ForPatients
by Roche

Multiple Sclerosis (MS)

A Study to Evaluate the Safety, Tolerability, Cellular Kinetics, and Pharmacodynamics of P-CD19CD20-ALLO1 in Participants With Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07008378 GN45773

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 I, Multicenter, Open-Label Study to Evaluate the Safety, Tolerability, Cellular Kinetics, and Pharmacodynamics of P-CD19CD20-ALLO1 in Patients With Multiple Sclerosis

Trial Summary:

This study aims to explore the safety, tolerability, cellular kinetics, and pharmacodynamics of P-CD19CD20-ALLO1 in participants with progressive multiple sclerosis (PMS) and relapsing multiple sclerosis (RMS).

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT07008378 GN45773
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 60 Years	No

Inclusion Criteria:

- Age 18-60 years (inclusive) at the time of signing Informed Consent Form
- Diagnosis of progressive MS according to the revised McDonald 2017 criteria, and:

Expanded disability status scale (EDSS) score at screening, from 3 to 6 inclusive Evidence of disability progression and no relapses in the 2 years prior to screening

- Diagnosis of relapsing MS according to the revised McDonald 2017 criteria, and: Evidence of clinical relapses and MRI activity within two years prior to screening while on a disease modifying therapy
- EDSS score at screening, from 0 to 6 inclusive
- No relapses within 45 days of screening

Exclusion Criteria:

- Pregnant or breastfeeding, or intention of becoming pregnant within the timeframe in which contraception is required
- Participants who have confirmed or suspected Progressive Multifocal Leukoencephalopathy (PML)
- Known or suspected history of Hemophagocytic Lymphohistiocytosis/ Macrophage Activation Syndrome (HLH/MAS) or neurotoxicity with prior therapies
- Known presence of other neurologic disorders that may mimic MS
- History of currently active primary or secondary (non-drug-related) immunodeficiency
- Significant or uncontrolled medical disease which would preclude patient participation
- High risk for clinically significant bleeding or any condition requiring plasmapheresis, IV Ig, or acute blood product transfusions
- History of recurrent serious infections or chronic infection
- Prior treatment with CAR T-cell therapy, gene-therapy product, total body irradiation, bone marrow transplantation, allograft organ transplant, or hematopoietic stem cell transplant at any point
- Any previous treatment with immunomodulatory or immunosuppressive medication without an appropriate washout period.
- Inability to complete an MRI scan