Liquidia Responds to United Therapeutics Corporation Lawsuit Alleging Infringement of Tyvaso Patents

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RESEARCH TRIANGLE PARK, N.C., June 05, 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 a patent infringement action under the Hatch-Waxman Act against the Company in the U.S. District Court for the District of Delaware asserting infringement of U.S. Patent Nos. 9,604,901 ('901) and 9,593,066 ('066) relating to UTC's Tyvaso, a nebulized treprostinil solution for the treatment of pulmonary arterial hypertension (PAH).

This lawsuit is in response to the New Drug Application (NDA) the Company filed with the U.S. Food and Drug Administration (FDA) requesting approval to market LIQ861, a dry powder inhalation of treprostinil for the treatment of PAH. The LIQ861 NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso® as the reference listed drug. Under the Hatch-Waxman Act, the FDA is automatically precluded from approving the LIQ861 NDA for up to 30 months or until resolution of the lawsuit, absent an earlier judgment unfavorable to UTC by the court.

Although the Company believes its LIQ861 dry powder inhaler (DPI) for the treatment of PAH is highly differentiated from Tyvaso®, since the Company is seeking approval of the LIQ861 NDA under the 505(b)(2) regulatory pathway, the LIQ861 NDA is subject to the provisions of the Hatch-Waxman Act.

"We believe these patents to be invalid and/or not infringed by the practice of LIQ861 and we will vigorously defend the suit and our freedom to pursue the commercialization of LIQ861," stated Neal Fowler, Chief Executive Officer at Liquidia. "We are acutely aware of the need that exists among PAH patients to have access to treatments beyond those which are currently available and are dedicated to addressing that need in the most expedient way possible."

The Company previously filed two petitions for *inter partes* review ("IPR") before the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office (USPTO) seeking a determination that all claims in the '066 and '901 patents are invalid. Both the '066 patent and the '901 patent are continuation patents of U.S. Patent No. 8,497,393 which was granted to UTC and subsequently invalidated by the USPTO in an IPR instituted in 2016 by SteadyMed Ltd.

A determination by the PTAB to institute the petitions is expected before the end of the third quarter of 2020, and a final written decision determining the validity of the challenged claims of the '066 and '901 patents, if the petitions are instituted by the PTAB, is expected within 12 months from institution. The Company believes it is positioned well for a favorable outcome in the IPR processes invalidating the '066 and '901 patents.

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 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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