ForPatients
by Roche

Multiple Myeloma

P-BCMA-ALLO1 Allogeneic CAR-T Cells in the Treatment of Subjects With Multiple Myeloma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Country	NCT04960579 XO44788 P-BCMA-ALLO1-001

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

Open-Label, Multicenter, Phase 1 Study to Assess the Safety of P-BCMA-ALLO1 in Subjects With Relapsed / Refractory Multiple Myeloma (MM)

Trial Summary:

Phase 1 study comprised of open-label, dose escalation, multiple cohorts of P-BCMA-ALLO1 allogeneic T stem cell memory (Tscm) CAR-T cells in subjects with relapsed / refractory Multiple Myeloma (RRMM).

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT04960579 XO44788 P-BCMA-ALLO1-001
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Must have signed written, informed consent.
- Males or females, #18 years of age.
- Must have a confirmed diagnosis of active MM.
- Must have measurable MM.
- Must have relapsed / refractory MM, having received treatment with a proteasome inhibitor, immunomodulatory agent (IMiD), and anti-CD38 therapy.

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- Must be willing to practice birth control from the time of Screening and throughout the first year of the study after P-BCMA-ALLO1 administration.
- Must have a negative serum pregnancy test at Screening and a negative urine pregnancy test within 3 days prior to initiating the lymphodepletion therapy regimen (females of childbearing potential).
- Must be at least 90 days since autologous stem cell transplant, if performed.
- Must have adequate vital organ function within pre-determined parameters.
- Must have recovered from toxicities due to prior therapies.
- Must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.

Exclusion Criteria:

- Is pregnant or lactating.
- Has inadequate venous access.
- Has active hemolytic anemia, plasma cell leukemia, Waldenstrom's macroglobulinemia, POEMS syndrome, disseminated intravascular coagulation, leukostasis, or amyloidosis.
- Has an active second malignancy (not disease-free for at least 5 years) in addition to MM, excluding low-risk neoplasms such as non-metastatic basal cell or squamous cell skin carcinoma.
- Has active autoimmune disease.
- Has a history of significant central nervous system (CNS) disease, such as stroke, epilepsy, etc.
- Has an active systemic infection.
- Has a history of hepatitis B, hepatitis C virus, human immunodeficiency virus (HIV), or human T-lymphotropic virus (HTLV) infection, or any immunodeficiency syndrome. Subjects with a history of treated hepatitis C can be enrolled if negative by Hepatitis C PCR on multiple occasions.
- Is positive for cytomegalovirus (CMV) by PCR, CMV immunoglobulin M (IgM) antibody, or Coronavirus disease 2019 (COVID-19) by PCR.
- Has New York Heart Association (NYHA) Class III or IV heart failure, unstable angina, or a history of myocardial infarction or significant arrhythmia.
- Has any psychiatric or medical disorder that would preclude safe participation in and/or adherence to the protocol.
- Has received prior allogeneic cellular therapy or gene therapy.
- Has received anti-cancer medications within 2 weeks of the time of initiating conditioning LD therapy.
- Has received monoclonal antibody therapy within 4 weeks of initiating conditioning LD therapy.
- Has received immunosuppressive medications within 2 weeks of the time of administration of P-BCMA-ALLO1, and/or expected to require them while on study.
- Has received systemic corticosteroid therapy within 1 week or 5 half-lives (whichever is shorter) of the administration of P-BCMA-ALLO1 or is expected to require it during the course of the study.
- Has CNS metastases or symptomatic CNS involvement of their myeloma.
- Has a history of severe immediate hypersensitivity reaction to any of the agents used in this study.
- Has a history of having undergone allogeneic stem cell transplantation, or any other allogeneic or xenogeneic transplant, or has undergone autologous transplantation within 90 days.
- Arms R, RS, RP1, RP1.5 and RP2 Only: a) Has received a live vaccine within the last 28 days of the first administration of agents used in Arm R or RS, b) Has any known hypersensitivity or severe reactions or toxicity to agents used in Arms R or RS.
- Has received radiation within 1 week of initiating conditioning LD therapy.
- Administration of a live vaccine within the last 28 days prior to administration of LD therapy.

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