



NEWS RELEASE

Lantern Pharma Receives Taiwan Approvals to Open Next Stage of Phase 2 HARMONIC™ Trial of LP-300 in Never-Smoker, EGFR-Mutant NSCLC

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- The Taiwan FDA approved the amended protocol and the lead Taiwan site received IRB approval during September of 2026.
- The next stage (Part 2) is a single-arm study enrolling never-smoker patients with the EGFR exon 21 L858R mutation, with LP-300 dosing extended from six to a maximum of eight cycles.
- EGFR mutations are found in 55% of advanced lung adenocarcinomas in Taiwan and roughly half across Asia, compared with approximately 14% of NSCLC in Europe and 24% in the U.S.; the L858R mutation is also more common in Asian patients.
- In the U.S., a central IRB has approved the amended protocol and academic sites have begun identifying patients with the L858R mutation for enrollment.
- Lantern is exploring regional licensing, partnering and co-development opportunities for LP-300.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), a clinical-stage, AI-driven precision oncology company, today announced that it has received regulatory and IRB approvals in Taiwan to open the next stage (Part 2) of its Phase 2 **HARMONIC™ trial of LP-300**. The Taiwan Food and Drug Administration (TFDA) approved the amended protocol earlier in September, and the lead Taiwan site received local Institutional Review Board (IRB) approval on September 29, 2026. The lead site is now open to accrual and actively screening patients. The approval also allows additional Taiwan sites to proceed with their own IRB reviews. Lantern anticipates IRB approval in an additional two sites during Q4.

In the United States, a central IRB has approved the amended protocol, and academic clinical sites have begun identifying patients whose tumors carry the EGFR exon 21 L858R mutation. Patients enrolled under the amended protocol will be eligible for up to eight cycles of LP-300, which is an increase from the prior limit of up to six cycles.

The increase to eight cycles is supported by two key findings:

1. Longer progression-free survival in patients completing more cycles – In the ongoing Phase 2 trial, L858R patients who completed six cycles of LP-300 had a median progression-free survival (mPFS) of 8.9 months (n=9; three had not yet progressed), compared with 8.3 months for all L858R patients (n=16). These data are exploratory and need to be confirmed in additional patients.
2. Comparable safety with longer treatment – In **HARMONIC™**, the safety profile of patients who received six cycles was comparable to that of patients who received four. Additionally, in prior clinical trials with LP-300, up to eight cycles at the current dose did not alter LP-300's safety profile.

Taiwan: High Patient Population & Need

Lung cancer has been the leading cause of cancer death in Taiwan for decades, and more than half of lung cancer patients there have never smoked.^{1,2} According to Taiwan's 2025 national lung cancer treatment guidelines, 55% of Taiwanese patients with advanced lung adenocarcinoma harbor EGFR mutations, predominantly exon 19 deletions and exon 21 L858R substitutions.¹

Taiwan's health system is also set up to find these patients. National Health Insurance reimburses next-generation sequencing at the time of drug resistance, so patients progressing on EGFR-targeted therapy can be profiled at the point where they would become eligible for HARMONIC™. Lantern plans to open additional sites in Taiwan and expects this combination of high mutation prevalence and available molecular testing to support efficient enrollment in Part 2.

East Asia: A Consistent Pattern of Patient Need

Approximately one third of lung cancer patients in East Asia are never-smokers (39.7% in China, 38% in South Korea and 32.8% in Japan),³ compared with approximately 15% of NSCLC diagnoses in the United States.⁴ EGFR mutations are present in roughly half of advanced lung adenocarcinomas in Asian patients.⁵ By comparison, a pooled analysis of 456 studies put EGFR mutation prevalence in NSCLC at approximately 14% in Europe and 24% in the United States.⁶ The L858R mutation is also more common in Asia: a worldwide meta-analysis found that L858R accounts for approximately 41% of EGFR mutations in Asian patients with advanced NSCLC, compared with approximately 30% in European patients.⁷ Among East Asian never-smokers with lung adenocarcinoma, EGFR mutations are the most common driver, found in 60 to 78% of cases.³

Lantern has now enrolled or opened HARMONIC™ in two East Asian regions, having completed targeted enrollment in Japan across five clinical centers in 2025. The Company believes that data generated in Taiwan and Japan will be relevant to the broader East Asian patient population and will support discussions regarding partnering and regional co-development of LP-300 with Asia-focused biopharma companies.

Part 2 Clinical Trial Design

Part 2 implements the protocol amendments to which the FDA had no objections and that were announced by Lantern in May 2026:

- Enrollment is limited to patients with the EGFR exon 21 L858R mutation who have progressed after tyrosine kinase inhibitor treatment.
- LP-300 may be given for up to eight cycles, increased from six, in combination with carboplatin and pemetrexed.

“Never-smoker lung cancer is most common in East Asia. In Taiwan, more than half of lung cancer occurs in never-smokers, and a meaningful share of those patients carry the L858R mutation, where outcomes on current targeted therapies have lagged those of other EGFR-mutant patients. What we see in Taiwan is what clinicians see across the region. With these approvals, the next stage of HARMONIC™ opens where the need is high and where we expect enrollment to be efficient. That matters for how quickly we can get to a clear answer on LP-300.”

— Panna Sharma, President and Chief Executive Officer, Lantern Pharma Inc.

Rationale

Preliminary analyses from HARMONIC™ suggested that patients with L858R-mutant disease may derive greater benefit from the LP-300 combination than other EGFR-mutant subgroups, with a previously reported median progression-free survival of 8.3 months in this group (n=16).

The increase to eight cycles is supported by two findings. In the ongoing Phase 2 trial, L858R patients who completed six cycles of LP-300 had a median progression-free survival of 8.9 months (n=9; three had not yet progressed), with a safety profile comparable to that of patients who received four cycles. In addition, prior clinical experience showed that up to eight cycles at the current dose did not alter LP-300's safety profile.

These data are preliminary, exploratory and based on small patient numbers. Lantern expects to gather additional supporting data in the next stage of the **Harmonic clinical trial**.

Market Opportunity and Regional Partnering Strategy

Lung cancer is the most commonly diagnosed cancer worldwide, with approximately 2.5 million new cases in 2022. China and Japan together accounted for approximately 1.2 million of those cases, nearly half of the global total.⁸

Approximately 350,000 new cases of EGFR-mutant NSCLC are diagnosed worldwide each year, and Lantern estimates that 90,000 to 100,000 of those patients carry the EGFR exon 21 L858R mutation. Lantern estimates that the treatment of never-smokers with NSCLC represents an annual market opportunity of \$4 billion or more.

No therapy has been developed or labeled specifically for never-smoker NSCLC. Lantern is exploring regional licensing, partnering and co-development opportunities for LP-300 to accelerate its development and realize its commercial potential in the geographies where patient need is greatest.

About LP-300 and the HARMONIC™ Trial

LP-300 is an investigational small molecule being evaluated in Lantern Pharma's Phase 2 HARMONIC™ trial in combination with carboplatin and pemetrexed in never-smokers with advanced NSCLC adenocarcinoma who have progressed following treatment with EGFR tyrosine kinase inhibitors. Part 2 of HARMONIC™ is a single-arm study enrolling patients with EGFR exon 21 L858R mutations, with LP-300 dosing of up to eight cycles. The trial is registered on ClinicalTrials.gov under identifier NCT05456256. LP-300 has not received FDA marketing approval for any indication. All clinical data referenced in this press release are preliminary.

About Lantern Pharma

Lantern Pharma Inc. (NASDAQ: LTRN) is a clinical-stage, AI-driven precision oncology company developing targeted therapies for high-need cancer indications. The Company's proprietary RADR® AI platform integrates multi-omic biomarker data with clinical outcomes to identify patient subgroups most likely to respond to specific therapies, enabling more efficient clinical development and biomarker-driven trial design. Lantern's pipeline includes LP-300 (HARMONIC™ trial in never-smoker NSCLC), LP-184, and LP-284, with additional preclinical programs identified through RADR®.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, among other things, statements relating to: future events or our future financial performance; plans, objectives and expectations regarding the HARMONIC™ clinical trial; LP-300's potential clinical activity and

tolerability profile; our clinical development plans for LP-300; expectations and estimates regarding clinical trial timing, regulatory and IRB approvals, clinical site activation and patient enrollment for the HARMONIC™ clinical trial, including in Taiwan and the United States; estimates regarding patient populations, potential markets and potential market sizes; and our plans to discover and develop drug candidates and to maximize their commercial potential by advancing such drug candidates ourselves or in collaboration with others.

Any statements that are not statements of historical fact (including, without limitation, statements that use words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “target,” “model,” “objective,” “aim,” “upcoming,” “should,” “will,” “would,” or the negative of these words or other similar expressions) should be considered forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated by the forward-looking statements, such as (i) the risk that we may not be able to secure sufficient future funding when needed and as required to advance and support our existing and planned clinical trials and operations, (ii) the risk that observations in preclinical studies and emerging or preliminary observations in clinical studies do not ensure that later observations, studies and development will be consistent or successful, (iii) the risk that any clinical benefit observed to date relating to LP-300 may not be reproduced in the completed HARMONIC™ trial or in larger or confirmatory studies, (iv) the risk that clinical data referenced in this press release relating to the HARMONIC™ clinical trial are exploratory and preliminary, based on small patient cohorts, and may not be representative of outcomes in broader populations, (v) the risk that additional clinical sites may not receive IRB approval or be activated on the timelines we expect, or that patient enrollment in Part 2 of the HARMONIC™ clinical trial, including in Taiwan, may be slower than anticipated, (vi) the risk that our research and the research of our collaborators may not be successful, (vii) the risk that we may not be successful in licensing our product candidates or in completing potential partnerships and collaborations, (viii) the risk that none of our product candidates has received FDA marketing approval, and we may not be able to successfully initiate, conduct, or conclude clinical testing for or obtain marketing approval for our product candidates, (ix) the risk that no drug product based on our proprietary AI platforms has received FDA marketing approval or otherwise been incorporated into a commercial product, and (x) technical, scientific, regulatory, financial, competitive, and operational risks and those other factors set forth in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission on March 30, 2026 [, and in our subsequent Quarterly Reports on Form 10-Q].

You may access our Annual Report on Form 10-K for the year ended December 31, 2025 under the investor SEC filings tab of our website at www.lanternpharma.com or on the SEC’s website at www.sec.gov. Given these risks and uncertainties, we can give no assurances that our forward-looking statements will prove to be accurate, or that any other results or events projected or contemplated by our forward-looking statements will in fact occur, and we caution investors not to place undue reliance on these statements. All forward-looking statements in this press release represent our judgment as of the date hereof, and, except as otherwise required by law, we disclaim any

obligation to update any forward-looking statements to conform the statement to actual results or changes in our expectations.

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