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

Target Population: Small Cell Lung Cancer (SCLC)

Summary: This is a Phase 3, randomized, double-blind, placebo-controlled, multinational, and multicenter study to evaluate the efficacy of Rovalpituzumab Tesirine as maintenance therapy following first-line platinum-based chemotherapy.

Key Inclusion Criteria:
- Histologically or cytologically confirmed extensive-stage disease Small Cell Lung Cancer (ED SCLC) with ongoing clinical benefit (stable disease [SD], partial response [PR], or complete response [CR]) following completion of 4 cycles of first-line platinum-based therapy.
- At least 3 but no more than 9 Weeks between the administration of the last cycle of platinum-based chemotherapy and randomization.
- Participants 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.
- ECOG Performance Score of 0 or 1.
- Participants must have 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)-based or Indolinobenzodiazepine-based drugs, prior participation in a Rovalpituzumab Tesirine clinical trial, or known hypersensitivity or other contraindications to Rovalpituzumab Tesirine or excipient contained in the drug formulation.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03033511