



NEWS RELEASE

Lantern Pharma Receives FDA Authorization to Initiate its Phase 2 Clinical Trial, Harmonic™, for LP-300 in Never Smokers with Non-Small Cell Lung Cancer

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- The Harmonic™ trial is a Phase 2 multi-center study focused on never smokers with advanced non-small cell lung cancer (NSCLC) and will begin patient enrollment during Q3 2022.
- In a previous Phase 3 multi-center clinical trial, a subset of never smoker patients with NSCLC receiving LP-300 with chemotherapy showed increased overall and two-year survival of 91% and 125%, respectively, compared to patients who received chemotherapy alone.
- In the US in 2021 there were an estimated 24,000 to 30,000 never smoker patients diagnosed with NSCLC.

DALLAS--(BUSINESS WIRE)-- **Lantern Pharma Inc. (NASDAQ: LTRN)**, a clinical stage biopharmaceutical company using its proprietary RADR® artificial intelligence ("A.I.") and machine learning ("ML") platform to transform the cost, pace, and timeline of oncology drug discovery and development, today announced that the Food and Drug Administration (FDA) has cleared the Company to proceed with its Phase 2 clinical trial, Harmonic™, for its investigational new drug LP-300. The Harmonic™ trial will be a 90 patient, multi-center, two arm, open-label, and randomized clinical trial evaluating LP-300 in combination with chemotherapy for never smoker patients with advanced non-small cell lung cancer (NSCLC).

"The launch of the Harmonic™ trial is a major milestone for LP-300. Our team is looking forward to beginning

patient enrollment during the third quarter,” said Panna Sharma, CEO and President of Lantern. “LP-300 is an innovative therapy that is being developed for never smokers with NSCLC, a unique and growing population of lung cancer patients whose cancer is genetically different from smokers with lung cancer. LP-300 will be delivered in combination with standard of care chemotherapy. Importantly, LP-300 has been well tolerated in prior clinical trials and has shown potential to protect against harmful effects of chemotherapy while also de-naturing many of the tyrosine kinase receptors through cysteine modification that are involved with NSCLC,” continued Sharma.

About the Harmonic™ Trial and LP-300:

The Harmonic™ trial is a Phase 2 clinical trial that will assess the effect of Lantern’s investigational new drug LP-300 in combination with standard of care (SOC) chemotherapy, pemetrexed and carboplatin, on the overall and progression-free survival of never smoker patients with advanced NSCLC. The study has been designed as a 90 patient trial with approximately 2/3rds of the patients receiving LP-300 with chemotherapy and the remaining 1/3rd receiving chemotherapy alone. Lantern expects that initial patients will be enrolled into the Harmonic™ trial during the third quarter of 2022. Enrollment is expected to occur over the next 12 to 16 months across multiple sites in the US.

In a previous multi-center Phase 3 clinical trial, a subset of never smoker NSCLC patients who received LP-300 with chemotherapy showed increased overall and two-year survival of 91% and 125%, respectively, compared to patients who only received chemotherapy. In addition, LP-300 has been administered in multiple clinical trials to more than 1,000 people and has been generally well tolerated. LP-300 has also exhibited chemoprotective properties that may reduce side effects from chemotherapy. Additional information on the Harmonic™ trial can be found in the table below and at the link for the study’s registration and listing on the ClinicalTrials.gov website <https://clinicaltrials.gov/ct2/show/NCT05456256>.

Protocol Title	A study of LP-300 with carboplatin and pemetrexed in never smokers with advanced lung adenocarcinoma (HARMONIC™)
Study Design	90 patient, two arm study; approximately 60 patients will receive LP-300 with pemetrexed and carboplatin, approximately 30 patients will receive only pemetrexed and carboplatin.
Investigational Product	LP-300 in combination with pemetrexed and carboplatin
Summary of Key Eligibility Criteria	Adult never smoker patients with inoperable and advanced primary adenocarcinoma of the lung. Patients may have received prior treatment of tyrosine kinase inhibitors (TKIs).
Primary Outcome Measures	Progression free and overall survival

Secondary Outcome Measures Objective response rate, duration of objective response, clinical benefit rate

About Lung Cancer in Never Smokers:

According to the American Cancer Society lung cancer is the second leading cause of cancer in the US. In 2021 there were an estimated 218,000 total patients diagnosed with lung cancer representing approximately a \$11.5 billion market size. Historically, never smokers with NSCLC make up about 15-20% of all lung cancer patients, representing an approximate market size of \$1.5 to 2.0 billion.

NSCLC presents differently in never smokers, which are defined by the CDC as a person who has smoked 100 cigarettes or less in their life, compared to smokers. These differences are believed due to a higher percentage of genetic mutations in a family of cancer-promoting genes called Tyrosine Kinases (TK). Changes in TK genes, such as EGFR, ALK, ROS and MET, can contribute to the development of healthy cells into cancer cells, leading to tumor formation and growth. LP-300's intended mechanism is to work together with chemotherapy by strongly interacting in the TK gene pathways, interrupting their activity to slow or prevent tumor growth and spread.

About Lantern Pharma:

Lantern Pharma (NASDAQ: LTRN) is a clinical-stage oncology-focused biopharmaceutical company leveraging its proprietary RADR[®] A.I. and machine learning platform to discover biomarker signatures that identify patients most likely to respond to its pipeline of genomically targeted therapeutics. Lantern is currently developing four drug candidates and an ADC program across nine disclosed tumor targets, including two phase 2 programs. By targeting drugs to patients whose genomic profile identifies them as having the highest probability of benefiting from the drug, Lantern's drug development approach represents the potential to deliver best-in-class outcomes. Lantern is also partnering with leading academic institutions including Johns Hopkins, Fox Chase Cancer Center, and UT Health Science Center – San Antonio to accelerate the development of Lantern's drug programs.

Please find more information at:

Website: www.lanternpharma.com

LinkedIn: <https://www.linkedin.com/company/lanternpharma/>

Twitter: [@lanternpharma](https://twitter.com/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," "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 impact of the COVID-19 pandemic, (ii) the risk that our research and the research of our collaborators may not be successful, (iii) 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, (iv) the risk that no drug product based on our proprietary RADR[®] A.I. platform has received FDA marketing approval or otherwise been incorporated into a commercial product, and (v) those other factors set forth in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 10, 2022. You may access our Annual Report on Form 10-K for the year ended December 31, 2021 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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