



Precedential Opinion Panel Denies United Therapeutics' Request for Review of '793 Inter Partes Review Decision

October 27, 2022

MORRISVILLE, N.C., Oct. 27, 2022 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) announced today that on October 26, 2022, the Precedential Opinion Panel (POP) of the United States Patent and Trademark Office (USPTO) denied a request by United Therapeutics (UTC) to review the decision by the Patent Trial and Appeals Board (PTAB), which found in July 2022 through *inter partes* review (IPR) that all claims in U.S. Patent No. 10,716,793 ('793 Patent) are unpatentable over certain prior art cited by Liquidia.

The PTAB's decision, which invalidated the '793 patent claims, was based on three specific pieces of prior art, one patent and two publications. The prior art status of the previously issued patent is not at issue. To establish the prior art status of the two publications, Liquidia presented evidence in the IPR that: (1) the publications were presented at major medical conferences, (2) the publications were publicly accessible at public libraries, and (3) the publications were referenced in other articles in large medical journals, which served as research aids. Any one of these three grounds, alone, could establish that the publications constitute prior art. Based on these arguments presented in the IPR, the PTAB determined that the publications did constitute prior art for purposes of the '793 Patent.

In UTC's August request for a rehearing of the PTAB's decision, and later request for POP review, UTC took issue with only the third of the three grounds supporting the two publications' status as prior art. In issuing its rejection of the POP request, the POP noted that the PTAB is best suited to make the appropriate factual findings on the prior art status of the references because the record had been fully developed on these issues during the '793 IPR process. The PTAB has been directed to clarify the grounds upon which it based its finding that the publications constitute prior art. The PTAB's review of UTC's rehearing request remains ongoing.

Roger Jeffs, Chief Executive Officer of Liquidia, stated: "Yesterday's decision clears the way for the PTAB to make a final decision with respect to UTC's rehearing request. We believe that the requested clarification of the PTAB's original decision will help to make the PTAB's decision even stronger. We remain confident that the rehearing request will be denied and that the PTAB's favorable decision will be affirmed on appeal, thereby unlocking the path to potential approval of YUTREPIA by mid-2024, if not earlier."

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 trademark 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 or rehearing requests 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.

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