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 source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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
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.