A Study to Investigate the Efficacy and Safety of Sonrotoclax Plus Zanubrutinib Compared With Placebo Plus Zanubrutinib in Adults With Relapsed/Refractory Mantle Cell Lymphoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Histologically confirmed diagnosis of MCL based on the World Health Organization 2022 classification of Haematolymphoid Tumors (WHO-HAEM5), or based on International Consensus Classification (ICC) * Received 1 to 5 prior lines of systemic therapy including an anti-CD20 monoclonal antibody (mAb)-based immunotherapy or chemoimmunotherapy and requiring treatment in the opinion of the investigator * Relapsed or refractory disease after the last line of therapy * Measurable disease defined as ≥ 1 nodal lesion that is \> 1.5 cm in longest diameter, or ≥ 1 extranodal lesion that is \> 1 cm in longest diameter * Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2 * Adequate organ function

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Exclusion Criteria:

* Prior therapy with B-cell lymphoma-2 inhibitor * Prior therapy with covalent or non-covalent Bruton tyrosine kinase inhibitor (BTKi) unless the participant was intolerant of non-zanubrutinib covalent or non-covalent BTKi * Prior autologous stem cell transplantation or chimeric antigen receptor T-cell therapy within 3 months before first dose of study drug * Prior allogeneic stem cell transplant within 6 months of the first dose of the study drug * Known central nervous system involvement by lymphoma * Clinically significant cardiovascular disease * History of stroke or intracranial hemorrhage within 6 months before first dose of study drug Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Conditions & Interventions

Interventions:
DRUG: Sonrotoclax, DRUG: Zanubrutinib, DRUG: Placebo
Conditions:
Mantle Cell Lymphoma, B Cell Lymphoma
Keywords:
mantle cell lymphoma, MCL, relapsed/refractory mantle cell lymphoma, sonrotoclax

More Information

Contact(s): Study Director - clinicaltrials@beigene.com
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT06742996

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