Version: 03/14/17

NCI National Clinical Trials Network

S1400G

S1400G Available Through the CTSU

A Phase II Study of Talazoparib (BMN 673) in Patients with Homologous Recombination Repair Deficiency Positive Stage IV Squamous Cell Lung Cancer (LUNG-MAP Sub-Study)

Patient Population

See Sub-Study Section 5.0 for Full Eligibility Details

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 S1400IG.

- Must be assigned to S1400G. S1400G biomarker eligibility defined as Homologous Recombination Repair Deficiency (HRRD) Positive per Section 5.1a criteria.
- Must not have had prior exposure to any agent with a PARP inhibitor (e.g., veliparib, olaparib, rucaparib, niraparib, talazoparib [BMN 673]) as its primary pharmacology. See Section 5.1.b.
- Must have achieved stable disease, a partial response, or a complete response at their first disease assessment after initiating firstline platinum-based chemotherapy. Patients determined to have progressed (in the opinion of the treating physician) at their first disease assessment are not eligible.
- Must not have any impairment of gastrointestinal function or gastrointestinal disease that may significantly alter the absorption of talazoparib (BMN 673) (e.g., ulcerative disease, uncontrolled nausea,vomiting, diarrhea, malabsorption syndrome, small bowel resection, or active peptic ulcer disease).
- Must not have active small or large intestine inflammation such as Crohn's disease or ulcerative colitis (within 12 months of sub-study registration).
- Must be able to take oral medications. Patients must be able to swallow capsules whole without crushing or altering them in any way.
- Must not be taking, nor plan to take while on protocol treatment strong P-gp inhibitors, P-gp inducers, or BCRP inhibitors (see Section 3.1.c.3 for list of medications).
- Must agree to have blood specimens submitted for pharmacokinetic analysis as outlined in Section 15.3.

Treatment Plan

See Sub-Study Section 7.0 for Full Treatment Details

Arm 1: Talazoparib
1000 mcg PO Daily Continuous

* A cycle of treatment is 21 days. Disease assessment must occur every 6 weeks. Treatment will continue until any of the criteria in Section 7.4 is met.

Number of Participants: 64 patients will be registered to this sub-study.

S1400G Sub-Study Chairs:

NCTN Group: ECOG-ACRIN
Taofeek K. Owonikoko, M.D., Ph.D. MSCR

NCTN Group: SWOG
Lauren A. Byers, M.D.

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org/open

Protocol Information

CTSU Help Desk: CTSUcontact@westat.com, 1-888-823-5923, www.ctsu.org
Eligibility Related Questions: S1400Question@crab.org, 206-652-2267.

Please Enroll Your Eligible Patients!

For

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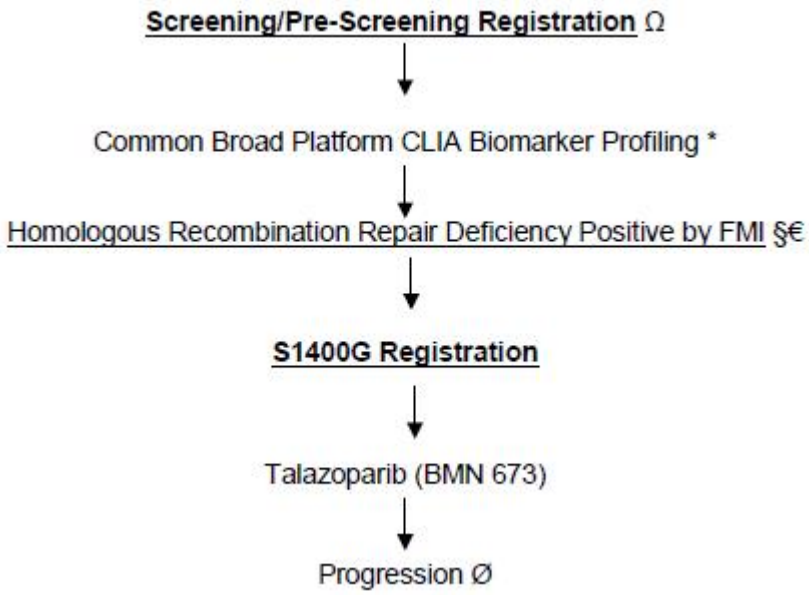
(LUNG-MAP Sub-Study)

Schema



Ω See **S1400** Section 5.1 for screening/pre-screening registration information.
* Archival formalin-fixed paraffin-embedded (FFPE) tumor, fresh core needle biopsy if needed
€ Notification of sub-study assignment will be provided by the SWOG statistical center (see Section 11.0 in **S1400** for details).
§ See Section 5.0 for the definition of Homologous Recombination Repair Deficiency Positive by FMI criteria.
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 14.4).