FAST FACTS

S1400, “A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer”

S1400B, “A Phase II Study of GDC-0032 (Taselisib) for Previously Treated PI3K Positive Patients with Stage IV Squamous Cell Lung Cancer (Lung-MAP Sub-Study)”

Drug Supplied: GDC-0032
(a potent, selective small molecule inhibitor of Class I PI3K)

Patient must meet the eligibility criteria in Section 5.0 of S1400B to be eligible for S1400B. If the patient does not meet the sub-study specific eligibility criteria listed in Section 5.1 and Section 5.2 of S1400B, but meets the common sub-study criteria listed in Section 5.3 of S1400B, submit the S1400 Request for Sub-Study Reassignment Form for sub-study reassignment.

Disease Related Criteria
1. Patients must be assigned to S1400B. S1400B biomarker eligibility defined as PI3K Positive is as follows:

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<tr>
<th>Gene</th>
<th>Alteration Type</th>
<th>Eligible Alteration</th>
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Clinical Laboratory Criteria
1. Patients must have a HbA1c < 7% and fasting glucose < 125mg/dL obtained within 28 days prior to sub-study registration.
2. Patients must not have type I or II diabetes that requires anti-hyperglycemic medication.
3. Patients must not have active or a history of small or large intestine inflammation such as Crohn’s disease or ulcerative colitis.
4. Patients must not require daily supplemental oxygen
5. Patients must be able to take oral medications. Patients may not have any impairment of gastrointestinal function or gastrointestinal disease that may significantly alter the absorption of GDC-0032 (e.g. ulcerative disease, uncontrolled nausea, vomiting, diarrhea, malabsorption syndrome, or small bowel resection).
6. Patients must not be taking, nor plan to take while on protocol treatment and for 14 days post the last dose of study treatment, drugs, herbal supplements or foods that are known to be strong/moderate CYP3A4 substrates. A list of these medications can be found in Section 7.4 of this sub-study.
7. Patients must have a Lipase and Amylase performed within 7 days prior to substudy registration. Additional timepoints are noted in Section 9.0, Study Calendar.
8. Patients must be offered participation in banking for future use of specimens as described in section 15.0.
9. Patients must not have received any prior systemic therapy (systemic chemotherapy, immunotherapy or investigational drug) within 21 days prior to sub-study registration. Patients must not have received any radiation therapy within 14 days prior to sub-study registration. (See 5.3e for criteria regarding therapy for CNS metastases).

TREATMENT – S1400B

Patients will be registered to the following treatment arm:

Arm 1: GDC-0032 4 mg PO Daily Continuous
Patients must take the GDC-0032 at the same time of day ± 2 hours, unless otherwise instructed and regardless of meals.

A cycle of treatment is 21 days. Disease assessment must occur every 6 weeks. Treatment will continue until any of the criteria in section 7.5 is met. Dexamethasone may be administered per local institutional guidelines.

PRE-STUDY PARAMETERS

- History, physical examination weight, ECOG Performance Status
- Disease and toxicity assessment
- CBC, CMP, LDH, calculated creatinine clearance
- HBA1c, fasting glucose, lipase and amylase
- CT or MRI for disease assessment
- Brain CT/MRI
- Tissue for biomarker profiling and banking
- Serum for banking
- Image submission