Stipulation of Partial Judgment In Favor of Liquidia Filed In Hatch-Waxman Litigation

December 29, 2021

MORRISVILLE, N.C., Dec. 29, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) announced today that United Therapeutics Corporation (UTC) has filed a stipulation of partial judgment with respect to U.S. Patent No. 9,604,901 ('901 patent) in the on-going litigation under the Hatch-Waxman Act (Hatch-Waxman). Under the stipulation of partial judgment, UTC has agreed to the entry of judgment of Liquidia's non-infringement of the '901 patent based on the Court's construction of certain terms in the patent. UTC has preserved its appellate rights with respect to the '901 patent in the event the Court's construction of those terms is reversed. With this stipulation of partial judgment, only U.S. Patent No. 9,593,066 ('066 patent) will now serve as a basis for the on-going regulatory stay for final approval of YUTREPIA™ (treprostinil) inhalation powder by theU.S. Food and Drug Administration (FDA).

Damian deGoa, Chief Executive Officer of Liquidia said: "We continue to methodically make our legal arguments in concurrent proceedings in district court and before the Patent Trial and Appeal Board (PTAB) that the patents that have been asserted against us by UTC are invalid and not infringed by our product. Today's announcement adds to our confidence in our position when combined with the favorable ruling in the *inter partes* review (IPR) of the '901 patent, the PTAB's decision to institute an IPR with respect to U.S. Patent No. 10,716,793 ('793 patent) and the favorable ruling with respect to the terms under consideration in the claim construction hearing. We will defend our right to bring YUTREPIA to market for the benefit of PAH patients."

In June 2020, UTC filed a lawsuit against Liquidia under Hatch-Waxman for infringement of the '901 and '066 patents. Upon initiation of the lawsuit, the FDA triggered a statutory regulatory stay on the final approval of YUTREPIA until October 27, 2022, or earlier resolution or settlement of the ongoing litigation. UTC later amended the lawsuit to include the '793 patent, but the '793 patent is not subject to the FDA's regulatory stay because it was not listed in the Orange Book for Tyvaso ® when Liquidia submitted the New Drug Application (NDA) for YUTREPIA.

In October 2020, the PTAB denied institution of an IPR against the '066 patent, a patent entitled "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®". Both the '066 patent and '901 patent are related to U.S. Patent No. 8,497,393 which was granted to UTC and subsequently invalidated by the PTAB in an IPR instituted in 2016 by SteadyMed Ltd. Despite the PTAB's decision to deny the IPR on '066, the Company remains confident in its arguments of non-infringement and invalidity to be made in district court with respect to the '066 patent.

In October 2021, the PTAB ruled in Liquidia's favor in the IPR proceeding against the '901 patent. In its ruling, the PTAB found that seven of the nine claims were unpatentable. Only the narrower dependent claims 6 and 7 remain, both of which require actual storage at ambient temperature of treprostinil sodium.

In August 2021, the PTAB instituted an IPR proceeding against the '793 patent. Upon instituting the IPR, the PTAB stated that Liquidia had demonstrated a reasonable likelihood of prevailing in its assertion that all of the claims of the '793 patent are unpatentable as obvious over the combination of certain prior art cited by Liquidia in its petition.

In December 2021, the Court granted Liquidia leave to file a motion for summary judgment of invalidity of the '066 and '901 patents due to collateral estoppel. Trial in the Hatch-Waxman litigation is scheduled for March 28-30, 2022.

Tyvaso® and Remodulin® are registered trademarks of United Therapeutics.

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.

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 rare disease pharmaceutical products, 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 future results of operations and financial position, strategic and financial initiatives, business strategy and plans and 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 Liquidia's patent litigation pending in the U.S. District Court for the District of Delaware or its *inter partes* review with the PTAB or any related appeals, the issuance of patents by the USPTO and Liquidia's ability to execute on its strategic or financial initiatives, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. 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. Liquidia has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that it believes may affect its 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 Liquidia's filings with the SEC, including the impact of the coronavirus (COVID-19) outbreak on the company and its financial condition and results of operations, as well as a number of uncertainties and assumptions. Moreover, Liquidia operates in a very competitive and rapidly changing environment and its industry has inherent risks. New risks emerge from time to time. It is not possible for Liquidia's management to predict all risks, nor can Liquidia assess the impact of all factors on its 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 Liquidia 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 Liquidia undertakes no duty to update its 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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