U.S. Patent Trial and Trademark Appeal Board Decides to Institute Inter Partes Review of United Therapeutics' Tyvaso® Patent

August 12, 2021

MORRISVILLE, N.C., Aug. 12, 2021 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) announced today that the U.S. Patent Trial and Appeal Board (PTAB) has instituted inter partes review (IPR) against U.S. Patent No. 10,716,793 ('793 patent), owned by United Therapeutics Corporation (UTC) and listed in the Orange Book for Tyvaso® (treprostinil).

In deciding to institute the IPR with respect to the '793 patent, 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 to the PTAB.

"The PTAB's decision to institute an IPR against the '793 patent is another important step forward for Liquidia's ongoing effort to bring LIQ861, a convenient and well tolerated inhaled dry powder formulation of treprostinil, to the PAH community. With a decision in the IPR for U.S. Patent No. 9,604,901 expected in October and our continued efforts in the ongoing litigation against United Therapeutics, we remain confident that the patents asserted against us will be found invalid and not infringed by Liquidia," stated Damian deGoa, Chief Executive Officer at Liquidia.

In June 2020, UTC filed a lawsuit against Liquidia under the Hatch-Waxman Act, based on the LIQ861 New Drug Application (NDA), for infringement of Tyvaso patents that triggered a 30-month stay on an FDA regulatory approval. The 30-month stay expires on the earlier of October 24, 2022 or resolution of the litigation, whichever occurs first.

In July 2020, UTC filed an amended complaint asserting infringement of the '793 patent. Although UTC's amended complaint brought 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 should have no effect on the FDA's review of the LIQ861 NDA.

On June 2, 2021, the FDA accepted for review the NDA resubmission for LIQ861 (treprostinil) inhalation powder and set a PDUFA goal date of November 7, 2021. The NDA has been submitted under the 505(b)(2) regulatory pathway and Tyvaso®, a nebulized treprostinil solution, is the Reference Listed Drug for the LIQ861 NDA.

About LIQ861

LIQ861 is an investigational inhaled dry powder formulation of treprostinil designed using Liquidia's PRINT ® technology with the goal of enhancing deep-lung delivery using a convenient, palm-sized dry powder inhaler for the treatment of pulmonary arterial hypertension (PAH). PRINT® technology 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 believes LIQ861 can overcome the limitations of current inhaled therapies and has the potential to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs. Liquidia has completed an open-label, multi-center phase 3 clinical study of LIQ861 in patients diagnosed with PAH known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil.

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 LIQ861, an inhaled dry powder formulation of treprostinil 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.

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