S1400 PROTOCOL CARD

Lung cancer
Protocol Version Date: 09/01/17

A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (LUNG-MAP)

Screening/Pre-screening Registration Eligibility

- Must have pathologically proven squamous cell carcinoma (SCCA) cancer of the lung confirmed by biopsy and/or FNA. Disease must be Stage IV SCAA as defined in section 4.0 or recurrent. Primary diagnosis of SCCA should be established using the current WHO/IASCLC-classification of Thoracic Malignancies. Mixed histologies are not allowed.
- To be eligible for screening at progression, must have at least one line of systemic therapy for any stage of disease (Stages I-IV) and must have progressed during or following most recent line of therapy. Patients whose prior systemic therapy was for Stage I-III disease only (i.e. has not received any treatment for Stage IV or recurrent disease), disease progression on platinum-based chemotherapy must occurred within one year from last therapy date. Patients whose prior therapy for Stage IV or recurrent disease must have at least one line of a platinum-based chemotherapy regimen or checkpoint inhibitor therapy (e.g. Nivolumab or Pembrolizumab).
- To be eligible for pre-screening, current treatment must be for Stage IV or recurrent disease and must have received at least one dose of the current regimen. Patients must have previously received or currently receiving platinum-based chemotherapy regimen or checkpoint inhibitor therapy (e.g. Nivolumab or Pembrolizumab). Patients on first-line platinum-based are eligible upon receiving Cycle 1, Day 1 infusion.
- Must have adequate tumor tissue, defined as $\geq$ 20% tumor cells and $\geq$ 0.2 mm^3 tumor volume.
- Must *not* have a known EGFR mutation or ALK fusion. EGFR/ALK testing is not required prior to registration and is included in the FMI testing for screening/prescreening.
- Must have Zubrod PS 0-1 documented within 28 days prior to screening/pre-screening registration and must be $\geq$ 18 years of age.
- Must be offered participation in banking for future use of specimens.
- Must be willing to provide prior smoking history.

Sub-study Eligibility

These criteria apply to all sub-studies. Additionally, each sub-study has its own set of eligibility criteria (see the protocol and the sub-study Protocol Cards). For patients screened at progression on prior treatment, a sub-study assignment from the SWOG Statistical Center should be received within 16 days of screening registration. For patients pre-screened prior to progression on current therapy, submission of the S1400 Notice of Progression Form is required to receive a sub-study assignment. The sub-study assignment should be received from the SWOG Statistical Center within 1 day of submission of the S1400 Notice of Progression (provided at least 16 days have passed since tissue submission). Patients must then register to the assigned sub-study in order to receive their treatment assignment.

- Patients whose biomarker profiling results indicate the presence of an EGFR mutation or EML4/ALK fusion are not eligible.
- Must have measurable disease documented by CT or MRI as per protocol section 5.2.d.
- Must have CT/MRI of brain to evaluate for CNS disease within 42 days prior to sub-study registration.

Lung cancer
Protocol Version Date: 09/01/17

- Patient must not have leptomeningeal disease, spinal cord compression or brain metastases unless: (1) metastases have been locally treated and have remained clinically controlled and asymptomatic for at least 14 days following treatment and prior to registration, AND (2) patient has no residual neurological dysfunction and has been off corticosteroids for at least 24 hours prior to sub-study registration.
- Patients must have progressed (in the opinion of the treating investigator) following most recent line of therapy.
- Patients must *not* have received any prior systemic chemo or investigational drug within 21 days prior to sub-study randomization. Patients must have recovered ($\leq$ Grade 1) from any side effects of prior therapy. Patients must not have received any radiation therapy within 14 days prior to sub-study registration. (See 5.2e for criteria regarding therapy for CNS metastases).
- Must be fully recovered from the effects of surgery at least 14 days prior to sub-study registration.
- Must *not* be planning to receive any concurrent chemotherapy, immunotherapy, biologic or hormonal therapy for cancer treatment. Concurrent use of hormones for non-cancer-related conditions is acceptable.
- Must have adequate hepatic and liver functions, ANC, platelet, and hemoglobin, as indicated in the required lab test section of the sub-study specific protocol cards.
- Must have Zubrod PS 0-1 documented within 28 days prior to sub-study registration.
- Must *not* have any grade III/IV cardiac disease as defined by the NYHAC, unstable angina pectoris, and MI within 6 months, or serious uncontrolled cardiac arrhythmia.
- Must *not* have documented evidence of acute hepatitis or have an active or uncontrolled infection.
- Patients with known history of HIV seropositivity must have (1) undetectable viral load using standard HIV assays in clinical practice, (2) CD4 count $\geq$ 400/mcL, (3) not require prophylaxis for any opportunistic infections, and (4) not be newly diagnosed within 12 months prior to sub-study registration.
- Prestudy history and physical exam must be obtained within 28 days prior to sub-study registration.
- Must not have other prior malignancy except for the following: adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, adequately treated Stage I or II cancer from which the patient is currently in complete remission, or any other cancer from which the patient has been disease free for five year.
- Female patients must not be pregnant or nursing. Women/men of reproductive potential must have agreed to use an effective contraceptive method.
- As part of the OPEN registration process the treating institution's identity is provided in order to ensure the current date of IRB approval for the study is entered in the system.
- Patients with impaired decision-making capacity are eligible as long as their neurological or psychological condition does not preclude safe participation in the study.

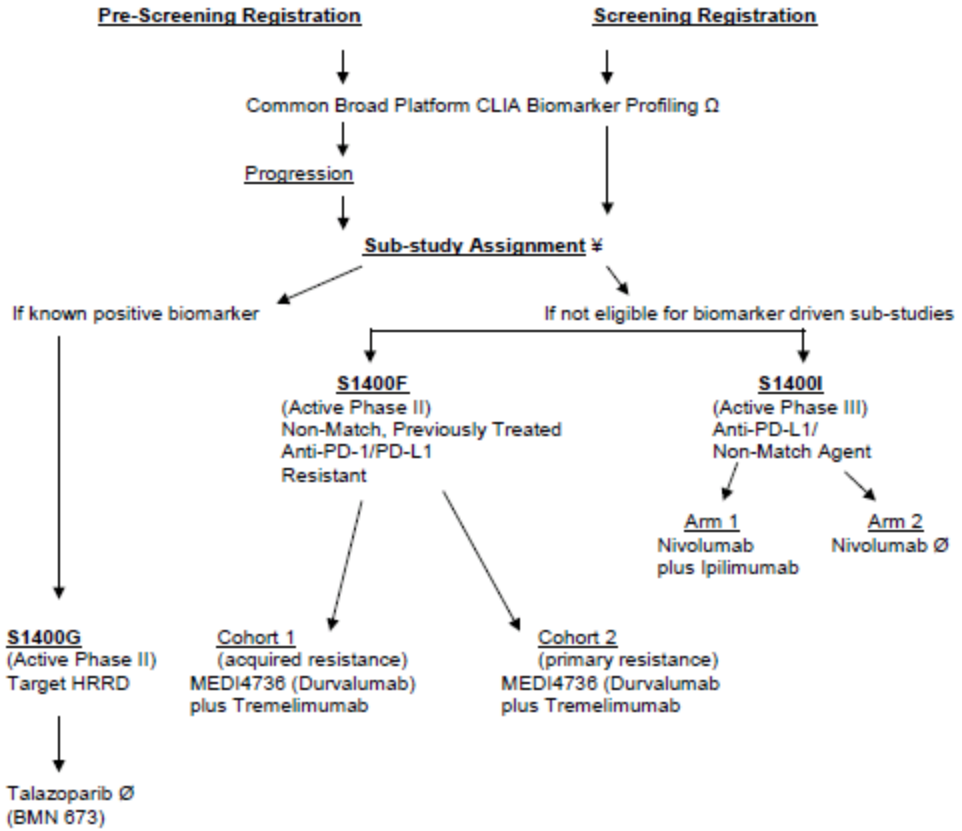
THIS INFORMATION IS INTENDED TO BE USED AS A SCREENING TOOL *ONLY* AND SHOULD NOT BE USED IN PLACE OF THE PROTOCOL.

CTSU Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
Linking practice to progress

NCI National Clinical Trials Network
a National Cancer Institute program

S1400 PROTOCOL CARD

SCHEMA



Ω Archival formalin-fixed paraffin-embedded (FFPE) tumor, fresh core needle biopsy if needed.

¥ Sub-study assignment will be determined by the SWOG Statistical Center. Sub-study assignment will be determined based on randomization for patients eligible for multiple sub-studies (see Section 11.0 for details).
Patients registered to the screening/pre-screening component, but not randomized to a treatment arm of any of the sub-studies will be followed until death or 3 years after screening/pre-screening registration, whichever comes first.

Ø Upon progression (as defined in Section 10.2d in **S1400**), patients may be eligible for another sub-study. The new sub-study assignment will be determined by the SWOG Statistical Center. (see Section 14.6).