

S1400K PROTOCOL CARD

Lung cancer
Protocol Version Date: 01/08/18

A PHASE II STUDY OF ABBV-399 (Process II) IN PATIENTS WITH C-MET POSITIVE STAGE IV OR RECURRENT SQUAMOUS CELL LUNG CANCER (LUNG-MAP SUB-STUDY)

*Note: Patients must first be registered to S1400, and then be assigned to a sub-study.
Patients must meet the eligibility criteria in section 5.0 of S1400K.*

Eligibility Criteria

- Must be assigned to **S1400K**. The c-Met testing will be performed at a protocol specified central laboratory. The S1400K biomarker eligibility defined as C-Met positive squamous cell is as follows:

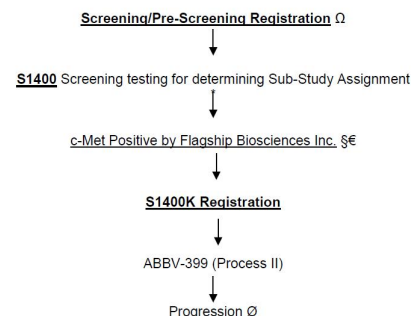
Analyte	Assay	Eligible definition
c-Met	Immunohistochemistry	IHC positive based on Ventana SP44 Assay (H score ≥ 150)

- Must have progressed during or after prior platinum-based chemotherapy. For Stage I-III disease patients, progression on platinum-based chemotherapy must have occurred within one year from the last date that patient received that therapy. See Section 5.1.b.
- Must not have peripheral edema > Grade 1, or peripheral neuropathy > Grade 1 at the time of sub-study registration.
- Must not have received prior treatment with c-Met pathway inhibitors.
- Must not be taking strong CYP3A4 inhibitors within 7 days prior to sub-study registration, nor plan to take while on protocol treatment and for 14 days after the last dose of study treatment. (see **S1400K** Section 7.2).
- Must have albumin ≥ 3.0 g/dL within 28 days prior to sub-study registration.
- Must have adequate hepatic function as defined by serum bilirubin \leq Institutional Upper Limit of Normal (IULN) and either ALT or AST $\leq 2.5 \times$ IULN (if both ALT and AST are done, both must be < 2.5 IULN) and gamma-glutamyl transferase (GGT) $\leq 5 \times$ ULN within 28 days prior to sub-study registration.
- Patients with extensive metastatic liver disease involving $\geq 50\%$ of the liver in the judgment of the Investigator or sum of longest diameters of RECIST measurable liver lesions ≥ 10 cm will not be enrolled.
- Must not be pregnant or nursing and agree to use an effective contraceptive method.
- Must agree to have blood specimens submitted for pharmacokinetic analysis as outlined in S1400K Section 15.3
- Must be offered participation in banking for future use of specimens.

**THIS INFORMATION IS INTENDED TO BE USED AS A SCREENING
TOOL ONLY AND SHOULD NOT BE USED IN PLACE OF THE
PROTOCOL.**

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Schema



Ω See **S1400** Section 5.1 for screening/pre-screening registration information.

€ Notification of sub-study assignment will be provided by the SWOG Statistics and Data Management Center (SDMC) (see **S1400** Section 11.0 for details).

§ See **S1400K** Section 5.0 for the definition of c-Met Positive by Flagship Biosciences Inc. criteria.

Ø Upon progression (as defined in **S1400K** Section 10), patients may be eligible for another sub-study. The new sub-study assignment will be determined by the SWOG SDMC (see **S1400K** Section 14.4).

Required Pre-Study Laboratory / Tests

(To be completed within 28 days prior to sub-study randomization unless specified otherwise)

Requirement

Criteria

- | | |
|---------------------------------------|--|
| • Required Physical Studies | |
| • Disease Assessment | |
| • CBC/Diff | |
| • ANC | $\geq 1500/\text{mcl}$ |
| • Platelet | $\geq 100,000/\text{mcl}$ |
| • Hemoglobin | $\geq 9 \text{ g/dL}$ |
| • Serum Bilirubin | \leq IULN ($\leq 5 \times$ IULN for patients with liver metastases) |
| • AST, ALT, or both | $\leq 2 \times$ IULN ($\leq 5 \times$ IULN for patients with liver metastases) |
| • Serum Creatinine | \leq IULN; or measured or calc. CC $\geq 50 \text{ mL/min}$ using Cockcroft-Gault Formula; multiply the calc. CC by 0.85 for female patients |
| • Calc CrCL | |
| • GGT | |
| • Albumin, GGT, Magnesium, Phosphorus | |
| • CT/MRI | For disease assessment |
| • CT/MRI of the brain | within 42 days prior to sub-study registration |
| • Testosterone | Males only |
| • Smoking Status Assessment | |
| • Image submission | |
| • Blood for banking | Optional, with consent |