

# Liquidia Announces Generic Treprostinil Injection Will Be Available for Subcutaneous Route of Administration

March 30, 2021

- Addressable market for generic Treprostinil Injection more than doubles
- FDA cleared 510(k) for RG 3ml Medication Cartridge for use with CADD-MS® 3 pump

RESEARCH TRIANGLE PARK, N.C., March 30, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) ("Liquidia" or the "Company") today announced that Treprostinil Injection, a generic form of Remodulin®, will soon be available for subcutaneous ("SC") administration to treat patients diagnosed with pulmonary arterial hypertension ("PAH").

On March 26, 2021, the U.S. Food and Drug Administration ("FDA") cleared the 510(k) application submitted by Liquidia PAH's manufacturing partner, Chengdu Shifeng Medical Technologies LTD ("Chengdu") for the RG 3ml Medication Cartridge which is indicated for use with the CADD-MS 3 pump. Manufactured by Smiths Medical, the CADD-MS 3 pump has been used for the SC administration of Remodulin for more than 10 years.

Damian deGoa, Liquidia's Chief Executive Officer, said: "We are very thankful for the effort and support Chengdu has demonstrated to enable the subcutaneous administration of Treprostinil Injection. We worked hard to overcome this obstacle, and we can now offer generic Treprostinil Injection to more than double the number of PAH patients. We will continue to offer patients, prescribers and payers the same high-touch services and support but at a lower cost compared to the branded product."

Since commercial launch two years ago, Treprostinil Injection has only been used for intravenous administration. The cartridges required to operate the only subcutaneous pump that could deliver treprostinil injection (CADD-MS 3) were not made available to patients using generic treprostinil injection. The introduction of the RG 3ml Medication Cartridge will enable the launch of SC administration of Treprostinil Injection for the first time.

Remodulin® (treprostinil) is a registered trademark of United Therapeutics Corporation. CADD-MS® 3 is a registered trademark of Smiths Medical ASD, Inc.

# **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 its commercial partner, who holds the Abbreviated New Drug Application (ANDA) with the FDA.

#### **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 is developing two product candidates: LIQ861, an inhaled dry powder formulation of treprostinil for the treatment of PAH, and LIQ865, an injectable, sustained-release formulation of bupivacaine for the management of local post-operative pain for three to five days after a procedure. Liquidia PAH provides the commercialization for rare disease pharmaceutical products, such as Treprostinil Injection.

### **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 anticipate submission contents and timelines, including our potential response to the Complete Response Letter received in November 2020, the potential for eventual FDA approval of the NDA for LIQ861, the timeline or outcome related to our patent litigation pending in the U.S. District Court for the District of Delaware or its inter partes review with the PTAB, 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 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 risk that the expected benefits and synergies from the Merger Transaction are not realized, 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.

Liquidia Corporation is headquartered in Research Triangle Park, NC. For more information, please visit www.liquidia.com.

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