A Dose-Escalation and Expansion Study of BGB-16673 in Participants With B-Cell Malignancies

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria : 1. Confirmed diagnosis (per World Health Organization (WHO) guidelines, unless otherwise noted) of one of the following: Marginal Zone Lymphoma (MZL) , Follicular Lymphoma (FL), R/R Mantle Cell Lymphoma (MCL), R/R chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL), Waldenström macroglobulinemia (WM), Diffuse large B-cell lymphoma (DLBCL), or \>2 treatments per the Richter's transformation to DLBCL. 2. Participants who have previously received a covalently-binding Bruton´s tyrosine kinase (BTK) inhibitor (BTKi) in any line of therapy must have received treatment with the BTK inhibitor for ≥ 8 weeks (unless reason for discontinuation is intolerance). 3. For dose-finding and dose-expansion, participants who had previously received a covalently-binding BTK inhibitor as monotherapy or in combination with other anticancer agents are eligible for the study if they meet any of the following criteria: discontinued the previous BTK inhibitor due to disease progression, experienced disease progression after completing treatment with a BTK inhibitor or discontinued the BTK inhibitor due to toxicity or intolerance. 4. Measurable disease by radiographic assessment or serum IgM level (WM only) 5. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2 6. Participants enrolling in the dose finding phase of the study may be previously treated with a BTKi or may be naïve to BTKi therapy depending on the diagnosis and country of enrollment; participants with MCL enrolling in the expansion cohorts (Phase 2) must have been treated with a BTKi in a prior line of therapy; CLL/SLL participants, in addition to being treated with a BTKi in a prior line of therapy, must also have received a Bcl-2 inhibitor in a prior line of therapy as well (Phase 2).

Exclusion Criteria:

1. Prior malignancy (other than the disease under study) within the past 2 years, except in situ malignancies that have been curatively resected, localized breast cancer treated with curative intent with no evidence of breast active disease for more than 3 years and receiving adjuvant hormonal therapy, localized Gleason score ≤ 6 prostate cancer undergoing observation or treatment with androgen depravation, or any other cancer treated with curative intent, not on adjuvant treatment, and in the opinion of the investigator is unlikely to recur. 2. Requires ongoing systemic treatment for any other malignancy 3. Requires ongoing systemic (defined as ≥ 10 mg/day of prednisone or equivalent) corticosteroid treatment. 4. Current or history of central nervous system involvement including the brain, spinal cord, leptomeninges, and cerebrospinal fluid (as documented by imaging, cytology, or biopsy) by B-cell malignancy, regardless of whether participants had received treatment for central nervous system disease 5. Known active plasma cell neoplasm, prolymphocytic leukemia, T-cell lymphoma, Burkitt lymphoma, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, Castleman disease, post-transplant lymphoproliferative disorders, hairy cell leukemia, germinal center B-cell (GCB), DLBCL, EBV+ DLBCL NOS, primary DLBCL of the central nervous system (CNS), primary cutaneous DLBCL

•leg type, DLBCL associated with chronic inflammation, primary mediastinal (thymic) large B-cell lymphoma, intravascular large B-cell lymphoma, ALK+ large B-cell lymphoma, primary effusion lymphoma, high-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements, high-grade B-cell lymphoma

•NOS, B-cell lymphoma unclassifiable with features intermediate between DLBCL and classical Hodgkin lymphoma, or history of or currently suspected transformation of an indolent lymphoma to an aggressive histology (except for participants with Richter Transformation to DLBCL are eligible for Part 1a, 1c, or Phase 2 and participants with history of follicular lymphoma transforming to non-GCB DLBCL who are eligible for Part 1a, 1c, or Phase 2). Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Conditions & Interventions

Interventions:

DRUG: BGB-16673

Conditions:

B-cell Malignancy, Marginal Zone Lymphoma, Follicular Lymphoma, Non-Hodgkin Lymphoma, Waldenstrom Macroglobulinemia, Chronic Lymphocytic Leukemia, Small Lymphocytic Lymphoma, Mantle Cell Lymphoma, Diffuse Large B Cell Lymphoma

More Information

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Principal Investigator:

Phase: PHASE1

IRB

Number:

System ID: NCT05006716
