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FDA Grants Lantern Pharma Orphan Drug Designation for Drug Candidate LP-184 in the Treatment of Pancreatic Cancer

DALLAS, Aug. 11, 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 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 pancreatic cancer.

Pancreatic cancer is the fourth leading cause of cancer deaths in the United States with a five-year survival rate of 7.9% and a 10-year survival rate of just 1%. GLOBOCAN estimates that for pancreatic cancer there are approximately 490,000 thousand new cases of pancreatic cancer globally, with over 62,000 occurring in North America annually. Due to the late onset of symptoms, patients are often diagnosed after the cancer has progressed to locally advanced or metastatic stages of the disease. LP-184 is designed to target a specific subset of pancreatic cancer patients that are genetically defined, which has the potential to increase beneficial therapeutic options for patients and may ultimately improve survival for those with this cancer.

"Receipt of Orphan Drug Designation is an important accomplishment for the LP-184 program and for our company. This designation further validates our data-driven approach

to oncology drug development as well as the groundbreaking collaborative R&D approach we are advancing with leading institutions such as Fox Chase Cancer Center," stated Panna Sharma, President & CEO of Lantern Pharma. "Orphan Drug Designation is designed to provide a number of benefits, including seven years of market exclusivity, which complements our growing portfolio of patents that provide us additional commercial and market protections."

"This orphan designation is one of many upcoming milestones that we expect to achieve for our LP-184 program in pancreatic cancer. We recently reported that LP-184 demonstrated significant and rapid pancreatic tumor shrinkage, by over 90%, within *in-vivo* mouse models over 8 weeks. In comparison, the tumors in the untreated mice grew by over eleven-fold in volume during the same 8-week period. We are excited to advance this groundbreaking research to help patients suffering from this devastating disease where the benefits of current treatment options are very limited."

Lantern has begun discussions on the design of first-in-human clinical studies for LP-184 in collaboration with Dr. Igor Astsaturov, an established, NCI -funded, physician scientist and co-leader of the Marvin & Conchetta Greenberg Pancreatic Cancer Institute at Fox Chase Cancer Center, as well as other key opinion leaders in the pancreatic cancer treatment landscape.

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 seven 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 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, (iii) 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 (iv) 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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