

#### **NEWS RELEASE**

# Lantern Pharma Announces Completion of Type C Meeting with FDA, Providing Clarity on Regulatory Pathway for Pediatric CNS Cancer Trial

#### 2025-09-03

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), an Al-driven clinical -stage oncology company developing targeted therapies for cancer that are being advanced using its proprietary computational biology and machine learning platform, today announced the successful completion of a Type C meeting with the U.S. Food and Drug Administration (FDA). The meeting provided critical guidance on the regulatory pathway and trial design for a planned pediatric trial focused on CNS cancers, including Atypical Teratoid Rhabdoid Tumor (ATRT).

During the Type C meeting, the FDA provided constructive feedback on the proposed clinical trial structure, which includes a parallel cohort specifically for ATRT patients to accelerate data collection in this ultra-rare population. Additionally, the agency confirmed the potential incorporation of spironolactone as a combination agent, to allow for the assessment of spironolactone's synergistic effects with Lantern's lead investigational therapy, LP-184/STAR-001 in enhancing the potential efficacy in CNS cancers. This feedback aligns with Lantern's strategy to advance precision oncology solutions for pediatric patients facing limited treatment options. Lantern is now preparing to submit an IND (investigational new drug) application amendment for LP-184/STAR-001 under its wholly owned subsidiary, Starlight Therapeutics, based on the guidance and dialogue from the Type C meeting.

Lantern's program for ATRT has received Rare Pediatric Disease Designation and Orphan Drug Designation from the FDA, underscoring the urgent unmet need for innovative therapies in these aggressive childhood brain cancers.

The planned trial is expected to enroll pediatric patients across multiple sites, with primary endpoints focused on progression-free survival, overall response rate, and quality-of-life measures.

"We are thrilled with the constructive dialogue and positive feedback from our Type C meeting with the FDA," said Panna Sharma, President and CEO of Lantern Pharma. "This guidance not only reinforces our trial design but also highlights the potential of our AI platform, RADR®, in identifying and optimizing combination regimens like spironolactone for these devastating pediatric CNS cancers. We remain committed to rapidly advancing this program with the aim of bringing hope to children and families affected by brain cancer."

Lantern Pharma continues to leverage its proprietary RADR® Al platform to accelerate drug development, reduce costs, and identify patient responders across oncology indications. The company plans to submit an Investigational New Drug (IND) application amendment incorporating the FDA's guidance in the coming months, with planned trial initiation targeted for Q1 2026.

#### 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 200 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

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® or predictBBB.ai 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® or predictBBB.ai platforms 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<sup>®</sup> Al or predictBBB.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.

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