## Phase 3 Tahoe (M16-289)
### Study Design and Endpoints
A randomized, open-label, multicenter study comparing the efficacy, safety and tolerability of rovalpituzumab tesirine versus topotecan for high DLL3 expressing SCLC subjects with first relapse/recurrence following front-line platinum-based chemotherapy (TAHOE).

### Patient Population
- 18 years to 99 years of age
- Advanced or metastatic SCLC
- High DLL3 expression as determined by central immunohistochemistry laboratory

### Subjects will be randomized in 2:1 ratio

**Rova-T: Topotecan**

N = 411

**Rova-T**
Day 1 of each 6-week cycle for 2 cycles

**Topotecan**
Days 1 through 5 of each 3-week cycle

### Endpoints
#### Primary Endpoints
- Objective response rate
- Overall survival

#### Secondary Endpoints
- Progression-free survival
- Duration of objective response
- Change from baseline in physical functioning (Patient reported outcomes)

### Key Inclusion Criteria
- Adults aged 18 years or older
- Histologically or cytologically confirmed advanced or metastatic SCLC with documented first disease progression during or following front-line platinum-based systemic regimen
- High DLL3 expression in the tumor (≥ 75% tumor cells staining)
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Measurable disease, as defined per response evaluation criteria in solid tumors RECIST version 1.1 per the Central Radiographic Assessment Committee
- Subjects with a history of CNS metastases must have not active CNS disease

### Key Exclusion Criteria
- Documented history of a cerebral vascular event (stroke or transient ischemic attack), unstable angina, myocardial infarction, or cardiac symptoms consistent with New York Heart Association (NYHA) Class III-IV within 6 months prior to their first dose of study drug
- Known leptomeningeal metastases
- Prior exposure to >1 systemic therapy regimen for SCLC (front line platinum based regimen)
- Recent (within 2 weeks prior to randomization) or ongoing serious infection
- History of active malignancies other than SCLC within 2 years prior to study entry
- Prior exposure to pyrrolobenzodiazepine (PBD), topotecan, irinotecan, or any other topoisomerase I inhibitors

---

*Rova-T is an investigational drug which has not been approved by regulatory health agencies. Safety will be assessed by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE Version 4.0) and as defined by study protocol.*


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