



NEWS RELEASE

# Lantern Pharma Receives FDA Clearance of IND Application for Drug Candidate LP-184 in Solid Tumors

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- LP-184 is a novel, synthetically-lethal, small molecule that has been developed using insights from Lantern's AI platform, RADR®.
- The first-in-human Phase 1A clinical trial has been cleared to proceed by the FDA and is anticipated to launch this summer for multiple advanced solid tumors and brain and central nervous system (CNS) cancers.
- Lantern has been granted multiple Orphan Drug Designations by the FDA for LP-184 in pancreatic cancer, malignant gliomas, and atypical teratoid rhabdoid tumors (ATRT); in addition the FDA granted Rare Pediatric Disease Designation granted for LP-184 in ATRT.
- The cancer indications being pursued for LP-184 are estimated to have an annual market potential of \$11-13 billion; \$6-7 billion for solid tumors and \$5-6 billion for brain and CNS cancers.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), an artificial intelligence ("AI") company developing targeted and transformative cancer therapies using its proprietary RADR® AI and machine learning ("ML") platform with multiple clinical stage drug programs, today announced that the U.S. Food and Drug Administration (FDA) has cleared the investigational new drug (IND) application for LP-184, which is being developed for multiple advanced solid tumors and central nervous system (CNS) cancers. The first-in-human Phase 1A trial for LP-184 is anticipated to launch and dose its first patient during the current quarter.

"The clearance of the IND application is a significant milestone for our LP-184 program and validates our approach

of leveraging AI and machine learning to advance our pipeline of novel drug candidates,” stated Panna Sharma, Lantern’s CEO and President. “Insights from our AI platform RADR® were instrumental in our development of LP-184 and aided in discovering its mechanism of action, identifying and prioritizing its cancer indications, and generating machine learning biomarker signatures to assist with future clinical trial patient selection. We believe LP-184 has blockbuster potential for patients with multiple types of advanced solid tumors and CNS cancers, many of which have no or limited effective therapeutic options,” continued Sharma.

LP-184 is the first of Lantern’s drug candidates to be developed entirely internally, with the assistance of Lantern’s AI and ML platform RADR®, to advance to a first-in-human Phase 1A trial. The Phase 1A trial will assess the safety and tolerability of escalating doses of LP-184 to determine the maximum tolerated dose (MTD) in patients with advanced pancreatic cancer, recurrent high-grade gliomas/glioblastoma (GBM), metastatic brain and CNS cancers, and other solid tumors with DNA damage response (DDR) deficiencies. Lantern anticipates the Phase 1A trial to be completed by the first half of 2024.

After the Phase 1A trial is completed, Lantern will advance LP-184 into additional clinical trials for multiple solid tumor indications, and Lantern’s subsidiary, **Starlight Therapeutics**, will advance the clinical development of LP-184 for all brain and CNS indications under the name STAR-001. Globally, the aggregate annual market potential of LP-184/STAR-001’s programs is estimated to be approximately \$11-13 billion, consisting of \$6-7 billion for solid tumors and \$5-6 billion for CNS cancers.

### About LP-184:

LP-184 is a unique small molecule that utilizes its powerful mechanism of action known as synthetic lethality to exploit common vulnerabilities in solid tumor and CNS cancers with DNA damage repair (DDR) deficiencies. The anti-tumor potential of LP-184 has been demonstrated across an extensive number of in-vitro and in-vivo cancer models, including pancreatic, bladder, triple-negative breast cancer (TNBC), glioblastoma (GBM), brain metastases, and ATRT. In addition to LP-184’s promise as a single agent, its antitumor potency has the potential to be enhanced when used in combination with existing FDA-approved agents and other treatment modalities including spironolactone, PARP inhibitors, and radiation therapy. Results validating LP-184’s anti-tumor potential have been published at leading conferences and journals including, the American Association for Cancer Research annual meeting, the Society for Neuro-Oncology annual meeting, the San Antonio Breast Cancer Symposium, and the *Frontiers in Drug Discovery Journal*.

### About Lantern Pharma:

Lantern Pharma 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 25 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 including eleven cancer indications and an antibody-drug conjugate (ADC) program. On average, our newly developed drug programs have been advanced from initial AI insights to first-in-human clinical trials in 2-3 years and at approximately \$1.0-2.0 million per program.

Our lead development programs include two Phase 2 clinical programs and multiple upcoming Phase 1 clinical trials anticipated for 2023. We have also established a wholly-owned subsidiary, Starlight Therapeutics Inc., to focus exclusively on the clinical execution of our promising therapies for CNS and brain cancers, many of which have no effective treatment options. 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](http://www.lanternpharma.com)

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

Twitter: [@lanternpharma](https://twitter.com/lanternpharma)

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## 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<sup>®</sup> 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 drug discovery and ADC programs and the utilization of our RADR<sup>®</sup> 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 or ADC candidate; estimates regarding patient populations, potential markets and potential market sizes; sales estimates for our drug and ADC candidates and our plans to discover and develop drug and ADC candidates and to maximize their commercial potential by advancing such 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 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<sup>®</sup> AI 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, 2022, filed with the Securities and Exchange Commission on March 20, 2023. You may access our Annual Report on Form 10-K for the year ended December 31, 2022 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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