A Study to Assess the Effect of CC-95251 in Participants With Acute Myeloid Leukemia and Myelodysplastic Syndromes

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT05168202	RECRUITING	DECEMBER 23, 2021	MARCH 14, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to evaluate the safety, tolerability, and preliminary clinical activity of CC-95251 alone and in combination with antineoplastic agents in participants with relapsed or refractory acute myeloid leukemia and relapsed or refractory and treatment-naive higher risk melodysplastic syndromes.

Condition or Disease: Leukemia, Myeloid, Acute
Myelodysplastic Syndromes

Intervention/treatment: Drug: CC-95251
Drug: Azacitidine

Phase: Phase 1

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 30 participants

Allocation : Non-Randomized

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Study to Assess the Effect of CC-95251 in Participants With Acute Myeloid Leukemia and Myelodysplastic Syndromes

Actual Study Start Date: January 2022

Estimated Primary Completion Date: June 2026

Estimated Study Completion Date: June 2026

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: CC-95251 + azacitidine	Drug: CC-95251 Specified dose on specified days Drug: Azacitidine Specified dose on specified days
Experimental: CC-95251 monotherapy	Drug: CC-95251 Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures:
1. Number of participants with a Dose-limiting toxicity (DLT) [Time Frame: Up to 42 days]
2. Incidence of adverse events (AEs) [Time Frame: Up to 56 days after the last dose of study treatment]

Secondary Outcome Measures:
1. Complete remission rate (CRR) for acute myeloid leukemia (AML) according to the modified European Leukemia Net (ELN) response criteria [Time Frame: Up to 2 years after end of treatment]
2. Overall response rate (ORR) for AML [Time Frame: Up to 2 years after end of treatment]
3. CRR for myelodysplastic syndromes (MDS) according to the modified International Working Group (IWG) Response Criteria [Time Frame: Up to 2 years after end of treatment]
4. ORR for MDS [Time Frame: Up to 2 years after end of treatment]
5. Duration of remission [Time Frame: Up to 2 years after end of treatment]
6. Duration of response [Time Frame: Up to 2 years after end of treatment]
7. Stable disease rate is the rate of MDS participants whose best response is stable disease [Time Frame: Up to 2 years after end of treatment]
8. Relapse-free survival [Time Frame: Up to 2 years after end of treatment]
9. Event-free survival [Time Frame: Up to 2 years after end of treatment]
10. Progression-free survival [Time Frame: Up to 2 years after end of treatment]
11. Time to remission/response [Time Frame: Up to 2 years after end of treatment]
12. Transfusion independence [Time Frame: Up to 2 years after end of treatment]
13. Time to AML transformation for MDS participants [Time Frame: Up to 2 years after end of treatment]
14. Overall survival (OS) rates at 6 months [Time Frame: Up to 2 years after end of treatment]
15. OS rates at 12 months [Time Frame: Up to 2 years after end of treatment]
16. Maximum plasma concentration of drug (Cmax) [Time Frame: Up to 8 weeks post-dose of CC-95251]
17. Minimum serum concentration (Cmin) [Time Frame: Up to 8 weeks post-dose of CC-95251]

18. Trough observed serum concentration (Ctrough) [Time Frame: Up to 8 weeks post-dose of CC-95251]
19. Presence of anti-CC-95251 antibodies (ADAs) using a validated electrochemiluminescence (ECL) assay [Time Frame: Up to 8 weeks post-dose of CC-95251]
20. Frequency of ADAs using a validated ECL assay [Time Frame: Up to 8 weeks post-dose of CC-95251]

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:
• Eastern Cooperative Oncology Group Performance Status of 0 to 2
For Parts A & B:
Relapsed or refractory (R/R) acute myeloid leukemia (AML) as defined by the 2016 WHO Classification R/R myelodysplastic syndromes (MDS) as defined by the 2016 WHO Classification with intermediate, high or very high risk by Revised International Prognostic Scoring System (IPSS-R)
For Part C:
• Treatment-naïve (ie, previously untreated) MDS as defined by the 2016 WHO Classification with intermediate, high or very high risk by IPSS-R
Exclusion Criteria:
Acute promyelocytic leukemia Immediately life-threatening, severe complications of leukemia such as disseminated/uncontrolled infection, uncontrolled bleeding, and/or uncontrolled disseminated intravascular coagulation Participants who have received prior treatment with a CD47 or SIRPα targeting agent Participant is on chronic systemic immunosuppressive therapy or corticosteroids Prior systemic cancer-directed treatments or investigational modalities ≤ 5 half-lives or 4 weeks prior to starting study treatment, whichever is shorter (relapsed or refractory participants only). Any condition including, active or uncontrolled infection, or the presence of laboratory abnormalities, which places the participant at unacceptable risk if he/she were to participate in the study Pregnant or nursing participants.
Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Contact: BMS Study Connect Contact Center http://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, California	Local Institution	Marina Del Rey
United States, California	Local Institution	Stanford
United States, Florida	Local Institution	Miami
United States, Illinois	Local Institution	Chicago
United States, New York	Local Institution	Buffalo
United States, Texas	Local Institution	Houston
United States, Washington	Local Institution	Seattle
Australia, New South Wales	Local Institution	Wollongong
Australia, Victoria	Local Institution	Clayton
Australia, Victoria	Local Institution	Fitzroy
Australia, Victoria	Local Institution	Heidelberg
Canada, Alberta	Local Institution	Edmonton
Canada, British Columbia	Local Institution	Vancouver
Canada, Ontario	Local Institution	Toronto
Canada, Quebec	Local Institution	Montreal
Denmark	Local Institution	Odense
France	Local Institution	Marseille
France	Centre Hospitalier Universitaire de Nantes - L' Hopital l'hôtel-Dieu-hematology	Nantes
France	Local Institution	Pessac
France	Institut Claudius Regaud	Toulouse
France	Local Institution	Villejuif
Italy	Local Institution	Meldola
Italy	Local Institution	Milan

Italy	Local Institution	Rozzano
Norway	Local Institution	Bergen
Norway	Local Institution	Oslo
Spain	Local Institution	Badalona
Spain	Local Institution	Barcelona
Spain	Local Institution	Madrid
Spain	Local Institution	Salamanca
Spain	Local Institution	Santander
Sweden	Local Institution	Goteborg
Sweden	Local Institution	Huddinge
Sweden	Local Institution	Lund
United Kingdom	Local Institution	Edinburgh
United Kingdom	Local Institution	Oxford

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 :	NCT05168202
Other Study ID Numbers :	CA059-001, 2021-002799-38
First Posted :	December 23, 2021
Last Update Posted :	March 14, 2022
Last Verified :	March 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:	*Myelodysplastic Syndromes* *Acute Myeloid Leukemia* *AML* *MDS Hematologic Cancers* *Leukemia* *Anti-SIRPa antibody* *CC-95251*

Additional relevant MeSH terms :

Leukemia	*Pathologic Processes*
Leukemia, Myeloid	*Neoplasms by Histologic Type*
Leukemia, Myeloid, Acute	*Neoplasms*
Preleukemia	*Bone Marrow Diseases*
Myelodysplastic Syndromes	*Hematologic Diseases*
Syndrome	*Precancerous Conditions*
Disease	