ForPatients
by Roche

LeukemiaAcute Graft Versus Host Disease

A study to look at the side effects of a study medicine (efmarodocokin alfa) in patients undergoing hematopoietic stem cell transplantation (HSCT)

Study to Evaluate the Safety and Pharmacokinetics of UTTR1147A in Combination With Standard of Care in Participants Undergoing Allogeneic Hematopoietic Stem Cell Transplantation

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04539470 GA41825

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:

A Phase Ib, Open-Label, Dose-Escalation Study to Evaluate the Safety and Pharmacokinetics of Efmarodocokin Alfa in Combination With Standard of Care in Patients Undergoing Allogeneic Hematopoietic Stem Cell Transplantation

Trial Summary:

This clinical trial was done to study a new medicine called, “efmarodocokin alfa,” for the treatment of patients with “graft versus host disease.” This study was done to find out if efmarodocokin alfa was safe enough to be given to patients undergoing hematopoietic stem cell transplantation. Side effects seen in this study were to be taken into consideration when determining if the doses tested could be tolerated. This was an open-label, Phase 1b, dose escalation study.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 1b
Sponsor	Phase

NCT04539470 GA41825
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eligible for hematopoietic stem cell transplantation (HSCT)
- Donor meeting human leukocyte antigen (HLA) matching criteria of HLA-matched related or HLA-matched unrelated (HLA-A, HLA-B, HLA-C, and HLA-DRB1, eight out of eight) from either peripheral blood or bone marrow stem cells and meeting donor-eligibility criteria as outlined by the U.S. Food and Drug Administration (FDA) in 21 CFR 1271 (including screening for Zika and SARS-CoV-2 exposure or infection)
- Planned HLA (HLA-A, HLA-B, HLA-C, and HLA-DRB1)-matched (eight out of eight) related or planned HLA-matched (eight out of eight) unrelated HSCT, from either peripheral blood or bone marrow stem cells, for patients with acute myeloid leukemia (AML) or acute lymphocytic leukemia (ALL) in first complete remission (per institutional criteria) or patients with intermediate or high-risk myelodysplastic syndrome (MDS)
- Planned myeloablative conditioning regimen per institutional guidelines
- Planned aGvHD prophylaxis consisting of tacrolimus and methotrexate; in cases of tacrolimus intolerance, cyclosporine or sirolimus may be used as a substitute

Exclusion Criteria:

- Prior receipt of autologous or allogeneic HSCT
- Diagnosis of myelofibrosis or myelodysplastic/myeloproliferative overlap syndrome
- Treatment with investigational biologic or non-biologic therapy within 5 drug elimination half-lives (or within 90 days or 30 days, respectively, if half-life is unknown) prior to initiation of study drug
- Positive hepatitis B virus (HBV) or hepatitis C virus (HCV) serologies
- History of Grade >1 cervical intraepithelial neoplasia
- A marked baseline prolongation of QT/QTc interval
- Risk factors for torsades de pointes
- Pregnant or breastfeeding
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study