For Patients with Small Cell Lung Cancer

E2511 Available Through ECOG-ACRIN

Phase I and Randomized Phase II Double Blind Clinical Trial of Cisplatin and Etoposide in Combination with Veliparib (ABT-888) or Placebo as Frontline Therapy for Extensive Stage Small Cell Lung Cancer

Patient Population
See Section 3.0 for Complete Eligibility Details

Phase I Registration (Arms A, B, or C):
- Age ≥ 18, ECOG PS of 0 or 1, and adequate lab values
- Must have histologically or cytologically confirmed extensive stage small cell lung cancer or Stage IV (M1a/ M1b) large cell neuroendocrine NSCLC, or small cell carcinoma of unknown primary or extrapulmonary origin and must be a candidate for systemic therapy
- Must have measurable or non-measurable disease
- No CNS metastases or active seizures, or a history of either
- No prior chemotherapy or biologic therapy for SCLC, large cell neuroendocrine NSCLC, or small cell carcinoma of unknown primary/extrapulmonary origin. Patients receiving prior RT cannot register within 7 days after completion of RT, and must have resolved AEs attributed to RT to ≤ gr1. No previous irradiation to the only site of measurable or evaluable disease, unless that site had subsequent evidence of progression
- No history of allergic reactions attributed to compounds of similar chemical or biologic composition to Veliparib or other agents used in the study
- Must not have uncontrolled intercurrent illness (see protocol for examples)
- HIV-positive patients on combination antiretroviral therapy are ineligible
- Must be able to swallow pills

Phase II Randomization (Arms D and E):
- Must have extensive stage, histologically/cytologically confirmed small cell lung cancer
- Must have measurable disease, and adequate lab values
- No prior chemotherapy or biologic therapy for small cell lung cancer

Treatment Plan
See Section 5.0 for Complete Treatment Details

Cycle = 3 wks (21 days). A maximum of 4 cycles of therapy will be given.

Phase I Administration (Arms A, B, and C):
Arm A (Dose Level 1)
- Veliparib 60mg po BID, days 1-7
- Etoposide 100mg/m² IV over 60-120 mins, days 1-3
- Cisplatin 75mg/m² IV over 60-120 mins, day 1

Arm B (Dose Level 2)
- Veliparib 100mg po BID, days 1-7
- Etoposide 100mg/m² IV over 60-120 mins, days 1-3
- Cisplatin 75mg/m² IV over 60-120 mins, day 1

Arm C (Dose Level 1)
- Veliparib 40mg po BID, days 1-7
- Etoposide 100mg/m² IV over 60-120 mins, days 1-3
- Cisplatin 75mg/m² IV over 60-120 mins, day 1

Phase II Administration (Arms D and E):
Arm D
- Veliparib 100mg po BID days 1-7
- Etoposide 100mg/m² IV over 60-120 mins, days 1-3
- Cisplatin 75mg/m² IV over 60-120 mins, day 1

Arm E
- Placebo 100mg po BID days 1-7
- Etoposide 100mg/m² IV over 60-120 mins, days 1-3
- Cisplatin 75mg/m² IV over 60-120 mins, day 1

Day 1: Pre-medications for etoposide will be given, followed by the veliparib/placebo pills and then etoposide IV, followed by the pre-hydration for cisplatin, then cisplatin IV with post-cisplatin hydration. Cisplatin may be administered of Day 1 per institutional guidelines. Day 2-3: Etoposide pre-medications followed by the veliparib/placebo pills, then etoposide only and evening dose of veliparib/placebo at home. Etoposide may be given on days 2-3 per institutional guidelines. Days 4-7: Veliparib/placebo po BID at home. Days 8-21: Rest.

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

Protocol Information

Please Enroll Your Eligible Patients!
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Participants on Phase I = 18 / Participants on Phase II = 150

Refer to the Protocol for the Phase I Schema. Phase I accrual is closed & Arm B was established as the RP2D.