



NEWS RELEASE

Lantern Pharma Completes Targeted Enrollment for Lung Cancer Phase 2 Harmonic™ Clinical Trial in Japan for LP-300

2025-07-31

- Japanese patient cohort enrollment is completed ahead of schedule at multiple clinical sites including the National Cancer Center in Tokyo
- The incidence rate of never-smokers with non-small cell lung cancer (NSCLC) in Japan is 35 to 40%, double that of the rates in US and European populations
- The treatment of never-smoker with NSCLC represents a market opportunity estimated at over \$4 billion annually
- There are no approved therapies specifically targeted at the treatment of never-smokers with NSCLC
- Additional clinical data and updates from the US and Asian patient cohorts is expected by the end of the third quarter of 2025

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), an artificial intelligence (AI) company developing targeted cancer therapies using its proprietary RADR® AI platform, today announced the successful completion of targeted enrollment for its Phase 2 HARMONIC™ clinical trial in Japan. The company enrolled 10 patients ahead of schedule across five clinical sites in Japan, including the National Cancer Center Japan.

The HARMONIC™ trial is evaluating LP-300 in combination with carboplatin and pemetrexed in never-smoker patients with non-small cell lung cancer (NSCLC) who have progressed after receiving treatment with tyrosine kinase inhibitors (TKIs). The successful Japanese enrollment validates Lantern's strategic decision to expand the trial

internationally to regions with significantly higher rates of never-smoker NSCLC patients such as Japan and Taiwan.

"Completing our targeted enrollment in Japan ahead of schedule demonstrates excellent execution of our international expansion strategy and validates our decision to focus on regions where never-smoker NSCLC has the highest prevalence," said Panna Sharma, President and CEO of Lantern Pharma. "This achievement builds momentum as we continue enrollment in Taiwan and the United States, bringing us closer to generating the clinical data that could establish LP-300 as a treatment option for this underserved patient population with significant unmet medical need."

The completion of Japanese enrollment represents an important milestone in the global HARMONIC™ trial, which is designed to enroll approximately 90 patients across multiple regions. Japan's notably higher rate of never-smoker NSCLC patients (33-40% of new cases) compared to Western populations (typically 15%) makes it a strategically important region for the trial. Similarly, Taiwan, where more than 50% of lung cancer cases occur in never-smokers, represents another key enrollment region.

The HARMONIC™ trial previously demonstrated encouraging results in its initial safety lead-in cohort, showing an 86% clinical benefit rate and 43% objective response rate among the first seven patients enrolled in the United States. Notably, **recent data revealed that one patient has achieved a durable complete response** in target cancer lesions with survival continuing for nearly two years, demonstrating the potential for LP-300 to deliver meaningful long-term outcomes for never-smoker NSCLC patients.

Never-smoker NSCLC is increasingly recognized as a distinct disease entity with unique clinical and genomic characteristics¹, representing a global market opportunity estimated at over \$4 billion annually. Currently, there are no therapies specifically approved for never-smoker NSCLC patients, highlighting the significant unmet medical need this population faces.

Lantern is actively exploring collaboration and partnering opportunities to maximize LP-300's commercial potential in multiple geographies. Lantern is scheduled to provide further clinical and outcome data from the HARMONIC™ trial later this quarter, with updates covering both Asian and U.S. patient cohorts.

About LP-300 LP-300 is a disulfide small molecule and investigational drug candidate with a multimodal mechanism of action directed toward tyrosine kinase receptors and cell redox enzymes. It modulates cellular redox in key signaling pathways in NSCLC and directly engages with TKI receptors via cysteine modification. LP-300 has been evaluated in multiple Phase 1, 2, and 3 clinical trials in over 1,000 subjects, with retrospective analysis showing significant survival benefit in never-smoker lung adenocarcinoma patients.

About the HARMONIC™ Trial The HARMONIC™ trial is a multicenter, open-label, randomized Phase 2 trial designed

to evaluate the efficacy and safety of LP-300 in combination with standard-of-care chemotherapy (pemetrexed/carboplatin) versus chemotherapy alone in never-smoker NSCLC patients who have relapsed following TKI treatment. The trial is expected to enroll approximately 90 patients across sites in the United States, Japan, and Taiwan. The primary endpoints are progression-free survival (PFS) and overall survival (OS). For more information about the trial, visit www.harmonictrial.com or clinicaltrials.gov (NCT05456256).

About Lantern Pharma: Lantern Pharma (NASDAQ: LTRN) is an AI company transforming the cost, pace, and timeline of oncology drug discovery and development. Our proprietary AI and machine learning (ML) platform, RADR®, leverages over 100 billion oncology-focused data points and a library of 200+ advanced ML algorithms to help solve billion-dollar, real-world problems in oncology drug development. By harnessing the power of AI and with input from world-class scientific advisors and collaborators, we have accelerated the development of our growing pipeline of therapies that span multiple cancer indications, including both solid tumors and blood cancers and an antibody-drug conjugate (ADC) program. Our lead development programs include a Phase 2 clinical program and multiple Phase 1 clinical trials. Our AI-driven pipeline of innovative product candidates is estimated to have a combined annual market potential of over \$15 billion USD and have the potential to provide life-changing therapies to hundreds of thousands of cancer patients across the world.

Please find more information at:

- Website: www.lanternpharma.com
- Harmonic Trial: www.harmonictrial.com
- LinkedIn: <https://www.linkedin.com/company/lanternpharma/>
- X: @lanternpharma

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 potential advantages of our RADR® platform in identifying drug candidates and patient populations that are likely to respond to a drug candidate; our strategic plans to advance the development of our drug candidates and antibody drug conjugate (ADC) development program; estimates regarding the development timing for our drug candidates and ADC development program; expectations and estimates regarding clinical trial timing and patient enrollment; our research and development efforts of our internal drug discovery programs and the utilization of our RADR® platform to streamline the drug development process; our intention to leverage artificial intelligence, machine learning and genomic data to streamline and transform the pace, risk and cost of oncology drug discovery and development and to identify patient populations that would likely respond to a drug candidate; estimates

regarding patient populations, potential markets and potential market sizes; sales estimates for our drug candidates 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 early or preliminary observations in clinical studies do not ensure that later observations, studies and development will be consistent or successful, (iii) the risk that our research and the research of our collaborators may not be successful, (iv) the risk that we may not be successful in licensing potential candidates or in completing potential partnerships and collaborations, (v) 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, (vi) the risk that no drug product based on our proprietary RADR® AI platform has received FDA marketing approval or otherwise been incorporated into a commercial product, and (vii) those other factors set forth in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission on March 27, 2025. You may access our Annual Report on Form 10-K for the year ended December 31, 2024, under the investor SEC filings tab of our website at www.lanternpharma.com (<http://www.lanternpharma.com/>) or on the SEC's website at www.sec.gov (<http://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.

¹ Saito M, Shiraishi K, Matsumoto K, Schetter AJ, Ogata-Kawata H, Tsuchiya N, Kunitoh H, Nokihara H, Watanabe SI, Kamma H, Asamura H, Yamamoto S, Tan EM, Wang JY, Harris CC, Yokota J, Kohno T, Goto A. Lung cancer in patients who have never smoked — an emerging disease. PMC. 2024. <https://pmc.ncbi.nlm.nih.gov/articles/PMC11014425/>

Investor Contact

Investor Relations

ir@lanternpharma.com

+1-972-277-1136

Source: Lantern Pharma Inc.