Court Finds United Therapeutics' Interference with Launch of Generic Treprostinil Injection Caused Losses of More Than $137 Million

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MORRISVILLE, N.C., Sept. 16, 2024 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary diseases, announced today that the United States District Court for the District of New Jersey (District Court) has found that the interference by United Therapeutics Corporation (United Therapeutics) with the launch of generic Treprostinil Injection caused losses in excess of $137M. Treprostinil Injection is manufactured by Sandoz Inc. (Sandoz) and was launched as the first-to-file, fully-substitutable generic treprostinil for parenteral administration in March 2019. Liquidia PAH, LLC (formerly known as RareGen), a wholly owned subsidiary of Liquidia (Liquidia PAH), partnered with Sandoz in August 2018 on an exclusive basis to market and commercialize Treprostinil Injection.

Dr. Roger Jeffs, Ph.D., Chief Executive Officer of Liquidia, stated: "We are pleased with the court's decision to find United Therapeutics liable for its interference with the launch of generic Treprostinil Injection. The company's actions not only harmed us as competitors, but also harmed the healthcare system and pulmonary hypertension patients who were denied an alternative and more affordable treatment option. This is yet another positive milestone on our years-long fight with United Therapeutics to ensure that patients and healthcare providers have the treatment options they deserve and so desperately need."

The decision arises from the lawsuit filed in April 2019 by Liquidia PAH and Sandoz against United Therapeutics and another party in the District Court of New Jersey (Case No. No. 3:19 cv 10170), in which Liquidia PAH and Sandoz alleged that United Therapeutics violated the Sherman Antitrust Act of 1890, state law antitrust statutes, unfair competition statutes and a prior settlement agreement between Sandoz and United Therapeutics by taking calculated steps to restrict and interfere with the launch of generic Treprostinil Injection. Specifically, Liquidia PAH and Sandoz alleged that United Therapeutics and another party entered into anticompetitive agreements whereby restrictions were placed on the cartridges necessary for the subcutaneous administration of treprostinil such that they could not be used for generic Treprostinil Injection.

In March 2022, the District Court issued an order granting partial summary judgment to United Therapeutics with respect to the antitrust and unfair competition claims and granting partial summary judgment to Sandoz with respect to the breach of contract claim. After a trial, the District Court determined the damages caused by the breach of contract by United Therapeutics. Although the losses were determined by the District Court to be in excess of $137 million, the final damage award has yet to be determined by the District Court and will be offset by amounts that the District Court has ruled were costs avoided by Sandoz as a result of the breach, including amounts that would have been paid to Liquidia. The District Court's decisions can be appealed by any of the parties to the proceeding.

Under the agreement between Sandoz and Liquidia PAH, all proceeds from the litigation will be divided evenly between Sandoz and Liquidia PAH. Under the litigation finance agreements that Liquidia PAH has entered into with Henderson SPV, LLC (Henderson) and PBM RG Holdings, LLC (PBM), any net proceeds received by Liquidia PAH with respect to the damage award will be divided between Henderson and PBM such that no net proceeds will be retained by Liquidia PAH.

About Treprostinil Injection
Treprostinil Injection is the first-to-file, fully substitutable generic treprostinil for parenteral administration. Treprostinil Injection contains the same active ingredient, same strengths, same dosage form and same inactive ingredients as Remodulin® (treprostinil), and is offered to patients and physicians with the same level of service and support, but at a lower price than the branded drug. Liquidia PAH promotes the appropriate use of Treprostinil Injection for the treatment of PAH in the United States in partnership with Sandoz, Inc., who holds the Abbreviated New Drug Application (ANDA) with the FDA.

About Liquidia Corporation
Liquidia Corporation is a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary diseases. 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 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 the timeline or outcome of our lawsuits, including rehearings or appeals of decisions in any such proceedings, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The favorable decisions of courts or other tribunals are not determinative of the outcome of the appeals or rehearings of the decisions. The voluntary dismissal of a lawsuit without prejudice allows the underlying claims to be reasserted and does not address the merits of the underlying claims. 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.

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