Rova-T IO Combination Study (M16-300)

Study Design and Endpoints[1]

Multicenter, Phase 1/2, open-label, study to assess the safety and efficacy of rovalpituzumab tesirine (Rova-T) administered in combination with nivoumab or nivolumab and ipilumumab in participants with extenisve-stage small cell lung carcinoma (SCLC)

Patient Population

- 18 years to 99 years of age
- Histologically or cytologically confirmed extensive stage SCLC with progressive disease after ≥1 platinum-based regimen

N = 90

Rova-T 0.3 mg/kg IV and nivolumab*

Rova-T 0.3 mg/kg IV and nivolumab* + ipilimumab 1 mg/kg IV

Rova-T 0.3 mg/kg IV and nivolumab* + ipilimumab 3 mg/kg IV

* various dose regimens

Endpoints

Primary Endpoints

- Dose-limiting toxicities (DLT)

Secondary Endpoints

- Overall response rate
- Clinical benefit rate
- Duration of response
- Progression-free survival
- Overall survival

Key Inclusion Criteria

- Participants with histologically or cytologically confirmed extensive-stage small cell lung cancer (SCLC) with progressive disease after at least one platinum-based chemotherapeutic regimen and with evaluable or measurable disease
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Adequate hematologic, hepatic, and renal function

Key Exclusion Criteria

- Active, known, or suspected autoimmune disease
- Prior exposure to an immuno-oncology or pyrrolobenzodiazepine (PBD)-based drug

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

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.

1. https://clinicaltrials.gov/ct2/show/NCT03026166 (accessed April 2018)

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

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