TROPION-Lung15

A Study to Investigate the Efficacy and Safety of Dato-DXd With or Without Osimertinib Compared With Platinum Based Doublet Chemotherapy in Participants With EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer

This is the trial summary as assessed on clinicaltrials.gov. You can check this on this direct link:

Study Details | NCT06417814 | A Study to Investigate the Efficacy and Safety of Dato-DXd With or Without Osimertinib Compared With Platinum Based Doublet Chemotherapy in Participants With EGFR-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer | ClinicalTrials.gov

Participants will be randomized in a 1:1:1 ratio to one of the following intervention groups:

1. Dato-DXd + osimertinib combination therapy
2. Dato-DXd monotherapy
3. Platinum-based doublet chemotherapy

Inclusion Criteria:

- Histologically or cytologically confirmed non-squamous NSCLC.
- Must have evidence of documented pre-existing EGFRm information (EGFRm known to be associated with (epidermal growth factor receptor [EGFR] tyrosine kinase inhibitor [TKis] sensitivity [Ex19del, L858R, G719X, S768I, or L861Q], either alone or in combination with other EGFR mutations, which may include T790M).
- Documented extra-cranial radiologic progression on prior osimertinib monotherapy (as most recent line of treatment) in the adjuvant, locally advanced, or metastatic setting.
- Less than or equal to (<=2) prior lines of EGFR TKIs (osimertinib is the only permitted prior third generation EGFR TKI).
- At least one lesion, not previously irradiated, that qualifies as a RECIST v1.1 TL at baseline and can be accurately measured at baseline.
- World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
- Adequate bone marrow reserve and organ function within 7 days before randomization.

Exclusion Criteria:

- Use of chemotherapy, vascular endothelial growth factor inhibitor, immunotherapy or any anti-cancer therapy in the metastatic setting. Platinum-based chemotherapy in non-metastatic setting within 12 months prior to randomization.

- History of another primary malignancy except for malignancy treated with curative intent with no known active disease within 2 years before the first dose of study intervention.
- Any evidence of severe or uncontrolled systemic diseases, including, but not limited to active bleeding diseases, active infection, active ILD/pneumonitis, cardiac disease.
- Has significant third-space fluid retention (example [eg.], ascites or pleural effusion) as judged by the investigator and is not amenable for required repeated drainage.
- History of non-infectious ILD/pneumonitis including radiation pneumonitis that required steroids or drug-induced ILD, has current ILD/pneumonitis, or has suspected ILD/pneumonitis that cannot be ruled out by imaging at screening.
- Has severe pulmonary function compromise resulting from intercurrent pulmonary illnesses.
- Unstable spinal cord compression and/or unstable brain metastases.
- Participants with symptomatic brain metastases (including leptomeningeal involvement).
- Clinically significant corneal disease.
- Uncontrolled infection requiring IV antibiotics, antivirals, or antifungals, suspected infections or inability to rule out infections.
- Has known human immunodeficiency virus (HIV) infection that is not well controlled.