



NEWS RELEASE

## FDA Grants Lantern Pharma Orphan Drug Designation for Drug Candidate LP-284 in High-Grade B-cell Lymphomas (HGBL)

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- The Orphan Drug Designation strengthens LP-284's clinical development path and can provide for additional market exclusivity and commercial protection.
- Lantern has initiated a first-in-human Phase 1 trial (NCT06132503) for LP-284 in B-cell non-Hodgkin's lymphomas (NHL), including high-grade B-cell lymphoma (HGBL) and mantle cell lymphoma (MCL).
- This Orphan Drug Designation marks the second such designation for drug-candidate LP-284 this year.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), an artificial intelligence ("AI") company developing targeted and transformative cancer therapies using its proprietary RADR<sup>®</sup> AI and machine learning ("ML") platform with multiple clinical-stage drug programs, today announced that the U.S. Food and Drug Administration (FDA) has granted LP-284 Orphan Drug Designation (ODD) for the treatment of high-grade B-cell lymphoma with MYC and BCL2 rearrangements.

HGBL represents a rare and aggressive form of B-cell non-Hodgkin's lymphoma (NHL) with no established standard of care treatment approach. Typically, frontline intervention involves a combination of chemo-immunotherapies such as R-CHOP or DA-R-EPOCH. However, approximately 20-30% of HGBL patients stop responding to these therapeutic agents and continue cancer progression. For those with relapsed or refractory (R/R) disease, the survival prognosis is 8.6 to 16 months (**Laude et al., 2021**). This underscores the pressing clinical need for novel and effective therapies in treating HGBL and improving patient outcomes.

LP-284 is a novel small molecule agent that damages DNA in cancer cells leading to the death of cancer cells. Lantern is developing LP-284 for several aggressive B-cell NHL, including MCL and HGBL, where LP-284 has shown potent anti-tumor activity in preclinical models. Lantern has been able to advance LP-284 from initial RADR<sup>®</sup> A.I. insights regarding anti-cancer activity and potential mechanisms of action in hematological cancers, to selection of specific subtypes of lymphomas with superior response, to late-stage IND enabling studies and initiation of first-in-human clinical trials in a short span of approximately 2.5 years.

"Receiving Orphan Drug Designation is an important milestone for our latest drug candidate, LP-284, and further validates our data-driven approach to oncology drug discovery and development," stated Panna Sharma, President & CEO of Lantern Pharma. "At SOHO 2023, **we reported positive preclinical data** demonstrating LP-284's potent anti-tumor activity as a monotherapy as well as in combination with FDA-approved lymphoma targeting antibody Rituximab in High-Grade B-cell Lymphoma (HGBL). These findings hold significant importance given the elevated rate of relapse and the unfavorable prognosis observed in the majority of HGBL patients," continued Sharma.

"This marks the second Orphan Drug Designation (ODD) granted by the FDA for LP-284. The initial ODD for LP-284 was granted in January 2023, and with this most recent ODD for LP-284 announced today, a total of five orphan designations have now been granted to Lantern, with the other three granted for our drug candidate LP-184. Acquiring these orphan designations is a key element of our business model as they provide a number of benefits including seven years of market exclusivity and eligibility for expedited drug development programs. Looking forward, these designations further position Lantern to advance our discussions with biopharma companies for partnering and collaborative development opportunities."

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. ODD 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.

Reference:

Laude MC, Lebras L, Sesques P, et al. First-line treatment of double-hit and triple-hit lymphomas: Survival and tolerance data from a retrospective multicenter French study. *Am J Hematol.* 2021;96(3):302-311. doi:10.1002/ajh.26068

**About Lantern Pharma:**

Lantern Pharma (NASDAQ: LTRN) is a clinical-stage oncology-focused biopharmaceutical company leveraging its proprietary RADR<sup>®</sup> A.I. and machine learning platform to discover biomarker signatures that identify patients most likely to respond to its pipeline of genomically-targeted therapeutics. Lantern's lead development programs include a Phase 2 clinical program, multiple Phase 1 clinical trials and an ADC program, across 11 disclosed tumor targets. 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.

Please find more information at:

Website: [www.lanternpharma.com](http://www.lanternpharma.com)

LinkedIn: <https://www.linkedin.com/company/lanternpharma/>

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## 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<sup>®</sup> 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<sup>®</sup> platform to streamline the drug development process; our intention to leverage artificial intelligence, machine learning and biomarker 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 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<sup>®</sup> AI 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, 2022, filed with the Securities and Exchange Commission on March 20, 2023. You may access our Annual Report on Form 10-K for the year ended December 31, 2022 under the investor SEC filings tab of our website at [www.lanternpharma.com](http://www.lanternpharma.com) or on the SEC's website at [www.sec.gov](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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Investor Relations

[ir@lanternpharma.com](mailto:ir@lanternpharma.com)

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