2024, the U.S. Food and Drug Administration (FDA) granted tentative approval of YUTREPIA (treprostinil) inhalation powder to treat adults with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). In doing so, FDA confirmed that the amendment to add PH-ILD to the YUTREPIA New Drug Application (NDA) was proper and that application otherwise meets the requirements for approval under the Federal Food, Drug, and Cosmetic Act. Final approval of YUTREPIA for PAH and PH-ILD may occur after expiration of 3-year regulatory exclusivity for Tyvaso DPI on May 23, 2025.

There are no patents that are preventing final FDA approval of YUTREPIA. None of the valid claims of the three patents asserted by UTHR in original Hatch-Waxman litigation have been found to be infringed. All of the decisions are final and not subject to further appeal. Additionally, the U.S. District Court of the District of Delaware denied UTHR's request for a preliminary injunction with respect to a fourth patent, U.S. Patent No. 11,826,327 ('327 Patent), in a separate patent lawsuit filed by UTHR in September 2023. A trial in the '327 Patent lawsuit is scheduled for June 2025.

About YUTREPIA™ (treprostinil) Inhalation Powder
YUTREPIA is an inhaled dry-powder formulation of treprostinil delivered through a convenient, low-effort, palm-sized device. 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 enhanced 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 is currently being studied in the ASCENT trial, an Open-Label Prospective Multicenter Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in Pulmonary Hypertension, with the objective of informing YUTREPIA's dosing and tolerability profile in patients with PH-ILD. YUTREPIA was previously referred to as LIQ861 in investigational studies.

About Liquidia Corporation
Liquidia Corporation is a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary disease. The company's current focus spans the development and commercialization of products in pulmonary hypertension and other applications of its proprietary PRINT® Technology. PRINT enabled the creation of Liquidia's lead candidate, YUTREPIA™ (treprostinil) inhalation powder, an investigational drug for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). The company is also developing L606, an investigational sustained-release formulation of treprostinil administered twice-daily with a next-generation nebulizer, and currently markets generic Treprostinil Injection for the treatment of PAH. To learn more about Liquidia, please visit https://www.liquidia.com.

Tyvaso® is a registered trademark of United Therapeutics Corporation

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 final FDA approval of the NDA for YUTREPIA, the timeline or outcome of our lawsuit against the FDA or the cross-claims that United Therapeutics has brought in that lawsuit, the timeline or outcome related to patent litigation in the U.S. District Court for the District of Delaware, including rehearings or appeals of decisions in any such proceedings, 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 filings with the SEC, 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

Investors:
Jason Adair
919.328.4350
jason.adair@liquidia.com

Media:
Patrick Wallace
919.328.4383
patrick.wallace@liquidia.com

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