Rova-T Basket
Study Design and Endpoints

Multicenter, open-label, study to assess the safety and tolerability of rovalpituzumab tesirine (Rova-T) in subjects with specific delta-like protein 3 (DLL3) expressing advanced solid tumors

Patient Population

**Eight Patient Cohorts**
- Malignant melanoma
- Medullary thyroid cancer (MTC)
- Glioblastoma
- Large cell neuroendocrine carcinoma (LCNEC)
- Neuroendocrine prostate cancer (NEPC)
- High-grade gastroenteropancreatic neuroendocrine carcinoma (GEP NEC)
- Other NEC
- Other solid tumors

Endpoints

**Primary Endpoints**
- Maximum tolerated dose
- Adverse events

**Secondary Endpoints**
- Overall response rate
- Duration of response
- Progression-free survival
- Overall survival
- Clinical benefit rate
- Maximum plasma concentration (Cmax)
- Area under the curve (AUC)
- Anti-therapeutic antibodies (ATA)

Key Inclusion Criteria

- Histologically confirmed, unresectable advanced solid tumor with measurable disease, that is relapsed/refractory to prior standard systemic therapy
- DLL3 expression ≥1%
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Minimum life expectancy of at least 12 weeks
- Subjects with a history of central nervous system (CNS) metastases must have documentation of stable or improved brain imaging
- Adequate hematologic and organ function

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
- Recent or ongoing serious infection
- History of another invasive malignancy that has not been in remission for at least 3 years
- Prior exposure to a pyrrolobenzodiazepine (PBD)-based drug, prior participation in a Rova-T clinical trial
- Systemic therapy with corticosteroids at >20 mg/day within 1 week

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 these studies, please visit https://ClinicalTrials.gov

or email abbbvieclinicaltrials@abbvie.com

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