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FDA Grants Lantern Pharma Additional Orphan Drug Designation for Drug Candidate LP-184 in Glioblastoma Multiforme & Malignant Gliomas

Builds upon recent orphan drug designation (ODD) of LP-184 for the treatment of Pancreatic Cancer

DALLAS, Aug. 30, 2021 /PRNewswire/ -- **Lantern Pharma** (NASDAQ: LTRN), a clinical stage biopharmaceutical company using its proprietary RADR[®] artificial intelligence ("A.I.") platform to transform the cost, pace, and timeline of oncology drug discovery and development, today announced that the U.S. Food and Drug Administration (FDA) has granted LP-184 Orphan Drug Designation (ODD) for the treatment of glioblastoma multiforme (GBM) and other malignant gliomas. This news follows the [recent announcement](#) of the FDA granting LP-184 ODD for the treatment of pancreatic cancer.



LP-184 is a small molecule drug candidate and next generation alkylating agent that preferentially damages DNA in cancer cells that over-express certain biomarkers or that harbor mutations in DNA repair pathways. LP-184 is being developed for several targeted indications in cancer, including glioblastoma and pancreatic cancer.

GBM is a rare disease with an overall five-year survival rate of 5%. This means that only approximately 5 in 100 people survive GBM for five years and beyond. In 2020, 12,000 new GBM cases were diagnosed in the U.S. and more than 154,000 new cases were diagnosed worldwide. LP-184 acts by damaging DNA selectively in tumors that express high levels of

the enzyme PTGR1. Analyses driven by RADR[®], Lantern's proprietary machine learning-based artificial intelligence platform, have identified, in clinical databases, GBMs with elevated PTGR1 expression and harboring defects in DNA damage repair components as a targeted subset of genetically defined patients who could potentially benefit from LP-184-based therapy. According to market analysts at GlobalData, the global GBM market is expected to reach \$1.8 billion USD in therapy sales and is growing at a CAGR of 12.8%.

"GBM represents an important, underserved clinical opportunity, with a significant unmet medical need," stated Panna Sharma, President & CEO of Lantern Pharma. "This second Orphan Drug Designation from the FDA for the LP-184 program marks another major milestone and is further validation of the power of our data-driven approach to oncology drug development, aimed at more targeted and effective oncology therapies."

"We recently reported [positive preclinical data](#) that demonstrated LP-184 inhibits tumor growth by greater than 106% and improved survival in animal models of GBM," continued Mr. Sharma. "This new data that we reported, in collaboration with the Kennedy Krieger Institute and Johns Hopkins, on the efficacy of LP-184 in GBM cell lines, in-vivo animal models, and in patient-derived neurospheres, validated in-silico predictions generated by our RADR[®] A.I. platform. We believe LP-184's ability to cross the blood-brain barrier, together with its anti-tumor efficacy and sensitivity correlations with relevant biomarkers, highlight LP-184's potential to be used as both monotherapy as well as a synergistic agent in combination with other drugs to address the unmet needs in GBM and other aggressive central nervous system tumors."

"With our extended and expanded agreement with the Kennedy Krieger Institute and Johns Hopkins, we look forward to further advancing the potential of LP-184 as a new, potent treatment option for GBM, especially in areas of unmet clinical need, including MGMT-unmethylated, temozolomide (TMZ)-resistant GBMs, and also EGFR-aberrant or recurrent GBMs, all of which are often associated with poor prognosis and outcome for patients."

The FDA's Office of Orphan Products Development grants orphan status to drugs intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. Orphan Drug Designation is designed to provide drug developers with various benefits to support the development of novel drugs, including market exclusivity for seven years upon FDA approval, eligibility for tax credits for qualified clinical trials, waiver of marketing registration application fees, reduced annual product fees, clinical protocol assistance and qualification for expedited development programs.

About Lantern Pharma

Lantern Pharma (LTRN) is a clinical-stage oncology-focused biopharmaceutical company leveraging its proprietary RADR[®] A.I. platform and machine learning to discover biomarker signatures that identify patients most likely to respond to its pipeline of genomically targeted therapeutics. Lantern is currently developing four drug candidates and an ADC program across eight disclosed tumor targets, including two phase 2 programs. By targeting drugs to patients whose genomic profile identifies them as having the highest probability of benefiting from the drug, Lantern's approach represents the potential to deliver best-in-class outcomes. More information is available at: www.lanternpharma.com and Twitter @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; 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 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," "objective," "aim," "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 in the area of glioblastoma and other central nervous system cancers 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 A.I. 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, 2020, filed with the Securities and Exchange Commission on March 10, 2021. You may access our Annual Report on Form 10-K for the year ended December 31, 2020 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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