

# FDA Grants Lantern Pharma Orphan Drug Designation for Drug Candidate LP-284 in Mantle Cell Lymphoma

- The Orphan Drug Designation strengthens LP-284's clinical development path and provides the opportunity for additional market exclusivity and commercial protection.
- Lantern is anticipating filing the IND with the FDA and initiating a first-in-human Phase 1 trial for LP-284 in B-cell non-Hodgkin's lymphomas (NHL), including mantle cell lymphoma (MCL), by mid 2023.
- In the US, MCL is diagnosed in approximately 4,500 patients each year and has an estimated annual market potential of \$600 million.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), a clinical stage biopharmaceutical company using its proprietary RADR<sup>®</sup> artificial intelligence ("A.I.") and machine learning ("M.L.") 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-284 Orphan Drug Designation (ODD) for the treatment of mantle cell lymphoma (MCL). MCL is a rare and aggressive form of B-cell non-Hodgkin's lymphoma (NHL) that is typically diagnosed at advanced stages in elderly patients. As nearly all MCL patients acquire resistance and relapse from treatment with standard-of-care (SOC) agents, there is an urgent and unmet clinical need for new and effective therapies to treat MCL.

LP-284 is a novel small molecule agent that preferentially damages DNA in cancer cells harboring mutations in DNA damage repair pathways. Lantern is developing LP-284 for several aggressive B-cell NHL's, including MCL and double hit lymphoma (DHL), 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 initial design of first in human clinical trials in less than 2 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 ASH, [we recently reported positive preclinical data](#) demonstrating LP-284's potent anti-tumor activity in new MCL tumors and also against tumors that had grown resistant to the MCL standard-of-care agents Ibrutinib and Bortezomib. These findings are critically pertinent due to the high relapse rate, and poor prognosis of the majority of MCL patients," continued Sharma.

"This orphan designation is the fourth overall designation 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.

In addition to the ODD granted for LP-284 in MCL, Lantern was previously granted ODD's by the FDA for its drug candidate LP-184 for the treatment of malignant gliomas, atypical teratoid rhabdoid tumors (ATRT), and pancreatic cancer. Lantern has also been granted a Rare Pediatric Disease Designation for LP-184 in ATRT.

### **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 is currently developing four drug candidates and an ADC program across 12 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.

### **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 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 impact of the COVID-19 pandemic, (ii) the risk that our research and the research of our collaborators 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<sup>®</sup> 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, 2021, filed with the Securities and Exchange Commission on March 10, 2022. You may access our Annual Report on Form 10-K for the year ended December 31, 2021 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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20230105005372/en/>

Nicole Leber

Investor Relations Associate

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

Please find more information at:

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

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

Twitter: [@lanternpharma](https://twitter.com/lanternpharma)

Monthly Newsletter: Sign-up [here](#)

Source: Lantern Pharma Inc.