Liquidia and Pharmosa Biopharm Expand Collaboration to Develop Sustained Release Inhaled Treprostinil (L606)

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- Liquidia amends exclusive license to include key markets in Europe, Japan and elsewhere
- Liquidia also obtains rights to Pharmosa's next-generation nebulizers for use with L606
- Pharmosa to receive $3.5 million upfront and up to $157.75 million in additional development and sales milestones tied to commercial sales outside of North America

MORRISVILLE, N.C., Oct. 02, 2024 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA), a biopharmaceutical company developing innovative therapies for patients with rare cardiopulmonary diseases, and Pharmosa Biopharm (Pharmosa) today announced that they have amended the current exclusive licensing agreement for the development and commercialization 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). The amended agreement expands Liquidia's licensed territory beyond North America to include key markets in Europe, Japan and elsewhere. Pharmosa will retain certain territories, including China, Korea, Taiwan, Middle East, North Africa, Turkey and Southeast Asia.

Liquidia has also obtained certain rights to Pharmosa's next-generation smart-technology nebulizers for use with its proprietary liposomal drug formulations. Unlike current nebulized treatments for PAH and PH-ILD, these palm-sized, lightweight, virtually silent nebulizers provide portability like a dry-powder inhaler and rapidly deliver a dose using breath-actuated smart technology that adapts to a patient's normal breathing pattern.

Dr. Rajeev Saggar, Chief Medical Officer of Liquidia, stated: "This is a great example of our approach to research and development in pulmonary hypertension. This partnership has the potential to be transformational for people living with PAH and PH-ILD, as it will combine Liquidia's expertise as a leader in the field of pulmonary hypertension with Pharmosa's deep experience in inhaled liposomal formulations. We are delighted by the interest from the global medical and patient communities, many of which lack access to inhaled formulations of treprostinil, as we prepare to initiate the L606 pivotal study in PH-ILD later this year. We are also encouraged by the recent scientific advice from the European Medicines Agency that supports our plan to proceed with the study as designed."

Pei Kan, Ph.D., President of Pharmosa, added: "This expanded partnership with Liquidia is a strong endorsement for our L606 programs and our contribution to the fight against pulmonary hypertension including PAH and PH-ILD. With more than 100,000 PAH and PH-ILD patients in the major countries outside North America, improvements of the treatment strategies in this region are essential since there is no approved treatment for PH-ILD outside the U.S. We believe Liquidia's commitment to move quickly and execute its global clinical program will accelerate the potential for long-term value creation for both parties in this partnership."

Consistent with the agreement from June 2023, Liquidia will be responsible for the development, regulatory and commercial activities of L606 in the expanded territory. Pharmosa will continue to manufacture clinical and commercial supplies of L606. In consideration for these incremental exclusive rights, Liquidia will pay Pharmosa an upfront payment of $3.5 million and up to $157.75 million in additional milestone payments for the development of PAH and PH-ILD indications and commercial sales outside of North America. Royalties payable by Liquidia to Pharmosa on global net sales of L606 have not changed and remain two tiers of low, double-digit royalties as set forth in the original agreement.

Clinically, L606 continues to generate encouraging data in an open-label safety study in the United States in both PAH and PH-ILD. As reported in a poster presentation at the 2024 American Thoracic Society International Conference, the tolerability and titratability profile of L606 observed to date has been favorable up to the maximum dose allowed in the study of 378 mcg twice daily, a dosage comparable to 26 to 28 breaths of Tyvaso administered four times daily. Pharmacokinetic studies in healthy volunteers demonstrated therapeutic levels of L606 up to 12 hours and 7-times lower peak plasma concentration compared to Tyvaso®. The increased apparent half-life of L606, in concert with comparable systemic exposure and clearance rate, suggests that L606 provides controlled, continuous drug coverage during sleeping and waking hours, and supports twice-daily administration using a breath-actuated, smart-technology nebulizer.

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 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 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 developing innovative therapies for patients with rare cardiopulmonary disease. The company's current focus spans the development and commercialization of products in pulmonary hypertension and other applications of its proprietary PRINT® Technology. PRINT enabled the creation of Liquidia's lead candidate, YUTREPIA™ (treprostinil) inhalation powder, an investigational drug for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). The company is also developing L606, an investigational sustained-release formulation of treprostinil administered twice-daily with a next-generation nebulizer, and currently markets generic Treprostinil Injection for the treatment of PAH. To learn more about Liquidia, please visit https://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.

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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 submission contents and timelines, 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, 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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