A Study to Compare the Efficacy and Safety of Oral Azacitidine Plus Best Supportive Care Versus Best Supportive Care as Maintenance Therapy in Japanese Participants With Acute Myeloid Leukemia (AML) in Complete Remission

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT05197426	RECRUITING	JANUARY 19, 2022	MAY 27, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to assess the efficacy and safety of oral azacitidine plus best supportive care versus best supportive care as maintenance therapy in a cohort of Japanese participants ≥ 55 years of age with Acute Myeloid Leukemia (AML) and in complete remission/complete remission with incomplete blood count recovery after conventional induction chemotherapy with or without consolidation chemotherapy.

Condition or Disease: Acute Myeloid Leukemia

Intervention/treatment: Drug: Oral Azacitidine
Other: Placebo

Phase: Phase 2

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 66 participants

Allocation : Randomized

Intervention Model : Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: A Study to Compare the Efficacy and Safety of Oral Azacitidine Plus Best Supportive Care Versus Best Supportive Care as Maintenance Therapy in Japanese Participants With Acute Myeloid Leukemia (AML) in Complete Remission

Actual Study Start Date: January 2022

Estimated Primary Completion Date: June 2024

Estimated Study Completion Date: April 2026

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Oral Azacitidine	Drug: Oral Azacitidine Specified dose on specified days
Placebo Comparator: Placebo	Other: Placebo Specified dose of specified days

OUTCOME MEASURES

Primary Outcome Measures: 1. Relapse-free Survival (RFS) [Time Frame: Up to 27 months]

Secondary Outcome Measures:
1. Overall Survival (OS) [Time Frame: Up to 27 months]
2. Time to relapse from Complete Remission (CR) [Time Frame: Up to 27 months]
3. Time to relapse from complete remission with incomplete blood count recovery (CRi) [Time Frame: Up to 27 months]
4. Time to discontinuation from treatment [Time Frame: Up to 27 months]
5. Number of participants with Adverse Events [Time Frame: Up to 50 months]
6. Number of participants with physical examination abnormalities [Time Frame: Up to 50 months]
7. Number of participants with vital sign abnormalities [Time Frame: Up to 50 months]
8. Number of participants with clinical laboratory abnormalities [Time Frame: Up to 50 months]
9. Maximum observed plasma concentration (Cmax) [Time Frame: Up to 27 months]
10. Time of maximum observed plasma concentration (Tmax) [Time Frame: Up to 27 months]
11. Area under the plasma concentration-time curve from time zero to time of the last quantifiable concentration (AUC(0-T)) [Time Frame: Up to 27 months]
12. Area under the serum concentration-time curve from time 0 to infinity AUC(INF) [Time Frame: Up to 27 months]
13. Number of participant-reported outcomes utilizing the Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-Fatigue) Scale [Time Frame: Up to 27 months]
14. Number of participant-reported outcomes utilizing the EuroQol 5-dimension 5-level questionnaire (EQ-5D-5L) [Time Frame: Up to 27 months]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 55 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
≥ 55 years of age inclusive at the time of signing the informed consent Newly diagnosed, histologically confirmed de novo Acute Myeloid Leukemia (AML) or AML secondary to prior myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML) Should have undergone induction therapy with intensive chemotherapy with or without consolidation therapy as recommended in appropriate guideline(s) or equivalent regimen according to institutional standard: having achieved first complete remission (CR)/complete remission with incomplete blood count recovery (CRi) status within 4 months prior to starting study therapy
Exclusion Criteria:
Suspected or proven acute promyelocytic leukemia; or AML with previous hematologic disorder such as chronic myeloid leukemia or myeloproliferative neoplasms, excluding MDS and CMML Prior bone marrow or stem cell transplantation Received therapy with hypomethylating agents for MDS and went on to develop AML within four months of discontinuing the therapy with hypomethylating agents Have achieved CR/CRi following therapy with hypomethylating agents 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 NCT # and Site #.

Locations

Japan, Aichi	Local Institution	Nagoya
Japan, Aichi	Local Institution	Nagoya
Japan, Aichi	Local Institution	Nagoya
Japan, Aichi	Local Institution	Toyoake
Japan, Chiba	Local Institution	Kamogawa
Japan, Chiba	Local Institution	Kashiwa
Japan, Ehime	Matsuyama Red Cross Hospital	Matsuyama
Japan, Fukui	University of Fukui Hospital	Yoshida gun
Japan, Fukuoka	Local Institution	Fukuoka-shi
Japan, Gifu	Local Institution	Ogaki
Japan, Gunma	Local Institution - 0001	Maebashi
Japan, Hokkaido	Aiiku Hospital	Sapporo
Japan, Ishikawa	Local Institution	Kanazawa
Japan, Kanagawa	Local Institution	Isehara
Japan, Kanagawa	Local Institution	Sagamihara
Japan, Kanagawa	Local Institution	Yokohama
Japan, Miyagi	Local Institution	Sendai-shi
Japan, Osaka	Local Institution	Osaka Sayama
Japan, Saitama	Local Institution	Saitama shi
Japan, Tochigi	Local Institution	Shimotsuke
Japan, Tokyo	Local Institution	Bunkyo Ku
Japan, Tokyo	Local Institution	Shinagawa ku
Japan, Tokyo	Local Institution	Shinjyuku Ku
Japan, Tokyo	Local Institution	Sumida ku
Japan	Local Institution	Aomori
Japan	Local Institution	Fukuoka
Japan	Local Institution	Fukuoka

Japan	Local Institution	Nagasaki
Japan	Local Institution	Okayama
Japan	Local Institution	Osaka
Japan	Local Institution	Yamagata

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 :	NCT05197426	
Other Study ID Numbers :	CA055-005	
First Posted :	January 19, 2022	
Last Update Posted :	May 27, 2022	
Last Verified :	May 2022	
Studies a U.S. FDA-regulated Drug Product:	Yes	
Studies a U.S. FDA-regulated Device Product:	No	
Product Manufactured in and Exported from the U.S.:	Yes	
Additional relevant MeSH terms :	*Leukemia* *Leukemia, Myeloid* *Leukemia, Myeloid, Acute*	*Neoplasms by Histologic Type* *Neoplasms*