October 15, 2024

Lantern Pharma's Investigational Drug-Candidate, LP-184, Receives Fast-Track Designation in Glioblastoma from the FDA

- Fast Track Designation is designed to expedite FDA review of important new drugs to treat serious conditions and fill an unmet medical need.
- Fast Track Designation for LP-184 (STAR-001) recognizes Glioblastoma (GBM) as a serious condition impacting more than 13,000 U.S. adults each year and approximately 300,000 globally.
- A phase 1b/2a clinical trial for recurrent GBM is targeted to start in late 2024/early 2025.
- LP-184, which will be developed as STAR-001 for CNS and other neuro-oncology indications by Starlight Therapeutics, a wholly owned subsidiary of Lantern Pharma, has the potential to be the first new drug for treating GBM in more than 20 years.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), an artificial intelligence (AI) company dedicated to developing cancer therapies and transforming the cost, pace, and timeline of oncology drug discovery and development, today announced that the FDA has granted Fast Track Designation for investigational drug candidate, LP-184, for treatment of Glioblastoma. LP-184 is currently in a Phase 1A clinical trial designed to evaluate the safety and tolerability of the synthetically lethal investigational drug candidate in a broad range of solid tumors, including Glioblastoma (GBM). LP-184 was optimized and advanced in part with Lantern's AI platform, RADR®, to aid in the validation of mechanisms that could be exploited in the clinical setting to eradicate challenging cancers, and uncover insights in targeted patient populations. RADR® is Lantern's AI platform for cancer therapy discovery, development and rescue with over 100 billion data points and aiding in the development of both Lantern's portfolio and development initiatives with Lantern's collaborators.

About GBM and the need for improved and novel therapies.

Glioblastoma (GBM) affects nearly 13,000 patients annually in the US and approximately 300,000 globally, with a mortality rate of 94%. Current standard of care therapies result in a life expectancy in GBM patients of less than 15 months. A major limitation to development of new drugs in the treatment of GBM is the need for potential drugs to have the ability to cross the blood brain barrier (BBB) as well as the ability to counteract the inherent and adaptive resistance of GBM cancer cells to temozolomide, the current standard of care in GBM. This resistance is largely derived from the expression of the DNA repair enzyme MGMT[1]. LP-184 activity is agnostic to MGMT expression, meaning it does not depend on the under or over-expression of MGMT in GBM and has shown in-vivo, preclinical activity in both types of GBM models.

No new drugs for GBM have been approved in over two decades. Lantern Pharma is

advancing LP-184, a molecule which demonstrates synthetic lethality when combined with agents that cause DNA damage repair deficiency.[2] Additionally, LP-184 has shown that it causes double-stranded breaks in the DNA of recurrent GBM (rGBM) cancer cells in multiple in-vivo models and is currently being advanced in early clinical stage studies.

“Receiving FDA Fast Track Designation for Lantern Pharma’s LP-184 in GBM reinforces our belief that this drug-candidate can help in the critical need to find effective treatment options for patients with GBM and further supports the potential of LP-184 to address the challenges in aggressive CNS cancers, where patients have a critical need for novel and life extending therapies” said Panna Sharma, President and CEO of Lantern Pharma.

Current status of LP-184 & STAR-001 in clinical trials & development

LP-184 is currently being studied in a phase 1A clinical trial to evaluate the safety, tolerability and maximum tolerated dose (MTD) of the potential therapy in a wide range of tumors, including GBM. The full study design can be viewed here (clinicaltrials.gov). Once the MTD has been established, Lantern has plans to advance the drug-candidate LP-184 as STAR-001 through its wholly owned subsidiary, Starlight Therapeutics, in GBM and other CNS and brain cancers.

Lantern also anticipates further using RADR® to determine potential additional suitability for LP-184 in combination with other approved agents for the control of cancer progression in multiple other patient subgroups. Lantern has provided information on the development of LP-184 in GBM and has also discussed its plan to advance STAR-001 (LP-184 for CNS cancers) in multiple publicly available webinars, including on:

- June 26, 2024 — *STAR-001 in Multiple Brain and CNS Cancers* with Dr. Marc Chamberlain, and
- July 31, 2024 — *Born from AI, Lighting The Way in CNS Cancer Treatment* with Mr. Panna Sharma.

The proposed goals for the development of Phase 1b/2a clinical studies are targeting a rGBM specific trial to begin in late 2024 or early 2025. This trial is being planned to assess LP-184 in a Phase 1b/2a study as mono-therapy and in combination with spironolactone in rGBM to assess safety, pharmacokinetics and preliminary efficacy. Concurrently, Lantern will conduct a retrospective correlative analysis of multiple key markers of DNA damage as exploratory endpoints. EGFR expression or mutation status, MGMT status and expression of DNA damage repair pathway are also planned to be studied as potential response predictors to help inform and guide future late-stage trials and to stratify enrollment.

About the FDA Fast Track process

The FDA’s Fast Track process is designed to facilitate development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs to potentially bring important new medicines to patients sooner. Companies whose programs are granted Fast Track Designation are eligible for more frequent interactions with the FDA during clinical development. For more information on Fast Track designation, please visit the FDA’s website at www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

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. 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 - 2.5 million per program.

Our lead development programs include a Phase 2 clinical program and multiple Phase 1 clinical trials. We have also established a wholly-owned subsidiary, Starlight Therapeutics, 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
- 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 our research and the research of our collaborators may not be successful, (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 we may not be successful in licensing potential candidates or in completing potential partnerships and collaborations, (iv) 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, (v) 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 (vi) those other factors set forth in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission on March 18, 2024. You may access our Annual Report on Form 10-K for the year ended December 31, 2023 under the investor SEC filings tab of our website at www.lanternpharma.com or on the SEC's website atwww.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] In patients with glioblastoma (GBM) an aggressive and severe type of brain tumor, the cancer medicine temozolomide is more effective in those with amethylation of the gene's promoter. Overall, MGMT methylation or hyper-methylation is associated with prolonged patient survival in clinical prediction models, while under-methylation or no-methylation can be derived as a result of exposure to temozolomide and cause resistance to temozolomide therapy and therefore no benefit from the use of temozolomide in GBM.

[2] Bachchu Lal, Aditya Kulkarni, Joseph McDermott, Rana Rais, Jesse Alt, Ying Wu, Hernando Lopez-Bertoni, Sophie Sall, Umesh Kathad, Jianli Zhou, Barbara S. Slusher, Kishor Bhatia, John Laterra; Preclinical Efficacy of LP-184, a Tumor Site Activated Synthetic Lethal Therapeutic, in Glioblastoma. Clin Cancer Res 15 October 2023; 29 (20): 4209 4218. https://doi.org/10.1158/1078-0432.CCR-23-0673

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