



Patent Trial and Appeal Board (PTAB) Reaffirms Decision to Invalidate All Claims of United Therapeutics (UTHR) Patent No. 10,716,793 ('793 Patent)

February 2, 2023

- PTAB rejects UTHR's request for rehearing of its decision in the *inter partes* review of the '793 Patent ('793 IPR)
- PTAB clarified grounds upon which it based its finding that the cited publications, which invalidated the claims, constituted prior art
- Company reaffirms expectation of legal resolution in late 2023 or the first half of 2024

MORRISVILLE, N.C., Feb. 02, 2023 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) announced that the PTAB has reaffirmed its original decision in the '793 IPR, which found all claims of the '793 patent to be unpatentable due to the existence of known prior art cited by Liquidia. In denying UTHR's request for a rehearing and for a reconsideration of the PTAB's decision in the '793 IPR, the PTAB clarified that the publications cited by Liquidia constituted prior art due to public distribution at large medical conferences more than a year before the filing of the initial patent application that led to the issuance of the '793 patent.

Roger Jeffs, Chief Executive Officer of Liquidia, stated: "We are pleased that the PTAB has confirmed its earlier determination that all claims of the '793 patent are invalid. Our focus remains to bring YUTREPIA™ (treprostinil) inhalation powder as a differentiated treatment choice to patients and their providers. This decision takes us one important step closer to that goal as the countdown towards final resolution of the litigation, and potential full approval of YUTREPIA, has now begun. Depending on the outcome of the appeals, the scheduling of oral arguments and the possibility of summary affirmance, we remain confident that we will reach final legal resolution in late 2023 or the first half of 2024."

Based on earlier statements, UTHR is expected to file an appeal of the PTAB decision to the U.S. Court of Appeals for the Federal Circuit. The deadline for UTHR's appeal is 63 days from the date on which UTHR's rehearing request was denied. If the PTAB's decision on the '793 IPR is affirmed on appeal, then the '793 patent will be cancelled, overriding any finding of infringement in the lawsuit filed by UTHR against Liquidia under the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in the U.S. District Court for the District of Delaware.

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.

Tyvaso® is a registered trademarks of United Therapeutics Corporation.

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.

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 related to appeals arising from our patent litigation in the U.S. District Court for the District of Delaware or *inter partes* review proceedings conducted at 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 decisions of

the PTAB in the IPRs for the '793 and '901 patents and of the Court in the Hatch-Waxman litigation are not determinative of the outcome of any appeal of those decisions. 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

Senior Vice President, Corporate Development and Strategy

919.328.4400

jason.adair@liquidia.com

 [Primary Logo](#)

Source: Liquidia Corporation