A Study to Investigate Efficacy and Safety of BCL2 Inhibitor Sonrotoclax as Monotherapy and in Combination With Zanubrutinib in Adults With Waldenström Macroglobulinemia

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Clinical and definitive histologic diagnosis of WM. * Meeting ≥ 1 criterion for treatment according to consensus panel criteria from the 2nd International Workshop on Waldenström's Macroglobulinemia (IWWM). * For Cohorts 1-3, refractory or relapsed disease at study entry unless participants had intolerance to the most recent therapy. Refractory disease is defined as not attaining at least a major response, or progressing while on or within 6 months of completing therapy. Relapsed disease is defined as attaining at least a major response to therapy and meeting the criteria for disease progression beyond 6 months after completing therapy. * For Cohort 4, patients must not have received prior therapy for WM (except for plasmapheresis). * Adequate organ function.

Exclusion Criteria:

* Central nervous system (CNS) involvement by WM. * Transformation to aggressive lymphoma, such as diffuse large B-cell lymphoma. * History of other malignancies ≤ 2 years before study entry. * Uncontrolled active systemic infection or recent infection requiring parenteral antimicrobial therapy that was completed ≤ 14 days before the first dose of the study drug. Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Conditions & Interventions

Interventions:
DRUG: Sonrotoclax, DRUG: Zanubrutinib
Conditions:
Waldenstrom Macroglobulinemia, Waldenstrom's Macroglobulinemia Recurrent, Waldenstrom's Macroglobulinemia Refractory
Keywords:
Waldenström's macroglobulinemia, Waldenstrom's Macroglobulinemia Recurrent, Waldenstrom's Macroglobulinemia Refractory, Lymphoma, BGB-11417, BCL-2i

More Information

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Phase: PHASE2
IRB
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