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 ≤ Institutional Upper Limit of Normal (IULN) and either ALT or AST ≤ 2.5 x IULN (if both ALT and AST are done, both must be < 2.5 IULN) and gamma-glutamyl transferase (GGT) ≤5 x ULN within 28 days prior to sub-study registration.
- Patients with extensive metastatic liver disease involving ≥ 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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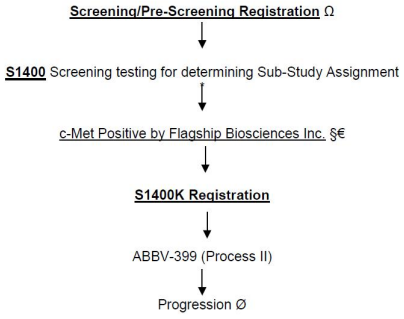
Schema



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	≥ 1500/mcl
• Platelet	≥ 100,000/mcl
• Hemoglobin	≥ 9 g/dL
• Serum Bilirubin	≤ IULN (≤ 5 x IULN for patients with liver metastases)
• AST, ALT, or both	≤ 2 x IULN (≤ 5 x IULN for patients with liver metastases)
• Serum Creatinine	≤ IULN; or measured or calc. CC ≥ 50 mL/min using Cockroft-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