NEWS RELEASE

Lantern Pharma's LP-284 Receives FDA Orphan Drug Designation for Soft Tissue Sarcomas

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- Third FDA orphan designation for LP-284; Sixth overall for Lantern's A.I.-driven precision oncology pipeline
- Orphan designation expands LP-284's potential for an estimated ~96,000 global annual soft tissue sarcoma cases; annual market valued at $2.4 billion in 2025 and projected to reach $4.7 billion by 2035

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), a clinical-stage biopharmaceutical company using artificial intelligence 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 Orphan Drug Designation (ODD) to LP-284 for the treatment of soft tissue sarcomas.

This marks the third orphan designation for LP-284, following previous orphan designations in Mantle Cell Lymphoma (MCL) in January 2023 and High-Grade B-Cell Lymphoma (HGBL) with MYC and BCL2 rearrangements in November 2023. It is the sixth overall orphan designation granted to Lantern Pharma's clinical programs.

"Receiving orphan drug designation for LP-284 in soft tissue sarcomas expands this molecule's potential beyond hematologic malignancies into solid tumors," said Panna Sharma, CEO of Lantern Pharma. "Adult soft tissue sarcomas are a compelling opportunity for LP-284. Unlike pediatric sarcomas driven by specific gene fusions, adult sarcomas commonly exhibit complex genomic alterations, chromosomal instability, and DNA damage response deficiencies – including BRCA-ness and homologous recombination repair defects – that align with LP-284's synthetic lethal mechanism. With over 79% of cases occurring in adults, this designation addresses a distinct patient

population with significant unmet need. Our RADR® AI platform identified these DNA repair vulnerabilities, demonstrating its ability to uncover biomarker-driven precision oncology opportunities in rare cancers with limited treatment options."

Significant Unmet Need in Soft Tissue Sarcomas, a Global Market of ~96,000 Annual Cases with Limited Treatment Options

Soft tissue sarcomas are a diverse group of rare cancers that develop in the tissues that connect, support, and surround other body structures, including muscle, fat, blood vessels, nerves, tendons, and the lining of joints. According to the National Cancer Institute's SEER Program, approximately 13,520 new cases of soft tissue sarcoma are expected to be diagnosed in the United States in 2025. Over 79% of soft tissue sarcoma cases occur in patients 40 years of age or older.[1]

Globally, soft tissue sarcoma represents a significant health burden with approximately 96,200 new cases diagnosed worldwide in 2021, according to the Global Burden of Disease Study. The seven major pharmaceutical markets (United States, France, Germany, Italy, Spain, United Kingdom, and Japan) for soft tissue sarcoma therapeutics reached a value of approximately $2.4 billion in 2025 and are projected to reach approximately $4.7 billion by 2035.[2]

Adult soft tissue sarcomas exhibit distinct molecular characteristics compared to pediatric sarcomas. While pediatric sarcomas are largely driven by specific gene fusions, adult sarcomas more commonly harbor complex genomic alterations, chromosomal instability, and DNA repair deficiencies that may be susceptible to agents that target DNA repair pathways.[3] According to the Sarcoma Foundation of America's **2025 Sarcoma Statistics**, treatment options for advanced or metastatic soft tissue sarcomas remain limited, with five-year survival rates for distant disease at approximately 16-17%, representing a significant unmet medical need in adult oncology.

AI-Predicted & Clinically Observed Synthetic Lethal Mechanism of LP-284 Targets DNA Repair Deficiencies

LP-284 is a novel small molecule with a synthetic lethal mechanism targeting DNA repair deficiencies via transcription-coupled nucleotide excision repair (TC-NER). A member of the acylfulvene class, LP-284 has demonstrated promising activity across multiple cancer types in preclinical studies and early clinical development, with observed activity regardless of TP53 mutation status or surface antigen expression.

In July 2025, Lantern reported that LP-284 achieved a complete metabolic response in a heavily pretreated patient with aggressive diffuse large B-cell lymphoma (DLBCL) in its ongoing Phase 1 clinical trial. The 41-year-old patient had previously failed three aggressive treatment regimens including standard chemo-immunotherapy, CAR-T cell therapy, and CD3xCD20 bispecific antibody therapy – representing a therapeutically exhausted patient population.

Following enrollment in April 2025, the patient achieved complete metabolic response with non-avid lesions after completing just two 28-day cycles of LP-284, providing support for the drug's synthetic lethal mechanism and demonstrating meaningful clinical activity in a patient with one of the most challenging hematologic malignancies.

This clinical milestone is particularly significant as it demonstrates LP-284's ability to induce responses in patients who have exhausted advanced immunotherapies, addressing a critical treatment gap in relapsed/refractory cancers. The mechanism of action – targeting DNA repair deficiencies through TC-NER – is similarly applicable to adult soft tissue sarcomas, which commonly harbor complex genomic alterations and DNA repair pathway defects.

LP-284 is currently being evaluated in a Phase 1 clinical trial (NCT06132503) for B-cell non-Hodgkin lymphomas, including MCL and HGBL. With three orphan designations spanning both hematologic malignancies and solid tumors, LP-284 represents a versatile therapeutic development candidate with potential applications across diverse cancer types characterized by DNA repair vulnerabilities.

Strategic Regulatory Pathway: Orphan Drug Designation Provides 7 Years of Exclusivity & Benefits Accelerated Development

The FDA's Orphan Drug Designation program provides incentives for the development of drugs intended to treat rare diseases affecting fewer than 200,000 people in the United States. Benefits of orphan drug designation include seven years of market exclusivity upon regulatory approval, tax credits for qualified clinical trials, exemption from FDA user fees, and FDA assistance in clinical trial design.[4]

About Lantern Pharma

Lantern Pharma (NASDAQ: LTRN) is a clinical-stage biotechnology company using artificial intelligence, machine learning, and genomic data to streamline oncology drug development and bring precision therapies to patients who need them. The company's proprietary RADR® AI platform integrates hundreds of billions of data points to identify biomarkers, predict drug response, and design smarter clinical trials. Lantern's clinical-stage pipeline includes LP-184, LP-284, and LP-300, each targeting genomically defined patient populations. 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; potential partnerships and collaborations; our strategic plans to advance the development of our drug candidates; estimates regarding the development timing for our drug candidates; 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.

[1] Global burden of soft tissue sarcomas in 204 countries and territories from 1990 to 2021: data from the global burden of disease study 2021. BMC Public Health. 2025. **https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-025-22782-5**

[2] Soft Tissue Sarcoma Market: Epidemiology, Industry Trends, Share, Size, Growth, Opportunity, and Forecast 2024-2034. IMARC Group. **https://www.imarcgroup.com/soft-tissue-sarcoma-market**

[3] National Institutes of Health. Gene Fusions in Pediatric Sarcomas. PA-16-251. **https://grants.nih.gov/grants/guide/pa-files/PA-16-251.html**

[4] U.S. Food and Drug Administration. Orphan Drug Designation Program. **https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products**

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