



NEWS RELEASE

Lantern Pharma's Subsidiary, Starlight Therapeutics, Announces U.S. Food and Drug Administration Clearance of IND for Phase Ib/2a Glioblastoma Multiforme (GBM) Trial

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- Novel combination therapy with STAR-001 targets the most aggressive and deadliest forms of brain cancer at first progression
- GBM represents an annual market opportunity of \$3 to \$5 billion USD with an accelerating number of cases globally
- Lantern Pharma has previously received both FDA Orphan and Fast Track Designations in GBM

DALLAS--(BUSINESS WIRE)-- **Starlight Therapeutics**, a wholly owned subsidiary of Lantern Pharma Inc. (NASDAQ: LTRN), today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for a Phase Ib/2a clinical trial to evaluate STAR-001 (LP-184) in combination with spironolactone for patients with glioblastoma multiforme (GBM) at first progression.

The planned Phase Ib/2a clinical trial (IND 178511) is designed to investigate the safety, tolerability, and preliminary efficacy of STAR-001 in combination with spironolactone in patients with recurrent GBM, one of the deadliest and most aggressive forms of brain cancer. GBM represents approximately 15% of all brain tumors and has a median survival of approximately 12 months from initial diagnosis, with fewer than 5% of patients surviving beyond five years.

"This FDA clearance represents a significant milestone for Starlight Therapeutics and our mission to bring innovative treatment options to patients facing the most challenging forms of brain and CNS cancers," said **Dr. Marc Chamberlain**, Chief Medical Officer of Starlight Therapeutics. "GBM remains one of the most difficult cancers to treat, with virtually no meaningful therapeutic advances in nearly 17 years. We believe our unique combination approach has the potential to offer new hope for patients and their families while advancing a novel mechanism to challenge these recurrent brain cancers."

Targeting GBM Through Innovative Synthetic Lethality

STAR-001 (also referred to as LP-184 when focused on other solid tumor indications) is a synthetically lethal, brain-penetrant, novel DNA-damaging agent that has demonstrated promising preclinical activity against various solid tumors, including pediatric and adult brain cancers. Lantern Pharma has previously been awarded both FDA Orphan Drug Designation and FDA Fast Track Designation for STAR-001 in GBM, underscoring the significant unmet medical need and the drug's potential to address it. An existing Phase 1a trial to determine safety, dosing, the maximum tolerated dose (MTD) and tolerability across a range of solid tumors, including GBM, is currently underway and expected to complete enrollment in the current quarter. This trial is expected to help establish a baseline dosing level and expectations of drug-concentration in tumor and plasma for future clinical trials, including those being planned by Starlight Therapeutics.

The combination of STAR-001 with **spironolactone**, an existing FDA approved drug, represents a scientifically rational approach to treating GBM. STAR-001 is a blood-brain barrier permeable small molecule that leverages synthetic lethality to exploit DNA damage repair (DDR) deficiencies, particularly those overexpressing PTGR1. Approximately 60% of **GBM cells overexpress PTGR1** levels sufficient to activate STAR-001. Spironolactone significantly enhances this therapeutic effect by inducing degradation of ERCC3, a critical protein involved in nucleotide excision repair (NER). This mechanism leads to NER deficiency (NERD), making GBM cells significantly more sensitive to STAR-001 and less capable of repairing the DNA damage caused by the administration of STAR-001. This synergistic approach is particularly promising in GBM which has often become resistant to therapies in the recurrent setting.

AI-Driven Drug Development Platform

Starlight Therapeutics was formed to pursue the focused clinical development of central nervous system (CNS) oncology indications developed and advanced through Lantern Pharma's proprietary artificial intelligence drug development platform, RADR®. This AI-driven approach enables the identification of optimal drug-cancer combinations and patient populations most likely to benefit from treatment, significantly reducing the time and cost typically associated with traditional drug development.

"The clearance of this IND demonstrates the power of our efficient, data-driven drug development model in identifying promising therapeutic opportunities in areas of high unmet medical need," said Panna Sharma, President and CEO of Lantern Pharma. "Through Starlight Therapeutics, we are positioned to dedicate focused resources and expertise to advancing treatments for some of the most challenging cancers affecting the brain and central nervous system in both adults and children, while developing meaningful therapies that can reach patients in an accelerated timeline compared to traditional drug development processes."

Market Opportunity and Next Steps

With GBM representing an annual market opportunity of \$3 to \$5 billion globally and case numbers accelerating worldwide, there is an urgent need for innovative treatment approaches. The current standard of care has remained largely unchanged for over 15 years, highlighting the critical importance of novel therapeutic strategies like the STAR-001 combination.

Starlight is targeting commencement of the Phase Ib/2a trial in late 2025 or early 2026, subject to additional funding, and plans to provide regular updates on trial preparation, patient enrollment progress, and preliminary data as they become available.

About Glioblastoma Multiforme (GBM)

Glioblastoma multiforme is the most common and aggressive form of primary brain tumor in adults, accounting for approximately 15% of all brain tumors. Despite aggressive multimodal treatment including surgery, radiation, and chemotherapy, the prognosis remains extremely poor, with a median survival of only 12 months and a five-year survival rate of less than 5%. The **blood-brain barrier presents a significant challenge** in treating GBM, as most therapeutic agents cannot effectively penetrate brain tissue.

About Starlight Therapeutics

Starlight Therapeutics is a wholly owned subsidiary of Lantern Pharma Corp., specifically focused on the clinical development of innovative treatments for central nervous system oncology indications. The company leverages Lantern Pharma's proprietary AI drug development platform to identify and advance promising therapeutic combinations for adult and pediatric patients with brain and CNS cancers.

About Lantern Pharma

Lantern Pharma (NASDAQ: LTRN) is an AI company transforming the cost, time, and failure rate of oncology drug discovery and development. Lantern's proprietary AI platform RADR® uses machine learning and multiomic data to

solve complex, billion-dollar drug development challenges. By harnessing the power of AI and with input from world-class scientific advisors and collaborators, Lantern has built a pipeline of promising, clinical stage drug candidates, including molecules that target novel cancer mechanisms and targets.

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; estimates and plans regarding our subsidiary Starlight Therapeutics Inc. and the product candidate STAR-001; our strategic plans to advance the development of our drug candidates, including STAR-001, and our antibody drug conjugate (ADC) development program; estimates regarding the development timing for STAR-001; 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 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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