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Zacks Small-Cap Research (NOTE)

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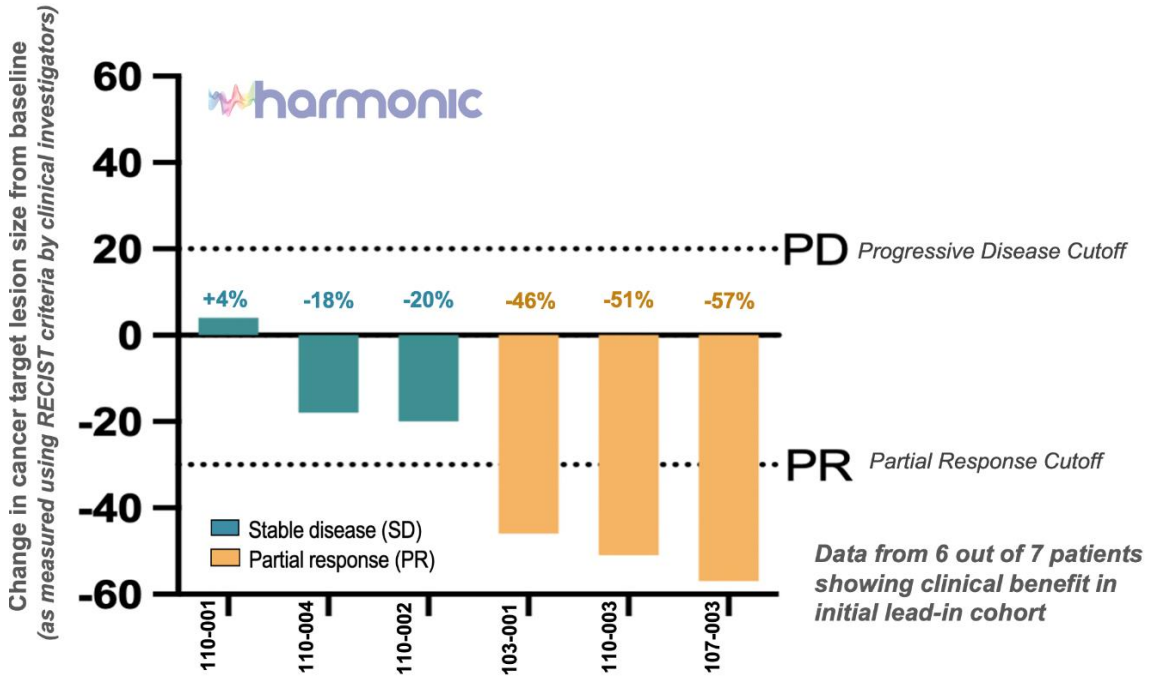
Lantern Pharma, Inc. (LTRN: NASDAQ)

LTRN: Harmonic Clinical Update

Research Note

Lantern Pharma, Inc. (NASDAQ: LTRN) provided a clinical update to its Phase II Harmonic trial highlighting that six of seven patients experienced clinical benefit from LP-300 combination treatment. Of these patients comprising the lead-in cohort, three showed partial response (PR) and three others exhibit stable disease (SD). Average tumor size reduction for the partial responders was 51% and for those with stable disease, 13%. These results produce a clinical benefit[1] and disease control[2] rate of 86% and an objective response rate (ORR) of 43%.

Exhibit I – Percent Change in Cancer Lesion Size by Patient



All patient data as of July 25, 2024

Source: Lantern Pharmaceuticals August 5th, 2024 Press Release

Safety was another strong point for Harmonic. A preliminary analysis found no safety concerns, dose limiting toxicities or treatment related serious adverse events. The most common adverse events were a decrease in white blood cell count and thrombocytopenia.

[1] Clinical Benefit Rate (CBR) is the percentage of patients who had a complete response, partial response, or had stable disease for 6 months or more. This is the proportion of patients who received a benefit from the intervention.
[2] Disease control rate (DCR) is the proportion of patients who, according to internationally recognized criteria for alleviating evaluation, achieve tumor relief (PR+CR) and stable disease (SD) after treatment and can maintain for the minimum duration requirement.

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Patients in this first stage of the trial were never smoker NSCLC patients who had failed on previous tyrosine kinase inhibitor (TKI) therapy. These individuals received treatment with LP-300 along with carboplatin and pemetrexed.

These results compare favorably to historical responses to other combination studies that measure an investigational drug with pemetrexed and carboplatin in non-small cell lung cancer (NSCLC) patients who have relapsed following TKI therapy.

Exhibit II – Historical Response Data for Pemetrexed + Carboplatin in NSCLC Patients Post TKI Treatment

Trial Name	Sponsor	Intervention	Median ORR	Median DOR	Median PFS	HR for PFS
Mariposa-2	Janssen	Amivantamab lazertinib	36%	5.6	4.2	0.48
Keynote-789	Merck	Pembro-lizumab	27%	5.6	5.5	0.8
CheckMate-722	BMS	Nivolumab	27%	5.6	5.4	0.75
Herthena-Lung	Daiichi Sankyo	HER3-DXd	30%	6.4	5.5	
Harmonic	Lantern Pharma	LP-300	43%	Immature	Immature	Immature

Source: Compiled by Zacks Analyst from Sources Cited Below[3,4,5,6]

Other highlights from the trial include a 57% reduction in tumor size for a patient that has been enrolled in the study for 14 months. The seventh patient that did not achieve a PR or SD experienced progressive disease. Investigators observed that the patients with low to intermediate tumor mutation burden were most responsive to LP-300 combination therapy.

A second stage of the trial is planned following the favorable safety profile generated in the first stage. The trial is now in the randomization and expansion phase where 80 additional patients will be placed in the LP-300 + SoC or SoC arms of treatment. Results from this portion of the study will be provided when 30 clinical events have been observed. If the data are supportive, Lantern will consider applying for a Breakthrough Therapy designation. Lantern is scheduled to report second quarter results on August 8th after the close and will be available to answer questions related to the interim update during the webinar following the release.

Harmonic Trial Background

In July 2022, Lantern announced the start of the Harmonic trial that is evaluating LP-300 in never smokers with non-small cell lung cancer (NSCLC). 90 subjects are expected to enroll in the Phase II study at 15 to 20 sites around the globe with enrollment expected to last from 12 to 16 months. It will target never smokers with lung adenocarcinoma who have relapsed after treatment with tyrosine kinase inhibitors (TKIs). The study will consist of two stages, the safety lead-in stage and the randomization stage. Patients on LP-300 + pemetrexed and carboplatin will be measured against patients on pemetrexed and carboplatin only in a 2:1 ratio. Primary endpoints are progression free survival (PFS) and overall survival (OS). Secondary endpoints include objective response rate (ORR), duration of objective response (DOR) and clinical benefit rate (CBR). The trial will also collect liquid biopsies and acquire genomic and transcriptomic data from patients.

A March 28th, 2023 press release announced that the first patient in the trial had been dosed, kicking off the Phase II effort led by lead principal investigator Dr. Joseph Treat of Fox Chase Cancer Center. Lantern has activated five clinical trial sites including Gabrail Cancer Center, Northwest Oncology, New York Cancer and Blood Specialists, Texas Oncology and Cancer and Blood Specialty Clinic. Further trial sites across the United States and Asia are expected, especially in regions where never-smoker NSCLC are prevalent including Taiwan, Japan and South Korea. Enrollment is anticipated to take 18-24 months.

[3] Passaro, A. *et al*. Amivantamab plus chemotherapy with and without lazertinib in EGFR-mutant advanced NSCLC after disease progression on osimertinib: primary results from the phase III MARIPOSA-2 study. Annals of Oncology. October 2023.
[4] Arter, Z.L., Nagasaka, M. The Nail in the Coffin?: Examining the KEYNOTE-789 Clinical Trial's Impact. Lung cancer. January 2024.
[5] Mok, T. *et al*. Nivolumab Plus Chemotherapy in Epidermal Growth Factor Receptor–Mutated Metastatic Non–Small-Cell Lung Cancer After Disease Progression on Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitors: Final Results of CheckMate 722. Thoracic Oncology. January 2024.
[6] Yu, H. *et al*. HERTHENA-Lung01, a Phase II Trial of Patritumab Deruxtecan (HER3-DXd) in Epidermal Growth Factor Receptor–Mutated Non–Small-Cell Lung Cancer After Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Therapy and Platinum-Based Chemotherapy. Thoracic Oncology. September 2023.

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