ForPatients
by Roche

Leukemia

A study of the safety of a new medicine (DCLL9718S) in patients with a type of blood cancer (acute myeloid leukemia)

A Study of DCLL9718S in Participants With Relapsed or Refractory Acute Myeloid Leukemia (AML) or DCLL9718S in Combination With Azacitidine in Participants With Previously Untreated AML Unsuitable for Intensive Induction Chemotherapy

Trial Status	Trial Runs In	Trial Identifier
Completed	2 Countries	NCT03298516 GO39902

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

An Open-Label, Phase I, Dose-Escalation Study Evaluating the Safety and Tolerability of DCLL9718S in Patients With Relapsed or Refractory Acute Myeloid Leukemia (AML) or DCLL9718S in Combination With Azacitidine in Patients With Previously Untreated AML Unsuitable for Intensive Induction Chemotherapy

Trial Summary:

This Phase Ia/Ib, open-label, multicenter study will evaluate the safety, tolerability, and preliminary efficacy of DCLL9718S as a single agent (Phase Ia, Arm A) in participants with relapsed or refractory AML or in combination with azacitidine (Phase Ib, Arm B) in participants with previously untreated AML who are not eligible for intensive induction chemotherapy. Each arm will consist of two stages: a dose-escalation stage and an expansion stage. The dose-escalation stage is designed to establish the maximum tolerated dose (MTD) and recommended Phase II dose (RP2D) for DCLL9718S alone (Arm A) or in combination with azacitidine (Arm B). The dose-expansion stage is designed to characterize the long-term safety and tolerability of DCLL9718S.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT03298516 GO39902
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	# 18 Years	No

This clinical trial was done to study a new medicine called, “DCLL9718S”, for the treatment of patients with “acute myeloid leukemia”, a type of blood cancer. Researchers wanted to find out what the safe dose of DCLL9718S was, and whether patients could tolerate the side effects. Researchers were also interested to find out if the study medicine had any effect on the cancer. Eighteen patients took part in this study at eight study centers in two countries.

Inclusion Criteria:

- Diagnosis of AML per World Health Organization (WHO) criteria (except acute promyelocytic leukemia)
- Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0, 1, or 2
- Adequate end-organ function
- Willing and able to undergo a pre-treatment bone marrow aspirate and biopsy and subsequent bone marrow aspirates and biopsies during treatment

Specifically for participants in Arm A:

- Age greater than or equal to (>/=) 18 years
- Relapsed or refractory acute myeloid leukemia
- Participants cannot have received more than two prior regimens

Specifically for participants in Arm B:

- Treatment-naive participants with AML who are >/=75 years old
- Treatment-naive participants unfit for induction chemotherapy for AML due to comorbidities who are >/=65 years old

Exclusion Criteria:

- Diagnosis of acute promyelocytc leukemia
- Prior allogeneic stem cell transplant or solid organ transplant
- Active central nervous system (CNS) involvement by leukemia
- History of idiopathic pulmonary fibrosis, organizing pneumonitis (for example [e.g.], bronchiolitis obliterans), drug-induced pneumonitis, or idiopathic pneumonitis
- Treatment with investigational therapy within 14 days prior to Cycle 1, Day 1
- Treatment with a monoclonal antibody within 30 days prior to Cycle 1, Day 1
- Positive for hepatitis C virus (HCV) antibody at screening
- Active hepatitis B virus (HBV) infection
- Known positivity for human immunodeficiency virus (HIV)
- History of other malignancy within 2 years prior to screening
- Family history of long QT syndrome, with a QTc interval greater than (>) 480 millisecond (msec) at screening, or taking concurrent medications known to prolong QT/QTc interval