Liquidia Corporation Files Response to United Therapeutics Lawsuit and Files Counterclaims

January 8, 2024

- Seeks dismissal of all claims related to ‘793 patent based on prior findings of invalidity which have been affirmed by the Federal Circuit
- Requests declaration that ‘327 patent is not infringed, is invalid and is unenforceable
- Files counterclaims asserting United Therapeutics failed to properly disclose prior art references and additional material information in its prosecution of the ‘327 patent that would have rendered the claims unpatentable

MORRISVILLE, N.C., Jan. 08, 2024 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) announced today it filed its answer, affirmative defenses and a partial motion to dismiss in response to the amended patent infringement complaint filed by United Therapeutics Corporation (UTHR) on November 30, 2023, under the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act) in the U.S. District Court for the District of Delaware (District Court) that alleges the infringement of U.S. Patent No. 10,716,793 (the ‘793 patent) and U.S. Patent No. 11,826,327 (the ‘327 patent) in association with Liquidia’s New Drug Application (NDA) for YUTREPIA™ (treprostinil) inhalation powder. Simultaneously, Liquidia filed counterclaims against UTHR seeking a declaration that all asserted claims of the ‘327 patent are not infringed, are invalid and are unenforceable. Furthermore, the counterclaims summarize certain publications, references and information that UTHR failed to submit to the United States Patent and Trademark Office (USPTO) during the prosecution of the ‘327 patent.

Dr. Roger Jeffs, Chief Executive Officer, said: “United Therapeutics seeks to interfere with our launch of YUTREPIA in PH-ILD by relitigating the same ‘793 patent that was previously found to be invalid and asserting a new patent that was procured without submitting highly material prior art references and important additional information to the USPTO. We will continue to aggressively defend ourselves and the ability of patients suffering from PAH and PH-ILD to have a choice of products to treat their rare and deadly disease.”

As previously disclosed, the asserted ‘793 patent was previously held to be invalid in a prior proceeding before the Patent Trial and Appeal Board (PTAB). On December 20, 2023, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) affirmed the PTAB’s finding that the ‘793 patent is invalid. Liquidia has therefore filed a partial motion to dismiss requesting that all claims related to the ‘793 patent be dismissed based on collateral estoppel.

With regard to the ‘327 patent, the counterclaims request declarations from the District Court that the patent is not infringed, is invalid and is unenforceable. Specifically, the counterclaims allege that UTHR failed to disclose to the USPTO the following prior art references, among others:

(i) a 2016 publication that UTHR helped support entitled *“Safety and Tolerability of High-dose Inhaled Treprostinil in Pulmonary Hypertension”* authored by Parikh et al. and published in the Journal of Cardiovascular Pharmacology, Volume 67, No. 4, pp. 322-325, which discloses methods improving exercise capacity in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD) by administering a dose of at least 15 micrograms of the inhalation formulation of treprostinil in a single event with each breath containing at least 6 micrograms and a demonstrated improvement in the 6 minute walk test and other efficacy measures;

(ii) UTHR’s arguments and expert testimony that the ‘793 patent, which constitutes prior art to the ‘327 patent, covered treatment of PH-ILD patients during prior *inter partes* review (IPR) proceedings; and

(iii) the District Court’s ruling in prior litigation that the ‘793 patent, which constitutes prior art to the ‘327 patent, includes treatment of all five groups of pulmonary hypertension, and the Federal Circuit’s affirmation of this ruling.

Liquidia has also asserted that these same references and information, as set forth in the counterclaims, also render the claims of the ‘327 patent invalid.

Because neither the ‘793 patent nor the ‘327 patent was issued prior to the filing of the original NDA for YUTREPIA, Liquidia does not believe that UTHR is entitled to a statutory 30-month regulatory stay by statute per Section 505(c)(3)(C) of the Federal Food, Drug and Cosmetic Act, which expressly addresses what patents can give rise to a 30-month stay and the effect of amendments to NDAs. As previously disclosed, the claims of the ‘327 patent relate solely to the PH-ILD indication.

Further information regarding these matters can be found in the Company’s publicly available court filings in the District Court for Case No.: 1:23-cv-00975-RGA at PACER case locator (https://pcl.uscourts.gov/) and in regulatory filings with the U.S. Securities and Exchange Commission (www.sec.gov).

About YUTREPIA™(treprostinil) inhalation powder

YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a convenient, low-resistance, palm-sized device. On November 5, 2021, the FDA issued a tentative approval for YUTREPIA 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. In July 2023, Liquidia filed an amendment to its New Drug Application for YUTREPIA, seeking to add PH-ILD to the label. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of January 24, 2024 for the amendment. Previously, the FDA has confirmed that YUTREPIA may add the treatment of PH-ILD to the label for YUTREPIA without additional clinical studies. 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 was previously referred to as LIQ861 in investigational studies.

About L606 (liposomal treprostinil) inhalation suspension

L606 is an investigational, sustained-release formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer. The L606 suspension uses Pharmosa Biopharm's proprietary liposomal formulation to encapsulate treprostinil which can be released slowly at a controlled rate into the lung, enhancing drug exposure over an extended period of time and reducing local irritation of the upper respiratory tract. L606 is currently being evaluated in an open-label study in the United States for treatment of PAH and PH-ILD with a planned pivotal study for the treatment of PH-ILD.

About pulmonary arterial hypertension (PAH)

PAH is a rare, chronic, progressive disease caused by hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death. Currently, an estimated 45,000 patients are diagnosed and treated in the United States. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression, and improve quality of life.

About pulmonary hypertension associated with interstitial lung disease (PH-ILD)

Pulmonary hypertension (PH) associated with interstitial lung disease (ILD) includes a diverse collection of up to 150 different pulmonary diseases, including interstitial pulmonary fibrosis, chronic hypersensitivity pneumonitis, connective tissue disease related ILD, and chronic pulmonary fibrosis with emphysema (CPFE) among others. Any level of PH in ILD patients is associated with poor 3-year survival. A current estimate of PH-ILD prevalence in the United States is greater than 60,000 patients, though population growth in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until March 2021, when inhaled treprostinil was first approved for this indication.

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. (Liquidia Technologies) and Liquidia PAH, LLC (Liquidia PAH). Liquidia Technologies has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of PAH and PH-ILD. Liquidia Technologies is also developing L606, an investigational liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer, for use in North America. Liquidia PAH provides for the commercialization of pharmaceutical products to treat pulmonary disease, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

Tyvaso® and Tyvaso DPI® are registered trademarks 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 related to patent litigation in the U.S. District Court for the District of Delaware or *inter partes* review proceedings conducted at the PTAB, including 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 favorable decisions of lower tribunals are not determinative of the outcome of the appeals of the 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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