



Quince Therapeutics Announces Clinically Meaningful Improvements Across Functional, Hemodynamic and Biomarker Measures in Phase 2 Study in PAH and PH-ILD

May 18, 2026

Data from Phase 2a study of LAM-001 on top of standard of care in PH-ILD patients with refractory PH demonstrated clinically meaningful improvement in multiple assessments of lung function, including improvement in 6MWD of 67.4 meters and PVR reduction of 33.9% at 24 weeks

Phase 2b trial in PH-ILD to initiate in mid-2026, with topline data anticipated in the first quarter of 2028

Conference call and webcast today, May 18, 2026, at 10:00 a.m. ET

SOUTH SAN FRANCISCO, Calif., May 18, 2026 (GLOBE NEWSWIRE) -- Quince Therapeutics, Inc. (Nasdaq: QNCX) announced Phase 2a data evaluating LAM-001, an inhaled formulation of rapamycin (mTOR inhibitor), in patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD), presented at the American Thoracic Society (ATS) conference in Orlando. The Company recently acquired LAM-001 through its previously announced acquisition of Orphai Therapeutics, Inc., a clinical-stage biotechnology company developing LAM-001 to treat rare pulmonary diseases

The Phase 2a study was a 24-week, open-label trial conducted across four clinical sites evaluating LAM-001 as an add-on therapy to standard of care (SOC) in 10 adult patients with PAH and PH-ILD who remained symptomatic despite background therapy. Primary endpoints included change from baseline in peak oxygen uptake (VO2 max) at Week 24, safety and tolerability. Secondary endpoints included pulmonary vascular resistance (PVR), six-minute walk distance (6MWD) and change in functional class, with change in N-terminal pro-B-type natriuretic peptide (NT-proBNP) assessed as an exploratory endpoint.

LAM-001 Demonstrated Clinically Meaningful Improvements Across Key Measures of Pulmonary Vascular Disease

Treatment with LAM-001 was associated with improvement or stabilization from baseline across multiple clinically relevant measures, including 6MWD, PVR, NT-proBNP and forced vital capacity (FVC), supporting potential benefit across exercise capacity, pulmonary hemodynamics, cardiac stress and lung function.

Improvements in 6MWD, a clinically meaningful endpoint commonly used in pulmonary hypertension clinical trials and regulatory submissions, were observed alongside favorable changes in hemodynamic and biomarker measures. All evaluable patients also transitioned from Functional Class III to Functional Class II by Week 24. In addition, two patients transitioned to Functional Class I at 16- and 52-week evaluations.

LAM-001 was generally well tolerated in patients receiving background standard-of-care therapy. A total of 6 patients were evaluable at the 24-week endpoint, of which 4 were PH-ILD patients. All 4 PH-ILD patients were receiving stable doses of treprostinil therapy before and throughout the study.

LAM-001 Phase 2a PH Efficacy

	Evaluable Population N=6	PH-ILD Subgroup N=4
Δ6MWD (m)	+81.3	+67.4
Δ VO2 Max (Predicted)	+5.4%	+6.7%
% Δ PVR (exercise)	-25.5%	-35.3%
% Δ PVR (supine)	-28.1%	-33.9%
% Δ NT-proBNP	-29.0%	-28.8%
Δ FVC (% Predicted)	+4.8%	+1.8%

6MWD = six-minute walk distance; VO2 Max = peak oxygen uptake; PVR = pulmonary vascular resistance; NT-proBNP = N-terminal pro-B-type natriuretic peptide; FVC = forced vital capacity; % predicted compares a patient's value to expected normal values based on demographic characteristics.

"Patients with PH-ILD continue to face substantial limitations in daily functioning and a high risk of clinical deterioration despite currently available therapies," said Aaron B. Waxman, M.D., Ph.D., Director of the Pulmonary Vascular Disease Program at Brigham and Women's Hospital and Associate Professor of Medicine at Harvard Medical School. "What is particularly notable in these early data is the consistency of improvement observed across several important markers of disease burden, including exercise capacity, pulmonary vascular resistance, cardiac stress biomarkers and lung function. Improvements in measures such as 6MWD and PVR are especially encouraging given their clinical relevance in pulmonary hypertension and may suggest broader effects on cardiopulmonary physiology. These findings are encouraging for patients and the broader pulmonary hypertension community and support continued development of LAM-001 in PH-ILD, where meaningful therapeutic advances remain urgently needed."

About LAM-001

LAM-001 is a proprietary, investigational, once-daily inhaled formulation of sirolimus, also known as rapamycin. LAM-001's potential as a disease-

modifying agent in pulmonary hypertension stems from its ability to inhibit mTOR-mediated pulmonary arterial smooth muscle cell proliferation. The mTOR pathway has been shown to be activated in the pulmonary arterial smooth muscle cells of patients with pulmonary hypertension, and mTOR inhibition with rapamycin has been shown to reverse smooth muscle cell hyperproliferation and attenuate pulmonary vascular remodeling and cardiopulmonary dysfunction in multiple nonclinical models. Additionally, mTOR signaling promotes fibroblast activation, myofibroblast differentiation, and extracellular matrix deposition in injured or inflamed lung tissue, and mTOR inhibition has been shown to exert direct anti-fibrotic activity, reducing collagen accumulation, suppressing profibrotic cytokine signaling, and attenuating parenchymal fibrosis. These effects are particularly relevant in pulmonary hypertension associated with interstitial lung disease (PH-ILD), where vascular remodeling and progressive fibrosis evolve in parallel and amplify pulmonary vascular load. LAM-001 is designed to enhance pulmonary delivery and reduce systemic exposure, offering a promising potential disease-modifying therapy for pulmonary disease.

LAM-001 is currently being studied in multiple indications including pulmonary hypertension associated with interstitial lung disease (PH-ILD), a serious and progressive condition affecting an estimated ~86K patients in the U.S. and ~120K in Europe. Based on compelling Phase 2a data presented at the American Thoracic Society (ATS) in May 2026, the company is advancing LAM-001 into a Phase 2b trial in PH-ILD, with initiation planned for mid-2026 and data anticipated in the first quarter of 2028. LAM-001 is also being evaluated in a Phase 2 study in bronchiolitis obliterans syndrome (BOS), a serious complication following lung transplantation affecting an estimated ~17K patients in the U.S. and ~11K in Europe, with data anticipated in the first quarter of 2027. In late 2026, the company also plans to initiate a Phase 2 study of LAM-001 in sarcoidosis-associated pulmonary hypertension (SAPH), a severe complication of sarcoidosis with no approved therapy affecting an estimated ~60K patients in the U.S. and Europe.

Phase 2a Study Design

The Phase 2a study ([NCT05798923](#)) was a 10-patient, multicenter, open-label trial evaluating the safety, tolerability and efficacy of LAM-001 as an add-on therapy to standard of care (SOC) in adult patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) who remained symptomatic despite background therapy. The 24-week study was conducted across four clinical sites in the United States. Primary endpoints included change in peak oxygen uptake (VO2 max) from baseline to Week 24 as well as safety and tolerability. Secondary endpoints included change in pulmonary vascular resistance (PVR), six-minute walk distance (6MWD) and functional class assessments. Exploratory endpoints included change in N-terminal pro-B-type natriuretic peptide (NT-proBNP) and forced vital capacity (FVC).

Webcast Details

Monday, May 18th @ 10:00 a.m. ET

Investors: 1-877-407-0784

International Investors: 1-201-689-8560

Conference ID: 13760654

Webcast: [Click Here](#)

Call me™: [Click Here](#) for instant telephone access to the event.

A replay of the webcast presentation will be temporarily archived on the Investors section of Quince's website following the presentation.

About Quince Therapeutics, Inc.

Quince Therapeutics, Inc. is committed to transforming the lives of patients facing serious, underserved diseases by developing disease-modifying therapies to treat their conditions. The company is currently developing LAM-001 for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD), bronchiolitis obliterans syndrome (BOS), and sarcoidosis associated pulmonary hypertension (SAPH). A Phase 2a study in PH patients has been completed, a Phase 2 clinical study in BOS patients is ongoing, a Phase 2b study in PH-ILD is anticipated to begin in mid-2026, and a Phase 2 study in SAPH is anticipated to begin in late-2026. By pioneering innovative approaches, the company aims to offer new hope and improved quality of life to patients worldwide.

Forward Looking Statements

Statements in this news release contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. All statements, other than statements of historical facts, may be forward-looking statements. Forward-looking statements contained in this news release may be identified by the use of words such as "believe," "may," "should," "expect," "anticipate," "plan," "believe," "estimated," "potential," "intend," "will," "can," "seek," or other similar words. Examples of forward-looking statements include, among others, statements relating to the design and potential benefits of LAM-001, including as a disease-modifying therapy for pulmonary disease; anticipated regulatory and development processes and timelines, including the expected timing to initiate the planned Phase 2b trial of LAM-001 in PH-ILD and the planned Phase 2 trial of LAM-001 in SAPH, the expected timing for data readouts from the ongoing Phase 2 trial of LAM-001 in BOS and the planned Phase 2b trial of LAM-001 in PH-ILD; the Phase 2a data of LAM-001 in PAH and PH-ILD supporting continued development of LAM-001 in PH-ILD and the potential benefit across exercise capacity, pulmonary hemodynamics, cardiac stress and lung function; observed improvements in 6MWD and PVR in the Phase 2a trial potentially suggesting broader effects on cardiopulmonary physiology; the estimated patient populations in the U.S. and Europe for PH-ILD, BOS and SAPH; and the potential advantages of mTOR inhibitors in PH-ILD. Forward-looking statements are based on Quince's current expectations and are subject to inherent uncertainties, risks, and assumptions that are difficult to predict and could cause actual results to differ materially from what the company expects. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Factors that could cause actual results to differ include, but are not limited to, clinical results may not be indicative of results that may be observed in the future, including in larger populations; potential safety and other

complications related to LAM-001; the ability to obtain and maintain regulatory approval; competition in the company's industry; the scope, progress and expansion of developing LAM-001; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies; the company's ability to attract or retain key management, members of the board of directors and other personnel; the impacts of general macroeconomic and geopolitical conditions on the company's business and financial position; and other risks and uncertainties described in the section titled "Risk Factors" in the company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on April 10, 2026 and other reports as filed with the SEC. Forward-looking statements contained in this news release are made as of this date, and Quince undertakes no duty to update such information except as required under applicable law.

Contacts

Corey Davis, Ph.D.
LifeSci Advisors, LLC
cdavis@lifesciadvisors.com
212-915-2577