NEWS RELEASE

# Lantern Pharma Announces Three U.S. FDA Rare Pediatric Disease Designations Granted to LP-184 in Multiple Ultra Rare Children's Cancers

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- Lantern Pharma was granted the rare pediatric disease designation (RPDD) for drug-candidate, LP-184, in three cancer indications: Malignant Rhabdoid Tumors, Rhabdomyosarcoma, and Hepatoblastoma.
- This brings the total number of RPDDs for LP-184 to 4, including one previously granted for ATRT (Atypical Teratoid Rhabdoid Tumors).
- Efficacy of LP-184 in these three rare pediatric cancers was demonstrated through evidence of tumor regression and extended event-free survival in specialized models developed as part of the Pediatric Preclinical Testing Program (PPTP), an initiative supported by the National Cancer Institute (NCI) to identify novel therapeutic agents that may have significant activity against childhood cancers.
- Companies with RPDDs might be eligible to receive a Priority Review Voucher (PRV) upon FDA marketing approval that could be redeemed to receive a priority review for any subsequent marketing application. If received, PRVs may be used by the sponsor or sold to another sponsor and have recently sold for over $100 million[(1)].

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), an artificial intelligence ("AI") company developing targeted and transformative cancer therapies using its proprietary RADR® AI and machine learning ("ML") platform with multiple clinical-stage drug programs, announced today that the company has been granted

three rare pediatric disease designations (RPDD) by the FDA. Lantern was granted these rare pediatric disease designations in: malignant rhabdoid tumors (MRT), rhabdomyosarcoma (RMS), and hepatoblastoma.

"At Lantern, we're harnessing AI and data-driven approaches to revolutionize cancer drug development, aiming to dramatically reduce costs, accelerate timelines, and enhance precision in bringing new therapies to patients," stated Panna Sharma, CEO and President of Lantern Pharma. "Our recent breakthrough in identifying three additional, high-potential indications for LP-184 in pediatric cancers exemplifies this progress. We believe that 'AI for good' should address both blockbuster opportunities as well as rare, often overlooked pediatric cases. The FDA's Rare Pediatric Disease designation for these three potential programs is a testament to this commitment. We're acutely aware that patients and their families are relying on innovators like us to speed up therapy development. These designations mark a crucial step forward in advancing our expanding portfolio of pediatric programs targeting these devastating and rare cancers. It reinforces our dedication to transforming hope into tangible solutions for those who need them most."

Rare pediatric diseases are defined by the FDA as serious or life-threatening conditions primarily affecting children under 18, with fewer than 200,000 cases in the U.S. A key benefit of obtaining a RPDD is the potential to receive a priority review voucher following FDA approval of a product with RPDD if the marketing application submitted for the product satisfies certain conditions, including approval prior to September 30, 2026 unless changed by legislation. These vouchers, often called "golden tickets," can significantly expedite the review process for future NDAs or biologic license applications, reducing the standard review time from about ten months to six. Sponsors can either use these vouchers themselves or sell them to other companies. These vouchers, in the recent past, have commanded sales prices of approximately $100 million USD.

Lantern's investigational drug candidate, LP-184, has shown preclinical activity in a wide range of solid tumors, garnering it multiple orphan and rare pediatric designations. LP-184 is currently in a multi-center **Phase 1A clinical trial** that is expected to enroll approximately 50 to 60 patients across a wide range of solid tumors. Based on the results and findings from this clinical trial and other collaborative studies, Lantern will plan and potentially develop future clinical trials for specific pediatric patients in ATRT, MRT, RMS and Hepatoblastoma.

## About MRT - Malignant Rhabdoid Tumors

Malignant rhabdoid tumors are rare childhood cancers that typically affect the kidneys and soft tissues, sometimes occurring in the brain as atypical teratoid rhabdoid tumors (ATRT). The kidney and soft tissue variant, known as malignant rhabdoid tumor (MRT), is most common in infants and toddlers, with an average diagnosis age of 15 months. In the United States, only 35 to 50 new cases of MRT are diagnosed annually. These tumors can spread to other parts of the body. While the exact cause is unknown, research has linked a mutation in the **SMARCB1 gene** to nearly all rhabdoid tumors. This mutation can sometimes occur in a patient's normal cells, increasing their risk of

developing multiple tumors. Often, the first sign of MRT is an abdominal lump or mass, with some children experiencing urination difficulties or blood in the urine.

## About RMS - Rhabdomyosarcoma

Rhabdomyosarcoma is a rare cancerous tumor that develops in the body's soft tissues, which connect, support, and surround organs and other structures. It originates from rhabdomyoblast cells, which form early in embryonic development, making this cancer more prevalent in children than adults. The tumor commonly appears in the head, neck, bladder, vagina, arms, legs, and trunk, but can also occur in areas with minimal skeletal muscle, such as the prostate, middle ear, or bile duct system. Despite being the most common childhood soft-tissue sarcoma, rhabdomyosarcoma affects only about 250-300 children annually in the United States. There are two primary types of this cancer: embryonal rhabdomyosarcoma (ERMS), which is more common and typically affects children under six, and alveolar rhabdomyosarcoma (ARMS), which accounts for approximately 20 percent of cases and is more frequently found in older children.

## About Hepatoblastoma

Hepatoblastomas are the most common primary malignant liver tumors in pediatric patients, typically occurring within the first two years of life. These tumors are classified into two histologic types: epithelial and mixed. While most hepatoblastomas are sporadic, about one-third of cases are associated with genetic conditions such as Beckwith-Weidemann syndrome, familial adenomatous polyposis (FAP), Edward syndrome (trisomy 18), nephroblastoma, and Down syndrome. Infants with low birth weight are at a higher risk of developing hepatoblastoma, and there is evidence linking the tumor to preeclampsia and parental tobacco smoking before and during pregnancy. The most common genetic mutation in hepatoblastoma involves the **Wnt signaling pathway**, leading to the accumulation of beta-catenin, particularly in sporadic cases. In more aggressive cases, activation of **TERT** (human telomerase reverse transcriptase) and MYC signaling has been observed. Hepatoblastoma is a rare tumor, accounting for approximately 1% of all pediatric tumors in North America and Europe. However, its incidence is slowly increasing globally, with a slight predominance in males.

## Please find more information at:

- Website: **www.lanternpharma.com**
- LinkedIn: **https://www.linkedin.com/company/lanternpharma/**
- X: **@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; 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 our research and the research of our collaborators may not be successful, (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 we may not be successful in satisfying the conditions necessary to receive a rare pediatric designation priority review voucher, (iv) the risk that we may not be successful in licensing potential candidates or in completing potential partnerships and collaborations, (viv) 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, 2023, filed with the Securities and Exchange Commission on March 18, 2024. You may access our Annual Report on Form 10-K for the year ended December 31, 2023 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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(1)Recent PRV (Priority Review Vouchers) sold and publicly disclosed in recent 12 months: Ipsen Pharma on 08/27/24 for $158 Mn; Day One Bio on 5/30/24 for $108 Mn.; X4 Pharmaceuticals on 05/09/24 for $105 Mn; Valneva SE on 02/25/24 for $103 Mn; Bluebird Bio on 10/30/23 for $103 Mn.

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