

LUN099_Inclusion Criteria

Inclusion:

1. Histologically or cytologically confirmed diagnosis of NSCLC with *KRAS* G12C mutation.
2. Receipt of prior treatment with a platinum (cisplatin or carboplatin)-containing regimen and an immune checkpoint inhibitor (i.e., anti-PD-1/PD-L1 inhibitor) concurrently or sequentially for advanced or metastatic disease with the outcome of objective disease progression on or after treatment. Source documents for historical disease evaluations to allow Investigator certification of disease progression on or after prior treatment must be available.
3. Candidacy to receive treatment with docetaxel in accordance with the local product label.
4. Metastatic disease.
5. Presence of evaluable or measurable disease per RECIST version 1.1.
6. Expected availability of representative tumor specimen (primary or metastatic, archival or newly obtained) for central laboratory testing of *KRAS* G12C mutation status and correlative gene alterations (minimum of 5 slides, preferably 15 slides).
7. Age ≥ 18 years.
8. Life expectancy of at least 3 months.
9. Recovery from the adverse effects of prior therapy to baseline or Grade 1 (excluding alopecia).
10. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
11. Laboratory values within the screening period:
 - a. Absolute neutrophil count $\geq 1,500/\text{mm}^3$ ($\geq 1.5 \times 10^9/\text{L}$)
 - b. Platelet count $\geq 100,000/\text{mm}^3$ ($\geq 100 \times 10^9/\text{L}$)
 - c. Hemoglobin ≥ 9 g/dL, in the absence of transfusions for at least 2 weeks
 - d. Total bilirubin ≤ 1 upper limit of normal (ULN)
 - e. Aspartate transaminase (AST) and alanine transaminase (ALT) $\leq 1.5 \times \text{ULN}$; if associated with liver metastases, $\leq 5 \times \text{ULN}$. If alkaline phosphatase $> 2.5 \times \text{ULN}$, then ALT and AST must be $\leq 1.5 \times \text{ULN}$ with or without liver metastases.
 - f. Creatinine clearance ≥ 60 mL/min
12. Women of child-bearing potential (WOCBP) or men whose partner is a WOCBP agrees to use contraception while participating in this study, and for a period of 6 months following termination of study treatment.
13. Completed informed consent process, including signing IRB/EC-approved informed consent form.
14. Willing to comply with clinical trial instructions and requirements.