Liquidia Corporation and Pharmosa Biopharm Announce Collaboration for Sustained-Release Inhaled Treprostinil Product in North America

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- Liquidia exclusively licenses North American rights to L606, an inhaled formulation of treprostinil administered twice-daily with a short duration, next-generation nebulizer
- Liquidia funds $10 million upfront payment from finance agreement with HealthCare Royalty
- Pharmosa to receive up to $215 million in development and sales milestones for PAH and PH-ILD indications, $10 million for each additional approved indication and additional product, and royalties on net sales of L606
- Creates industry leading portfolio in rapidly expanding market for inhaled treprostinil
- Liquidia to host webcast today at 8:30 a.m. Eastern Time

MORRISVILLE, N.C., June 28, 2023 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) and Pharmosa Biopharm (Pharmosa) today announced that they have entered into an exclusive licensing agreement for the development and commercialization in North America of L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD).

Roger Jeffs, Chief Executive Officer of Liquidia, stated: “L606 is the perfect life-cycle complement to our pipeline and furthers our mission to provide innovative treatment options that improve the lives of patients suffering from PAH or PH-ILD. As already observed in the ongoing Phase 3 open-label study of PAH patients, Pharmosa’s novel liposomal formulation offers potential to improve patient convenience and compliance with twice-daily dosing using a short-duration, next-generation nebulizer. More importantly, we believe that the inhaled drug-device combination may provide best-in-class treprostinil exposure over a 24-hour period, including during sleeping hours, which could translate to improved efficacy, tolerability, and patient outcomes. Our investment in this collaboration, alongside our continued preparation for a potential launch of YUTREPIA™ (treprostinil) inhalation powder, are clear examples of Liquidia’s long-term commitment to addressing unmet needs in treating pulmonary hypertension and enabling choice based on patients’ preferences and circumstances.”

Pei Kan, Ph.D., President of Pharmosa, added: “Liquidia is the ideal partner to bring L606 to the North American market. Liquidia has shown an unflinching determination to bring novel products to patients, and provides clear synergies with their commercial effort, clinical expertise and deep relationships with key opinion leaders. Pharmosa will focus on advancing its sustained-release liposomal technology which has demonstrated in L606 the ability to dramatically reduce maximum systemic drug concentrations while significantly increasing local concentrations deep in the lung.”

Under the agreement, Liquidia will be responsible for development, regulatory and commercial activities of L606 in North America. Pharmosa will manufacture clinical and commercial supplies of L606 and support Liquidia in establishing a redundant global supply chain. In consideration for these exclusive rights, Liquidia will pay Pharmosa an upfront payment of $10 million, potential development and sales milestone payments of up to $215 million tied to PAH and PH-ILD indications, and two tiers of low, double-digit royalties on net sales of L606. Pharmosa will also receive a $10 million milestone payment for each additional indication and additional product approved. Liquidia retains the first right to negotiate for development and commercialization of L606 in Europe and other territories should Pharmosa seek a partner, subject to satisfaction of certain conditions as set forth in the license agreement.

Liquidia intends to seek first regulatory approval of L606 in the United States under the 505(b)(2) regulatory pathway. The planned New Drug Application (NDA) is expected to include: (i) the completed Phase 1 trial demonstrating tolerability and comparable pharmacokinetics to nebulized Tyvaso (treprostinil) inhalation solution; (ii) clinical data from the on-going, open-label Phase 3 study in the United States in PAH and PH-ILD patients; and (iii) clinical data from a double-blind, randomized, placebo-controlled study to evaluate treatment of PH-LD patients with L606. Liquidia intends to initiate the PH-ILD trial in first half of 2024.

In support of today’s announcement, HealthCare Royalty (HCRx) will fund Liquidia $10.0 million from the Revenue Interest Financing Agreement (RIFA) announced in January 2023. The RIFA included a $7.5 million financing tranche at Liquidia’s discretion to support any acquisition of rights to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension. In connection with the transaction with Pharmosa, HCRx has agreed to advance an additional $2.5 million from the $25 million fourth tranche under the RIFA, which was to be funded upon the mutual election of both Liquidia and HCRx. Today’s announcement does not impact the $35 million tranche that will be available to Liquidia upon favorable resolution of the ongoing patent litigation with United Therapeutics Corporation. Total proceeds funded to Liquidia by HCRx are now $42.5 million of the up to $100 million contemplated by the RIFA. As previously announced, HCRx will receive a tiered royalty on net revenue generated by YUTREPIA and other products marketed by Liquidia. The aggregate payments to HCRx are capped at 175% of the total amounts advanced by HCRx, with the potential for a true-up payment to be made by Liquidia if HCRx’s internal rate of return is less than 18% on the date the cap is reached.

Conference Call
Liquidia will host a webcast call today at 8:30 a.m. Eastern Time. To listen to the webcast, please visit https://liquidia.com/investors/events-and-presentations.

About L606 (liposomal treprostinil) inhalation suspension

L606 is an investigational, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer. The L606 suspension uses Pharmosa’s proprietary liposomal formulation to encapsulate treprostinil which can be released slowly at a controlled rate into the lung, enhancing drug exposure over an extended period of time and reducing local irritation of the upper respiratory tract. L606 is currently being evaluated in an open-label study in the United States for treatment of pulmonary arterial hypertension (PAH) with a planned pivotal study for the

treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD).

About YUTREPIA™(treprostinil) inhalation powder

YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a convenient, low-resistance, 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. The FDA has confirmed that YUTREPIA may add the indication to treat pulmonary hypertension with interstitial lung disease (PH-ILD) without additional clinical studies. 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 enhanced 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 pulmonary arterial hypertension (PAH)

Pulmonary arterial hypertension (PAH) is a rare, chronic, progressive disease caused by hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death. Currently, an estimated 45,000 patients are diagnosed and treated in the United States. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression, and improve quality of life.

About pulmonary hypertension associated with interstitial lung disease (PH-ILD)

Pulmonary hypertension (PH) associated with interstitial lung disease (ILD) includes a diverse collection of up to 150 different pulmonary diseases, including interstitial pulmonary fibrosis, chronic hypersensitivity pneumonitis, connective tissue disease related ILD, and sarcoidosis among others. Any level of PH in ILD patients is associated with poor 3-year survival between 30 to 35%. A current estimate of PH-ILD prevalence in the United States is greater than 60,000 patients, though population growth in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until March 2021 with inhaled 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 has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH). Liquidia PAH provides the commercialization for pharmaceutical products to treat pulmonary disease, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

About Pharmosa Biopharm

Pharmosa Biopharm Inc. (PBI) is a Taiwan-based biotechnology company focused on developing new drugs by exploiting its proprietary liposomal formulations and manufacturing technology. With regional and global strategic partnerships, PBI develops products through 505(b)(2) or hybrid applications to regulatory authorities with the intent to expand the clinical potential of existing drugs by exploiting innovative delivery formulations and medical devices. For more information, please visit https://www.pharmosa.com.tw

About HealthCare Royalty

HCRx is a leading royalty acquisition company focused on commercial or near-commercial stage biopharmaceutical products. HCRx has $6.3 billion in cumulative capital commitments with offices in Stamford (CT), San Francisco, Boston and London. For more information, visit www.hcrx.com. HEALTHCARE ROYALTY® and HCRx® are registered trademarks of HealthCare Royalty Management, LLC.

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