

Lantern Pharma's Investigational Drug-Candidate, LP-184, Receives Second Fast Track Designation from FDA for Treatment of Triple Negative Breast Cancer (TNBC)

- This is the second Fast Track Designation granted to LP-184 in 2024, following the designation for Glioblastoma (GBM) announced in October 2024.
- Fast Track Designation for LP-184 recognizes TNBC as a serious condition impacting approximately 29,000 patients annually in the US, with over 50% of patients relapsing within 3-5 years.
- LP-184 has demonstrated significant preclinical efficacy in TNBC models, including those resistant to PARP inhibitors, and recent data shows promising synergy with checkpoint inhibitors in TNBC.
- Fast Track Designation is designed to expedite FDA review of important new drugs to treat serious conditions and fill an unmet medical need.
- LP-184 is currently being evaluated in a Phase 1A clinical trial (NCT05933265) across multiple solid tumor indications, including TNBC.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), an artificial intelligence (AI) company dedicated to developing cancer therapies and transforming the cost, pace, and timeline of oncology drug discovery and development, today announced that the FDA has granted Fast Track Designation for investigational drug candidate, LP-184, for treatment of Triple Negative Breast Cancer (TNBC). This marks the second Fast Track Designation received for LP-184 in 2024, following its designation for Glioblastoma in October.

This press release features multimedia. View the full release here:

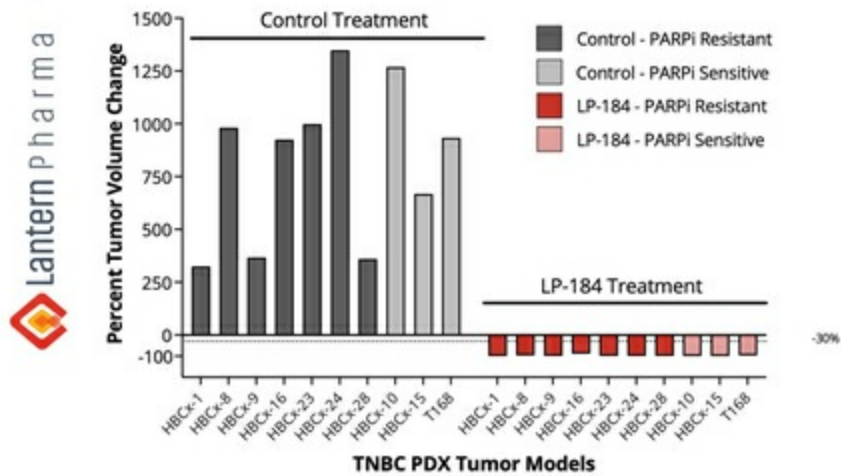
<https://www.businesswire.com/news/home/20241203997484/en/>

LP-184 is currently in a Phase 1A clinical trial designed to evaluate the safety and tolerability of this synthetically lethal investigational drug candidate in a broad range of solid tumors, including TNBC. LP-184 was optimized and advanced in part with Lantern's AI platform, RADR®, which helped validate mechanisms that could be exploited in the clinical setting to eradicate challenging cancers and uncover insights in targeted patient populations.

"Receiving a second FDA Fast Track Designation for LP-184 reinforces the significant potential of this drug candidate to address critical unmet needs in aggressive cancers, especially those like TNBC where patients have limited therapeutics options," stated Panna Sharma, President and CEO of Lantern Pharma. "Recent data presented at the Immuno-Oncology Summit demonstrated LP-184's ability to sensitize TNBC tumors that are non-responsive to checkpoint inhibitors, potentially expanding treatment options for patients with limited therapeutic choices."

Triple Negative Breast Cancer (TNBC)

Across 10 TNBC PDX mouse models (All 10 TNBC PDX models were HR deficient) LP-184 treatment resulted in 107-141% tumor growth inhibition



LP-184 demonstrated tumor regression of 107-141% in multiple TNBC PDX models. (Graphic: Business Wire)

median overall survival of less than one year. Currently available treatment options are limited, particularly for patients who develop resistance to existing therapies.

Compelling Preclinical Data Demonstrates LP-184's Potential in TNBC

The graph above demonstrates LP-184's remarkable anti-tumor activity across a panel of 10 TNBC patient-derived xenograft (PDX) models. Notably, LP-184 showed consistent efficacy in both PARPi (PARP inhibitor) resistant and PARPi sensitive tumors, with treatment resulting in complete tumor regression (107-141% tumor growth inhibition) across all models tested. This data is particularly significant as it suggests LP-184's potential as a novel therapeutic option for TNBC patients, including those who have developed resistance to existing PARP inhibitor treatments - a growing clinical challenge in TNBC therapy. This TNBC data was initially presented at the San Antonio Breast Cancer Symposium in 2022.

LP-184's unique mechanism of action is driven by the enzymatic activation of the drug by Prostaglandin Reductase 1 (PTGR1), which converts LP-184 into its highly potent cytotoxic form specifically within cancer cells. RADR® platform analysis and subsequent in-vivo validation studies have shown that PTGR1 is frequently elevated in TNBC tumors compared to normal tissue, making these cancers particularly susceptible to LP-184 treatment. This biomarker-driven approach allows for the potential identification of patients most likely to respond to LP-184 therapy, aligning with current and emerging precision medicine approaches in TNBC treatment.

About LP-184

LP-184 is a small molecule drug candidate and next-generation acylfulvene that preferentially damages DNA in cancer cells that overexpress specific biomarkers or harbor mutations in DNA damage repair pathways. LP-184 was developed using Lantern's proprietary RADR® AI platform to identify patient populations and cancer subtypes that have

About TNBC and the Need for Novel Therapies

TNBC represents approximately 20% of all breast cancers, affecting nearly 29,000 patients annually in the US. The prognosis for TNBC patients is considerably worse than hormone receptor-positive breast cancers, with over 50% of patients relapsing in the first 3-5 years and metastatic TNBC patients having a

the potential to respond to treatment. The compound is being evaluated in multiple solid tumors where it has shown nanomolar potency and activity in drug-resistant cancers. LP-184 has received Orphan Drug Designations from the FDA for the treatment of pancreatic cancer, glioblastoma (GBM), and ATRT, and has also been granted a Rare Pediatric Disease Designation for ATRT.

About Lantern Pharma

Lantern Pharma (NASDAQ: LTRN) is an AI company transforming the cost, pace, and timeline of oncology drug discovery and development. Our proprietary AI and machine learning (ML) platform, RADR®, leverages over 100 billion oncology-focused data points and a library of 200+ advanced ML algorithms to help solve billion-dollar, real-world problems in oncology drug development. By harnessing the power of AI and with input from world-class scientific advisors and collaborators, we have accelerated the development of our growing pipeline of therapies that span multiple cancer indications, including both solid tumors and blood cancers and an antibody-drug conjugate (ADC) program. Our lead development programs include a Phase 2 clinical program and multiple Phase 1 clinical trials. Our AI-driven pipeline of innovative product candidates is estimated to have a combined annual market potential of over \$15 billion USD and have the potential to provide life-changing therapies to hundreds of thousands of cancer patients across the world.

Please find more information at:

- Website: www.lanternpharma.com
- LinkedIn: <https://www.linkedin.com/company/lanternpharma/>
- X: @lanternpharma

FORWARD LOOKING STATEMENT:

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 able to secure sufficient future funding when needed and as required to advance and support our existing and planned clinical trials and operations, (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, 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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20241203997484/en/>

Investor Relations

ir@lanternpharma.com

(972) 277-1136

Source: Lantern Pharma Inc.