Protocol KEYLINK-013 (MSD)

A Randomized, Double-blind, Placebo-controlled Phase 3 Study of Pembrolizumab (MK-3475) in Combination with Concurrent Chemoradiation Therapy Followed by Pembrolizumab with or without Olaparib (MK-7339), Compared to Concurrent Chemoradiation Therapy Alone in Participants with Newly Diagnosed Treatment-Naïve Limited-Stage Small Cell Lung Cancer (LS-SCLC)

This is the trial summary as assessed on clinicaltrials.gov on 12/04/2022

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/show/NCT04624204?cond=KEYLYNK-013&draw=2&rank=1

Study design

Experimental: Group A - Pembrolizumab 200 mg
Participants will receive 4 cycles of standard-of-care chemotherapy (etoposide/platinum) plus pembrolizumab 200 mg every 3 weeks (Q3W) concurrently with standard thoracic radiotherapy, followed by 9 cycles of pembrolizumab 400 mg every 6 weeks (Q6W) plus olaparib matching placebo twice daily (BID) for 12 months or until specific discontinuation criteria are met.

Experimental: Group B - Pembrolizumab 200 mg plus Olaparib 300 mg BID
Participants will receive 4 cycles of standard-of-care chemotherapy (etoposide/platinum) plus pembrolizumab 200 mg Q3W concurrently with standard thoracic radiotherapy, followed by 9 cycles of pembrolizumab 400 mg Q6W plus olaparib 300 mg BID for 12 months or until specific discontinuation criteria are met.

Placebo Comparator: Group C (Pembrolizumab and Olaparib Matching Placebos)
Participants will receive 4 cycles of standard-of-care chemotherapy (etoposide/platinum) plus pembrolizumab placebo (saline) Q3W concurrently with standard thoracic radiotherapy, followed by 9 cycles of pembrolizumab placebo (saline) Q6W plus olaparib matching placebo for 12 months or until specific discontinuation criteria are met.

Inclusion Criteria:

1. Has pathologically (histologically or cytologically) confirmed Small Cell Lung Cancer (SCLC).
2. Has Limited-Stage SCLC (Stage I-III, by AJCC 8th Edition Cancer Staging), and can be safely treated with definitive radiation doses.
3. Has no evidence of metastatic disease by whole body positron emission tomography /computed tomography (PET/CT scan), CT or magnetic resonance imaging (MRI) scans
4. Has at least 1 lesion that meets the criteria for being measurable, as defined by Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1)
5. Has not received prior treatment (chemotherapy or radiotherapy or surgery resection) of LS-SCLC.
6. Is not expected to require tumor resection during the course of the study.

7. Must submit a pre-treatment tumor tissue sample (formalin-fixed, paraffin embedded blocks are preferred to slides) including cytologic sample, if tissue sample unavailable.
8. Has Eastern Cooperative Oncology Group (ECOG) Performance score 0 or 1 assessed within 7 days prior to the first administration of study intervention.
9. Has a life expectancy of at least 6 months.
10. Has adequate organ function.
11. Male and female participants who are not pregnant and of childbearing potential must follow contraceptive guidance during the treatment period and for the time needed to eliminate each study intervention.
12. Male and female participants who are at least 18 years of age at the time of signing the information consent.
13. Male participants must refrain from donating sperm during the treatment period and for the time needed to eliminate each study intervention.

Exclusion Criteria:

1. Has history, current diagnosis, or features suggestive of myelodysplastic syndrome/ acute myeloid leukemia (MDS/AML).
2. Has received prior therapy with an anti-programmed cell death 1 (anti-PD-1), anti-programmed cell death ligand 1 (anti-PDL1), or anti- programmed cell death ligand 2 (anti-PD-L2) agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor
3. Has received prior therapy with olaparib or with any other polyadenosine 5'diphosphoribose (polyADP ribose) polymerization (PARP) inhibitor.
4. Had major surgery <4 weeks prior to the first dose of study intervention (except for placement of vascular access).
5. Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study intervention.
6. Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior the first dose of study intervention.
7. Has a known additional malignancy that is progressing or has required active treatment within the past 5 years. Note: Participants with basal cell carcinoma of the skin, squamous cell carcinoma of the skin, superficial bladder cancer, or carcinoma in situ (e.g., breast carcinoma, cervical cancer in situ) that have undergone potentially curative therapy are not excluded.
8. Has severe hypersensitivity (≥ Grade 3) to study intervention and/or any of its excipients.
9. Has an active autoimmune disease that has required systemic treatment in past 2 years
10. Has a history of (non-infectious) pneumonitis/interstitial lung disease that requires steroids
11. Has an active infection requiring systemic therapy.
12. Has a known history of human immunodeficiency virus (HIV) infection or Hepatitis B or known active Hepatitis C virus infection.