Phase 3 Meru (M16-298)
Study Design and Endpoints

A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Rovapituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects with Extensive Stage Small Cell Lung Cancer (MERU)

Patient Population
- Adults aged 18 years or older
- Histologically or cytologically confirmed extensive-stage disease SCLC with ongoing clinical benefit following platinum based therapy
- At least 3 but no more than 9 weeks between the last cycle of platinum-based chemotherapy and randomization
- Patients with a history of central nervous system (CNS) metastases prior to the initiation of first-line platinum-based chemotherapy must have received definitive local treatment and have documentation of stable or improved CNS disease status
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Adequate bone marrow, renal, and hepatic function
- Availability of archived or representative tumor material for assessment of DLL3 expression

Endpoints
- N=740

Primary Endpoints
- Progression-free survival
- Overall survival

Secondary Endpoints
- Objective response rate
- Change from baseline in physical functioning
- Clinical benefit rate
- Duration of response

Key Inclusion Criteria
- Adults aged 18 years or older
- Extensive-stage disease with ongoing clinical benefit (stable disease, partial response, or complete response) following completion of 4 cycles of first-line platinum based therapy
- At least 3 but no more than 9 weeks between the last cycle of platinum-based chemotherapy and randomization
- Patients with a history of central nervous system (CNS) metastases prior to the initiation of first-line platinum-based chemotherapy must have received definitive local treatment and have documentation of stable or improved CNS disease status
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Adequate bone marrow, renal, and hepatic function
- Availability of archived or representative tumor material for assessment of DLL3 expression

Key Exclusion Criteria
- Any prior systemic chemotherapy, small molecule inhibitors, immune checkpoint inhibitors, other monoclonal antibodies, antibody-drug conjugates, radioimmunoconjugates, T-cell or other cell-based or biologic therapies, or any other anti-cancer therapy than that described in inclusion criteria
- Any disease-directed radiotherapy (except prophylactic cranial irradiation or pre-planned radiotherapy for CNS metastases present prior to start of first-line therapy and non-progressing) after last dose of first-line chemotherapy
- Prior exposure to a pyrrolobenzodiazepine (PBD) – or indolinobenzodiazepine-based drug, prior participation in a rovalpituzumab tesirine clinical trial, or known hypersensitivity or other contraindications to rovalpituzumab tesirine or excipient contained in the drug formulation

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.

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

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