



NEWS RELEASE

Lantern Pharma Announces Successful Outcome of FDA Type C Meeting Request for HARMONIC™ Phase 2 Trial of LP-300 in Never-Smokers with NSCLC

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- The FDA raised no objections to Lantern's key proposed protocol amendments to the HARMONIC™ clinical trial.
- Amendments include: (1) enriching enrollment for patients with EGFR exon 21 L858R mutations; (2) extending LP-300 dosing to a maximum of eight cycles; and (3) transitioning to a single-arm study design — changes that align with emerging data and support a clearer regulatory and partnering path.
- EGFR exon 21 L858R mutations account for approximately 40% of all EGFR-mutant NSCLC globally and up to 50% in Asian populations — a molecularly defined subset that consistently experiences inferior outcomes when treated with current EGFR-targeted therapies relative to patients with exon 19 deletions.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), a clinical-stage, AI-driven precision oncology company, today announced that it has received a successful response to its recent Type C meeting request from the U.S. Food and Drug Administration (FDA), focused on the ongoing Phase 2 HARMONIC™ trial of LP-300 in never-smokers with advanced non-small cell lung cancer (NSCLC) adenocarcinoma. In its written responses to Lantern's Type C meeting request, the FDA raised no objections to key proposed protocol amendments, providing a more focused, clearer regulatory path forward for the HARMONIC™ trial and for the future development of LP-300 in this distinct, high-need patient population.

The HARMONIC™ trial is designed to evaluate LP-300, a small molecule given in combination with carboplatin and

pemetrexed, in never-smokers with advanced NSCLC adenocarcinoma who have experienced disease progression following treatment with kinase inhibitors. Never-smoker NSCLC is increasingly recognized as a distinct disease entity with unique clinical and genomic features. Globally, approximately 400,000 to 500,000 patients are diagnosed with never-smoker NSCLC each year — a patient population that, if classified separately, would rank among the most common cancers worldwide. Despite this scale, no therapies have been specifically developed or labeled for the never-smoker NSCLC patient population, and the EGFR exon 21 L858R subset in particular continues to experience inferior outcomes when treated with currently available standards of care.

“In our view, this successful Type C interaction with the FDA is a meaningful de-risking milestone for the LP-300 program and for the HARMONIC™ trial. The FDA's response to our proposed amendments supports our strategy to focus HARMONIC™ on the EGFR exon 21 L858R-mutant never-smoker population, where emerging data suggest LP-300 may offer meaningful differentiated benefit when added to standard chemotherapy following TKI failure.”

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

Focused Enrollment in EGFR Exon 21 L858R Never-Smokers

Under the amended protocol supported by the FDA's Type C responses, Lantern plans to focus all future HARMONIC™ enrollment on patients harboring the EGFR exon 21 L858R mutation, a subtype of EGFR kinase domain mutations associated with lower TKI binding affinity and inferior outcomes on osimertinib-based therapy relative to patients with exon 19 deletions. Preliminary analyses from the ongoing HARMONIC™ trial suggest that patients with EGFR exon 21 L858R-mutant disease may derive greater clinical benefit from the LP-300 triplet regimen than other EGFR-mutant subgroups, providing a biologically and clinically compelling rationale to enrich the study for this population. Based on currently available data, preliminary multivariable Cox regression analyses incorporating race, gender, and TP53 mutation status have confirmed L858R as an independent predictor of progression-free survival benefit in the trial, suggesting the signal is not driven by demographic confounders.

“The preliminary signal in the EGFR exon 21 L858R cohort — including a median progression-free survival of 8.3 months and durable responses extending beyond two years in select patients — gives us confidence that an enriched, single-arm design is the right next step. Aligning the trial with that signal, and receiving no objection from the FDA to key aspects of our approach via a successful Type C interaction, positions us to generate a more focused, decision-enabling data-set for patients, regulators, and potential partners.”

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

Extended LP-300 Dosing Based on Safety and Emerging Outcomes

In addition to refining the molecularly defined patient population, the Type C feedback supports Lantern's proposal to increase the maximum number of LP-300 treatment cycles in HARMONIC™ from six to eight. This change is supported by historical safety data from prior clinical experience with LP-300 indicating that up to eight cycles at the current dose level did not alter the established safety profile of the drug, as well as by emerging HARMONIC™ data suggesting improved outcomes with longer LP-300 treatment duration.

By extending LP-300 dosing, Lantern aims to maximize the depth and durability of response without adding clinically meaningful toxicity beyond that expected with carboplatin and pemetrexed alone. In earlier studies, LP-300 has been administered in multiple clinical trials to more than 1,000 individuals and has generally been well tolerated, providing a substantial safety foundation for this dosing adjustment.

Transition to a Single-Arm, Enriched Study Design

As part of the protocol amendments proposed in the Type C meeting interaction, Lantern will discontinue enrollment into the control arm of the HARMONIC™ trial and migrate the study into a single-arm design that only enrolls additional patients with the EGFR exon 21 L858R mutation. This evolution reflects the rapidly changing treatment landscape in TKI-refractory NSCLC, where increasing availability of subsequent-line therapies and patient preferences have made continued randomization to a traditional chemo-doublet control arm operationally challenging in never-smokers.

The enriched, single-arm design is intended to accelerate enrollment, sharpen the clinical signal within a genomically defined subgroup, and enable more efficient comparisons to historical and real-world benchmarks in EGFR exon 21 L858R-mutant never-smoker NSCLC. Lantern anticipates that the amended design, coupled with continued integration of AI-driven insights from its RADR® platform, will support more informed discussions with regulators and prospective collaborators regarding potential registration-oriented strategies for LP-300.

Differentiated Safety Profile vs. Currently Approved Post-TKI Combinations

A central commercial rationale for the focused HARMONIC™ design is the differentiated safety profile of LP-300 plus chemotherapy relative to currently approved post-TKI regimens. In the recently published Phase 3 MARIPOSA-2 trial, amivantamab plus chemotherapy — now FDA-approved for EGFR-mutant NSCLC following progression on osimertinib — was associated with substantial rates of treatment-related serious adverse events, infusion reactions, and dermatologic toxicities that complicate real-world administration. Preliminary HARMONIC™ data (Data Cutoff: April 13, 2026; n=31 receiving LP-300 + chemotherapy) suggest a materially more manageable safety profile when LP-300 is added to a carboplatin/pemetrexed backbone:

The table below summarizes observations regarding Treatment-Related Adverse Events (TRAE) and Treatment-

Emergent Adverse Events (TEAE). A Treatment-Emergent Adverse Event in clinical trials is an unfavorable medical occurrence that starts or worsens in intensity or frequency **after** the first dose of study treatment.

Adverse Event (any grade unless noted)	LP-300 + Chemo (N=31)	Amivantamab + Chemo (N=130) ¹
Treatment-related serious adverse event	3%	23%
TEAE leading to dose delay (any study drug)	19%	65%
TEAE leading to drug discontinuation	6%	18%
Infusion-related reaction (TRAE)	7%	58%
Rash (TRAE)	7%	43%
Paronychia (TRAE)	0%	36%
Stomatitis (TRAE)	0%	31%

¹ Cross-trial comparison; not a head-to-head study. Amivantamab + chemotherapy data from Passaro A, et al. *Annals of Oncology* 2024;35(1):77-90 (MARIPOSA-2). LP-300 + chemotherapy data are preliminary, HARMONIC™ trial Data Cutoff: April 13, 2026.

The cleaner tolerability profile is particularly relevant in the post-TKI L858R setting, where patients have already been heavily pretreated and where treatment-emergent toxicities can drive dose interruptions, premature discontinuation, and erosion of efficacy in clinical practice. Lantern believes this safety differentiation, together with the emerging efficacy signal in the L858R subgroup, positions LP-300 as a potential future best-in-tolerability option in a treatment setting that currently demands meaningful infrastructure and supportive-care resources.

Ongoing Trial Progress and Emerging Clinical Data

The HARMONIC™ trial is currently enrolling patients at clinical sites in the United States and Taiwan, following the completion of targeted enrollment in Japan in July 2025 across five clinical centers, including the National Cancer Center Tokyo. Taiwan represents a particularly important region for HARMONIC™, as more than half of lung cancer cases there occur in never-smokers, underscoring the global relevance of LP-300 for this patient population.

The trial has already generated encouraging early clinical data: in its initial safety lead-in cohort in the United States, LP-300 in combination with carboplatin and pemetrexed demonstrated an 86% clinical benefit rate and a 43% objective response rate among the first seven patients enrolled, including one patient who achieved a durable complete response in target lesions that has now been sustained for more than two years. Additional emerging data presented in April 2026 showed a median progression-free survival of 8.3 months in EGFR exon 21 L858R-mutant patients treated with the LP-300 triplet after TKI failure, with no new safety signals and no clinically meaningful toxicity added beyond that of carboplatin and pemetrexed alone.

KOL Webinar: Never-Smoker Lung Cancer – May 21, 2026

Rodman & Renshaw is hosting a fireside chat with Joseph Treat, M.D., on Thursday, May 21, 2026, from 3:00 to 4:00 PM ET, moderated by Michael G. King, Jr., Senior Biotechnology Analyst at Rodman & Renshaw. Dr. Treat is Professor Emeritus in the Division of Medical Oncology at Fox Chase Cancer Center and has focused his clinical research exclusively on lung cancer since 1991, when he founded the first medical oncology thoracic program at the University of Pennsylvania Cancer Center. His prior work as a Senior Fellow at Eli Lilly on a Phase III anti-VEGF trial in EGFR-mutated lung cancer led to regulatory approvals by the FDA, EMA, and Japanese authorities, and his current research focuses on lung cancer in individuals who have never smoked. The discussion will address the evolving treatment landscape in lung cancer, the unmet need in never-smoker populations, and what durable disease control could mean for real-world patient outcomes.

To register, please [click here](#).

Lantern is actively exploring collaboration and partnering opportunities, both globally and regionally, to maximize the commercial potential of LP-300 across multiple geographies where never-smoker NSCLC is an increasingly recognized clinical challenge. The Company expects to provide additional clinical data updates from the HARMONIC™ trial, including outcomes in the enriched EGFR exon 21 L858R cohort under the amended protocol, in the second half of 2026.

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. Following a successful Type C meeting request outcome, HARMONIC™ is transitioning to a single-arm design that will enrich enrollment for patients with EGFR exon 21 L858R mutations and extend LP-300 dosing to a maximum of eight cycles. The trial is enrolling patients at clinical sites in the United States and Taiwan, with completed targeted enrollment in Japan. The HARMONIC™ trial is registered on [ClinicalTrials.gov](https://clinicaltrials.gov) under identifier NCT05456256. LP-300 has not received FDA marketing approval for any indication.

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; the planned implementation of protocol amendments and transitioning of the study design for the HARMONIC™ clinical trial; the planned development pathway for LP-300 in patients harboring the EGFR exon 21 L858R mutation; LP-300's potential clinical activity and tolerability profile; our clinical development plans; expectations and estimates regarding clinical trial timing and patient enrollment; 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 the planned development of LP-300 for treatment of patients harboring the EGFR exon 21 L858R mutation may not be successful, (iv) 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, (v) the risk that clinical data referenced in this press release are exploratory and preliminary, based on small patient cohorts, and may not be representative of outcomes in broader populations, (vi) the risk that cross-trial comparisons are provided for context only and should not be interpreted as direct evidence of comparative safety or efficacy, (vii) the risk that our research and the research of our collaborators may not be successful, (viii) the risk that we may not be successful in licensing our product candidates or in completing potential partnerships and collaborations, (ix) 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, and (x) 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.

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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