M14-361
Dose Escalation and Double-blind Study of Veliparib in Combination with Carboplatin and Etoposide in Treatment-naïve Extensive Stage Disease Small Cell Lung Cancer

**Patient Population**

- Extensive-Stage Disease (ED) SCLC
  - No CNS involvement
  - Treatment naïve

**Combination Treatment**

- Up to four 21-day cycles of combination chemotherapy
  - Carboplatin AUC 5 D1
  - Etoposide 100 mg/m² D1-3
  - Veliparib/placebo dosed orally at 240 mg BID for 14 days (CxD-2 to CxD12)

**Maintenance Treatment**

- Until disease progression or unacceptable toxicity
  - Veliparib 400 mg BID or
  - Placebo BID

**Phase 1 Dose Escalation**

Carboplatin, etoposide, veliparib (up to 4 cycles)

- Veliparib Dls: 80, 120, 160, 200, 240 mg BID

Veliparib, 400 mg BID

240 mg BID selected as RPTD

**Phase 2 Study Design**

1:1:1 Randomization (Double Blinded)

**Arm A**

N = 60

- Veliparib 240 mg / carbo / etoposide +
  - Veliparib monotherapy maint.

**Arm B**

N = 60

- Veliparib 240 mg / carbo / etoposide +
  - Placebo monotherapy maint.

**Arm C**

N = 60

- Placebo / carbo / etoposide +
  - Placebo monotherapy maint.

**Stratification Factors:**

- Baseline LOH (< ULN versus > ULN) and gender

**Phase 1 Dose Escalation Primary Endpoint**

- To establish recommended dose for veliparib in combination with carboplatin / etoposide

**Randomized Double Blind Phase 2 Primary Endpoint**

- To evaluate if veliparib (V) in combination with carboplatin (C) and etoposide (E) followed by V maintenance (Arm A) results in improved progression-free survival (PFS) vs. placebo (P) in combination with C and E followed by P maintenance (Arm C) in subjects with treatment-naïve ED SCLC

Veliparib is an investigational drug which has not been approved by regulatory health agencies. Efficacy and safety have not been established.


To learn more about our pipeline, please visit www.abbviescience.com/oncology

To learn more about these studies, please visit https://ClinicalTrials.gov or email abbvieclinicaltrials@abbvie.com