A Study to Evaluate the Safety and Tolerability of BMS-986403 in Participants With Relapsed and/or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT05244070	RECRUITING	FEBRUARY 17, 2022	JULY 8, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to evaluate the safety and preliminary efficacy of BMS-986403 in participants with relapsed and/or refractory chronic lymphocytic leukemia (R/R CLL) or small lymphocytic lymphoma (SLL).

Condition or Disease: Leukemia, Lymphocytic, Chronic, B-Cell
Lymphoma

Intervention/treatment: Drug: BMS-986403
Drug: Fludarabine
Drug: Cyclophosphamide

Phase: Phase 1

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 40 participants

Allocation : Non-Randomized

Intervention Model : Single Group Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Study to Evaluate the Safety and Tolerability of BMS-986403 in Participants With Relapsed and/or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

Estimated Study Start Date: June 2022

Estimated Primary Completion Date: June 2027

Estimated Study Completion Date: June 2027

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: BMS-986403 + Fludarabine + Cyclophosphamide	Drug: BMS-986403 Specified dose on specified days Drug: Fludarabine Specified dose on specified days Drug: Cyclophosphamide Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures:
1. Number of participants with adverse events (AEs) [Time Frame: Up to 2 years after BMS-986403 infusion]
2. Number of participants with serious adverse events (SAEs) [Time Frame: Up to 2 years after BMS-986403 infusion]
3. Number of participants with clinical laboratory abnormalities [Time Frame: Up to 2 years after BMS-986403 infusion]
4. Number of participants with dose-limiting toxicity (DLT) [Time Frame: Up to 2 years after BMS-986403 infusion]
5. Maximum-tolerated dose (MTD) based on the incidence of DLTs that occur during the DLT evaluation period [Time Frame: Up to 2 years after BMS-986403 infusion]
6. Recommended Phase 2 Dose (RP2D) based on the incidence of DLTs that occur during the DLT evaluation period [Time Frame: Up to 2 years after BMS-986403 infusion]

Secondary Outcome Measures:
1. Overall response rate (ORR) [Time Frame: Up to 2 years after BMS-986403 infusion]
2. Complete remission rate (CRR) [Time Frame: Up to 2 years after BMS-986403 infusion]
3. Duration of response (DOR) [Time Frame: Up to 2 years after BMS-986403 infusion]
4. Duration of complete remission (DOCR) [Time Frame: Up to 2 years after BMS-986403 infusion]
5. Time to response (TTR) [Time Frame: Up to 2 years after BMS-986403 infusion]
6. Time to CR (TTCR) [Time Frame: Up to 2 years after BMS-986403 infusion]
7. Progression free survival (PFS) [Time Frame: Up to 2 years after BMS-986403 infusion]
8. Overall survival (OS) [Time Frame: Up to 2 years after BMS-986403 infusion]
9. Pharmacokinetics by polymerase chain reaction (PCR): Maximum concentration (Cmax) [Time Frame: Up to 2 years after BMS-986403 infusion]

10. Pharmacokinetics by PCR: Time to peak (maximum) concentration (Tmax) [Time Frame: Up to 2 years after BMS-986403 infusion]
11. Pharmacokinetics by PCR: Area under the curve (AUC) [Time Frame: Up to 2 years after BMS-986403 infusion]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and high-risk features must have failed at least 2 lines of prior therapy and participants with CLL or SLL and standard risk features must have failed at least 3 lines of prior therapy Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1 Either currently has central vascular access or is a candidate to receive central vascular access or peripheral vascular access for leukapheresis procedure Has recovery to Grade ≤ 1 or baseline of any non-hematologic toxicities due to previous therapy, except alopecia (any Grade acceptable) and peripheral neuropathy (Grade ≤ 2 acceptable)
Exclusion Criteria:
Any condition, including active or uncontrolled infection, or the presence of laboratory abnormalities, that places the subject at unacceptable risk if they were to participate in the study Systemic fungal, bacterial, viral, or other infection that is not controlled Active autoimmune disease requiring immunosuppressive therapy Progressive deep vein thrombosis or pulmonary embolism requiring treatment, but not yet on a stable anticoagulation regimen
Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Contact: BMS Study Connect Contact Center www.BMSStudyConnect.com 855-907-3286 Clinical.Trials@bms.com
Contact: First line of the email MUST contain the NCT# and Site #.

Locations

United States, Alabama	Local Institution	Birmingham
United States, California	Local Institution	Duarte
United States, Massachusetts	Local Institution	Boston
United States, New Jersey	John Theurer Cancer Center	Hackensack
United States, Ohio	University of Cincinnati Medical Center-University of Cincinnati Cancer Center	Cincinnati
United States, Ohio	Local Institution	Columbus
United States, Texas	Local Institution	Houston
United States, Washington	Local Institution	Seattle
United States, Wisconsin	Local Institution	Milwaukee
Canada, Alberta	Local Institution	Calgary
Canada, Nova Scotia	Local Institution	Halifax
Canada, Ontario	Local Institution	Toronto
France	Local Institution	Marseille
France	Local Institution	Rennes
France	Local Institution	Villejuif
Italy	Local Institution	Bergamo
Italy	Local Institution	Bologna
Italy	Local Institution	Milano
Spain	Local Institution	Barcelona
Spain	Local Institution	Madrid
Spain	Local Institution	Salamanca
United Kingdom	Local Institution	Cambridge
United Kingdom	Local Institution	Leeds
United Kingdom	Local Institution	London
United Kingdom	Local Institution	Manchester

Sponsors and Collaborators

Bristol-Myers Squibb

Investigator

Study Director :	Bristol-Myers Squibb	Bristol-Myers Squibb

MORE INFORMATION

Responsible Party :	Bristol-Myers Squibb
ClinicalTrials.gov Identifier :	NCT05244070
Other Study ID Numbers :	CA097-001, 2021-003274-31
First Posted :	February 17, 2022
Last Update Posted :	July 8, 2022
Last Verified :	July 2022
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Bristol-Myers Squibb:	*BMS-986403* *Relapsed and/or Refractory Small Lymphocytic Lymphoma (CLL)* *Chronic Lymphocytic Leukemia (SLL)*
Additional relevant MeSH terms :	*Lymphoma* *Leukemia* *Leukemia, Lymphoid* *Leukemia, Lymphocytic, Chronic, B-Cell* *Neoplasms by Histologic Type* *Neoplasms* *Lymphoproliferative Disorders* *Lymphatic Diseases* *Immunoproliferative Disorders* *Immune System Diseases* *Leukemia, B-Cell*