



NEWS RELEASE

Lantern Pharma and Starlight Therapeutics Announce FDA Clearance of IND for a Planned Phase 1 Pediatric CNS Cancer Trial of STAR-001

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The Planned Multicenter Phase 1 Trial Will Evaluate STAR-001 as Monotherapy and in Combination with Spironolactone in Children with Relapsed or Refractory CNS Malignancies, Including ATRT, DIPG, GBM, Medulloblastoma, and Ependymoma

DALLAS--(BUSINESS WIRE)-- **Lantern Pharma Inc. (NASDAQ: LTRN)** and its CNS-oncology focused wholly owned subsidiary **Starlight Therapeutics** today announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for STAR-001 in a planned Phase 1 pediatric clinical trial (IND No. 179145).

STAR-001 is a precision oncology compound whose CNS and pediatric CNS indications were initially identified using Lantern's proprietary RADR® AI platform. The planned trial will evaluate STAR-001 as a single agent and in combination with spironolactone in pediatric patients with relapsed or refractory central nervous system (CNS) malignancies.

The trial is planned to be conducted in collaboration with POETIC — the Pediatric Oncology Experimental Therapeutics Investigators' Consortium — a multicenter network of 14 leading academic children's cancer centers across the United States, Canada, and Israel. The study protocol, as reviewed and cleared by the FDA, is titled:

"A PHASE 1, MULTICENTER, OPEN-LABEL, DOSE ESCALATION STUDY OF STAR-001 (LP-184) AS A SINGLE AGENT AND IN COMBINATION WITH SPIRONOLACTONE IN PEDIATRIC PATIENTS WITH RELAPSED OR REFRACTORY CENTRAL NERVOUS SYSTEM MALIGNANCIES."

ADDRESSING A CRITICAL UNMET NEED IN PEDIATRIC NEURO-ONCOLOGY

Pediatric CNS tumors represent one of the most devastating and treatment-resistant categories of childhood cancer. In the United States, an estimated 4,975 new cases of primary brain tumors will be diagnosed in children and adolescents in 2026 alone — making brain tumors the leading cause of cancer-related death among children and adolescents ages 0 to 19. The burden extends far beyond U.S. borders: globally, approximately 47,600 new pediatric CNS tumor cases are diagnosed each year, resulting in an estimated 23,500 deaths annually. Across Europe, the disease is similarly pervasive, with wide disparities in survival outcomes for children facing high-grade or relapsed cancers.

Despite significant advances in molecular profiling and surgical technique over the past two decades, survival outcomes for children with relapsed or refractory high-grade CNS tumors have improved only marginally. For certain diagnoses, the prognosis remains catastrophic. Diffuse Intrinsic Pontine Glioma (DIPG), for instance, carries a median survival of less than 12 months from diagnosis with no approved curative option. For children with relapsed ATRT, GBM, medulloblastoma, and ependymoma, current therapeutic options are equally limited and often associated with severe long-term toxicity.

The trial design provides for STAR-001 (LP-184) to be evaluated across a range of these aggressive pediatric CNS malignancies, including:

- Atypical Teratoid/Rhabdoid Tumor (ATRT) — for which Lantern Pharma holds FDA Rare Pediatric Disease Designation
- Diffuse Intrinsic Pontine Glioma (DIPG) — a brainstem tumor with virtually no long-term survivors under current standard of care
- Glioblastoma (GBM)
- Medulloblastoma
- Ependymoma

"This IND clearance is a defining milestone for Starlight Therapeutics and a meaningful step forward for pediatric neuro-oncology. For children with relapsed or refractory CNS tumors, the options are desperately limited — and the science behind this planned trial was built to change that. CNS and pediatric CNS cancers were initially identified as priority indications by our team in support from our RADR® AI platform, and that same analysis led us to ERCC3, a DNA repair enzyme that high-grade CNS tumors rely on to survive. Our

modeling, analysis and subsequent in-vivo and animal studies showed that spironolactone could dismantle that pathway by degrading ERCC3 before STAR-001 even enters the cancer cell. In ATRT models, the combination extended median survival by 181% compared to the control. We believe this represents a genuinely new way to attack these brain cancers, and we are proud to be advancing it through a network of some of the world's most respected pediatric oncology centers."

— Panna Sharma, CEO & President, Lantern Pharma Inc.; Founder & Chairman, Starlight Therapeutics

NOVEL BIOLOGY: TARGETING ERCC3 TO AMPLIFY DNA DAMAGE — A FIRST-IN-CLASS COMBINATION STRATEGY

A scientifically distinctive and potentially first-in-class feature of the planned trial is a dedicated combination cohort evaluating STAR-001 alongside spironolactone — exploiting a biological vulnerability in CNS tumor cells that Lantern's RADR® AI platform, helped in part to identify as a novel approach to creating synthetic lethality in these brain tumors.

STAR-001 operates through a precision bioactivation mechanism: selectively converted into a potent DNA-crosslinking agent within tumor cells that overexpress PTGR1 (Prostaglandin Reductase 1), it induces DNA double-strand breaks that are lethal to the cancer cell — if left unrepaired. By degrading ERCC3, spironolactone removes that option.

Lantern's RADR® AI platform identified ERCC3 (Excision Repair Cross-Complementation Group 3) — a key helicase in the nucleotide excision repair (NER) pathway — as a central repair mechanism that could be exploited in high-grade pediatric CNS malignancies including ATRT, medulloblastoma, and diffuse midline glioma, compared to low-grade gliomas. Spironolactone — a brain-penetrant, orally administered agent with a long safety record in pediatric patients — degrades ERCC3 through targeted proteasomal degradation, reducing ERCC3 protein levels by at least 50% across tumor models and confirming direct target engagement. With this repair pathway dismantled, STAR-001-induced DNA damage accumulates unrepaired, driving dramatically enhanced tumor cell death based on preclinical observations. In ATRT orthotopic xenograft models, the combination extended median survival from 27 to 76 days — a 181% improvement over control ($p = 0.0018$) — with comparable results across medulloblastoma and DMG models showing up to a 3- to 5-fold increase in apoptotic cells versus monotherapy ($p < 0.0001$).

This two-pronged strategy — AI-guided identification of a DNA repair vulnerability, precision bioactivation of a DNA-damaging agent, and pharmacological elimination of the tumor cell's repair escape route — represents a mechanistically coherent and potentially transformative approach to pediatric CNS cancers where conventional chemotherapy has reached its limits.

"High-grade pediatric brain tumors represent a significant unmet medical need, with few effective options for

children whose disease has relapsed or become refractory to standard therapy. STAR-001 is a novel, precision brain-penetrant alkylator, bioactivated by PTGR1, that has demonstrated meaningful activity across multiple malignant pediatric brain tumor types in preclinical models. In collaboration with the POETIC consortium, we have developed a Phase 1 pediatric protocol — reviewed and cleared by the FDA — to assess the safety, tolerability, and preliminary activity of STAR-001, both as a single agent and in combination with spironolactone, in children with recurrent malignant brain tumors. We look forward to initiating this planned trial and to the possibility of delivering a new therapeutic option to children who need it most."

— Marc Chamberlain, M.D., Chief Medical Officer, Starlight Therapeutics

MULTICENTER PEDIATRIC CLINICAL TRIAL DESIGN

The planned trial will be conducted across approximately 15 leading academic pediatric oncology centers in collaboration with **POETIC** (Pediatric Oncology Experimental Therapeutics Investigators' Consortium), a multicenter network of 14 institutions — including MD Anderson Cancer Center, Memorial Sloan Kettering Cancer Center, and Lucile Packard Children's Hospital at Stanford — spanning the United States, Canada, and Israel. The planned trial is subject to obtaining additional funding and it is designed to enroll approximately 18 to 42 pediatric patients aged 1 to 17 years. POETIC's established clinical infrastructure provides Starlight with the reach to enroll a geographically and demographically diverse patient population across North America and internationally.

ABOUT STAR-001 (LP-184)

STAR-001 is Starlight Therapeutics' CNS oncology compound, co-developed with Lantern Pharma as LP-184. CNS and pediatric CNS cancers were initially identified as priority indications for STAR-001 through Lantern's proprietary RADR® AI platform, which analyzed genomic and molecular data across tumor types to pinpoint the PTGR1 overexpression signature that makes these malignancies particularly susceptible to STAR-001's mechanism of action. STAR-001 is a precision acylfulvene-based agent engineered to exploit elevated PTGR1 (Prostaglandin Reductase 1) expression in tumor cells. Laboratory observations have demonstrated that PTGR1-mediated bioactivation selectively converts STAR-001 into a highly reactive DNA-crosslinking species within cancer cells, while normal tissues with lower PTGR1 activity are largely spared. LP-184/STAR-001 has received multiple FDA orphan and rare pediatric disease designations and has demonstrated encouraging activity in early-stage clinical and preclinical studies. In pediatric CNS cancers — where PTGR1 overexpression has been identified across ATRT, GBM, DIPG, medulloblastoma, and ependymoma — we believe STAR-001 represents a scientifically grounded precision approach to a historically intractable disease.

ABOUT STARLIGHT THERAPEUTICS

Starlight Therapeutics is a CNS-focused clinical-stage biopharmaceutical company and wholly owned subsidiary of

Lantern Pharma Inc. (NASDAQ: LTRN). Starlight is advancing STAR-001 (LP-184) as its lead program through planned pediatric and adult CNS cancer trials. For more information, visit www.starlightthera.com.

ABOUT POETIC

The Pediatric Oncology Experimental Therapeutics Investigators' Consortium (POETIC) is a collaborative network of 14 leading academic medical centers dedicated to accelerating the early clinical development of promising therapies for children, adolescents, and young adults with cancer and related disorders. Founded in 2003, POETIC has enrolled more than 429 patients across 16 completed clinical trials and currently has three new trials ongoing. POETIC's Research Development and Management Center is based at Stanford University. For more information, visit www.poeticphase1.org

ABOUT LANTERN PHARMA

Lantern Pharma (NASDAQ: LTRN) is an AI-driven biotechnology company focused on accelerating and optimizing the discovery, development, and commercialization of cancer therapies. Its proprietary RADR® platform leverages artificial intelligence and machine learning to uncover novel therapeutic opportunities, accelerate drug development timelines, and improve patient outcomes. For more information, visit www.lanternpharma.com.

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; potential partnerships and collaborations; 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 <http://www.lanternpharma.com/> or on the SEC's website at <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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