



United Therapeutics Corporation Files Lawsuit Alleging Infringement of Tyvaso Patent Already Found to Be Invalid by U.S. Patent Office

September 6, 2023

- Asserts '793 patent in new litigation filed under Hatch-Waxman Act in response to Liquidia's amendment to its NDA to add PH-ILD to YUTREPIA™ label
- Litigation is tied to same '793 patent previously ruled invalid by Patent Trial and Appeal Board (PTAB)

MORRISVILLE, N.C., Sept. 06, 2023 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company), announced today that United Therapeutics Corporation (UTHR) filed a patent infringement action under the Hatch-Waxman Act in the U.S. District Court for the District of Delaware (District Court) asserting infringement of U.S. patent No. 10,716,793 ('793 patent) in response to Liquidia's amendment to add the PH-ILD indication to the tentatively approved New Drug Application (NDA) for YUTREPIA™ (treprostinil) inhalation powder. The '793 patent was previously found to be unpatentable by the PTAB in an *inter partes* review (IPR) in July 2022, a decision that was reaffirmed by the PTAB in February 2023.

Dr. Roger Jeffs, Chief Executive Officer of Liquidia, said: "Our focus is and will always be on bringing better therapies and treatment options to patients. While we are disappointed that United Therapeutics has elected to file this lawsuit alleging that YUTREPIA infringes this same patent that has already been litigated and already found by the PTAB to be invalid, it was expected. We will use the same aggressive and dedicated approach to defending this lawsuit as we have used in successfully resolving prior litigation that has been brought against us by United Therapeutics."

The '793 patent asserted in this litigation will trigger and support an automatic regulatory stay on the FDA's final approval of YUTREPIA. The regulatory stay for final approval would last until the earlier of either (1) resolution of the lawsuit in Liquidia's favor with respect to the '793 patent, or (2) 30 months after the date in July 2023 when United Therapeutics received notice of Liquidia's Paragraph IV certifications in connection with the amendment to the NDA.

In the prior lawsuit in which the '793 patent was asserted against Liquidia, the District Court ruled against Liquidia in August 2022 finding that all of the asserted claims of the '793 patent were both valid and infringed based on the arguments presented by Liquidia to the District Court. That decision was recently affirmed by the Court of Appeals for the Federal Circuit (Federal Circuit). However, if the Federal Circuit affirms the PTAB's decision in the '793 IPR currently under appeal, then the entire '793 patent would be invalidated and the '793 patent would no longer be a barrier to final approval of YUTREPIA. The appeal of the PTAB decision is expected to be completed in the fourth quarter of 2023 or the first half of 2024.

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, 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. The FDA has confirmed that YUTREPIA may add the indication to treat pulmonary hypertension with interstitial lung disease (PH-ILD) 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 pulmonary arterial hypertension (PAH)

Pulmonary arterial hypertension (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. and Liquidia PAH, LLC. Liquidia Technologies has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (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 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 patent litigation in the U.S. District Court for the District of Delaware or *inter partes* review proceedings conducted at the PTAB, including any 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 the PTAB in the IPR for the '793 patent and of the Court and CAFC 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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