

APPENDIX
Abemaciclib in combination with single-agent options in patients
with stage IV non–small cell lung cancer (NSCLC): A phase 1b study

ES Kim et al.

Key Eligibility Criteria

1. Patients >18 years old diagnosed with stage IV NSCLC. Patients with known EGFR activating mutations or ALK alterations should have received and progressed after appropriate tyrosine kinase inhibitor or ALK-targeted therapy prior to enrollment.
2. Part A: nonsquamous NSCLC only; Parts B and C: any NSCLC histology
3. Received the following number of prior therapies for advanced/metastatic NSCLC:
 - Part A: one to three prior therapies, including one platinum-based chemotherapy. Patients who received pemetrexed as first-line or maintenance therapy must have an interval of at least 3 months since the last pemetrexed treatment.
 - Part B: one to three prior therapies
 - Parts C: two to three prior therapies
4. Adequate organ function
5. Measurable or nonmeasurable disease as defined by RECIST v1.1
6. Eastern Cooperative Oncology Group Performance Status (ECOG PS) ≤ 1
7. Discontinued all prior therapies for cancer (≥ 21 days for myelosuppressive agents, ≥ 14 days for non-myelosuppressive agents) prior to receiving study drug
8. No history of syncope of unexplained or cardiovascular etiology, ventricular arrhythmia, or sudden cardiac arrest
9. Central nervous system (CNS) metastases:
 - Parts A and B can have history of CNS metastasis, but remain asymptomatic and no evidence of neurological changes 14 days prior to receiving study drug. Untreated CNS metastases are not permitted.
 - Part C patient must not have known history or evidence of CNS metastases. Baseline screening is required.