

LUN100_Inclusion criteria

Inclusion

Patients with the following pathologically documented NSCLC that meets all of the following criteria:

- Has documented evidence of Stage IV NSCLC disease at the time of enrollment
- Has documented negative test results for EGFR and ALK
- Tumor tissue testing is required if EGFR, ALK, or PD-L1 when status is unknown
- Has **no** known genomic alterations in ROS1, NTRK, BRAF, RET mutations, or other actionable driver oncogenes with approved therapies for frontline treatment (actionable genomic alteration).
- Formalin fixed specimens after the patient has been diagnosed with metastatic disease will be preferred for evaluation of Trop-2 expression and determination of PD-L1 status prior to enrollment if not already performed by an approved 22C3 assay.
- Biopsies obtained prior to receipt of adjuvant/neoadjuvant chemotherapy will be permitted if recent biopsy is not feasible.
- Bone biopsies and fine-needle aspirations are not suitable tissues.
- If no tissue is available, a new biopsy may be obtained prior to enrollment to the study.
- No prior systemic treatment for mNSCLC.
- Patients who received adjuvant or neoadjuvant therapy are eligible if the adjuvant/neoadjuvant therapy was completed at least 6 months prior to the development of metastatic disease for a platinum agent.
- ECOG performance status score of 0 or 1 assessed within 7 days prior to treatment