Liquidia Responds to United Therapeutics Corporation Lawsuit Alleging Infringement of New Tyvaso Patent

July 24, 2020

RESEARCH TRIANGLE PARK, N.C., July 24, 2020 (GLOBE NEWSWIRE) -- Liquidia Technologies, Inc. (Nasdaq: LQDA), a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products utilizing its proprietary PRINT® technology, today announced that United Therapeutics Corporation (UTC) filed an amended complaint in its patent infringement action under the Hatch-Waxman Act against the Company in the U.S. District Court for the District of Delaware. The amended complaint asserts infringement of an additional recently issued U.S. Patent No. 10,716,793 ('793) allegedly relating to UTC's Tyvaso®, a nebulized treprostinil solution for the treatment of pulmonary arterial hypertension (PAH).

The lawsuit was originally filed in June 2020 in response to Liquidia's filing of a New Drug Application (NDA) for LIQ861 with the U.S. Food and Drug Administration (FDA). The original complaint asserted infringement of U.S. Patent Nos. 9,604,901 ('901) and 9,593,066 ('066) and triggered the statutory 30-month regulatory stay on the FDA approval of LIQ861. On July 16, 2020, Liquidia filed its Answer to UTC's original Complaint including Counterclaims of invalidity, non-infringement, and Orange Book de-listing of the '901 and '066 patents.

Although UTC's amended complaint brings the '793 patent into the pending lawsuit, the statutory 30-month stay on regulatory approval is not associated with the allegations of infringement of the '793 patent and the allegations of infringement of this patent should have no effect on the FDA's review of the LIQ861 NDA.

"We firmly believe that, if approved, LIQ861 will benefit PAH patients and the physicians who treat them by providing an alternative treatment option that delivers higher, tolerable doses through a convenient, inhaled route of administration," said Neal Fowler, Chief Executive Officer of Liquidia. "We stand firm in our commitment to PAH patients and will vigorously defend against any attempt to hinder our ability to bring LIQ861 forward."

About Liquidia

Liquidia is a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products using its proprietary PRINT® technology to transform the lives of patients. PRINT is a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. Currently, Liquidia is focused on the development of two product candidates for which it holds worldwide commercial rights: LIQ861 for the treatment of pulmonary arterial hypertension (PAH) and LIQ865 for the treatment of local post-operative pain. Liquidia is headquartered in Research Triangle Park, NC. For more information, please visit www.liquidia.com.

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 timelines, including potential U.S. Food and Drug Administration (FDA) approval of the New Drug Application (NDA) for LIQ861, the timeline related to our two petitions for *inter partes* review with the Patent Trial and Appeal Board, 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 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 Securities and Exchange Commission, including the risk that our proposed acquisition of RareGen, LLC is not consummated, 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.

Contact Information

Media:
Michael Parks
Corporate Communications
484.356.7105
michael.parks@liquidia.com

Investors:
Jason Adair
Vice President, Corporate Development and Strategy
919.328.4400
jason.adair@liquidia.com

LIQUIDIA_Logo.jpg

Source: Liquidia Technologies, Inc.