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		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