ForPatients
by Roche

NeoplasmsSalivary gland cancerMetastatic castration-resistant prostate cancerProstate Cancer

P-PSMA-101 CAR-T Cells in the Treatment of Subjects With Metastatic Castration-Resistant Prostate Cancer (mCRPC) and Advanced Salivary Gland Cancers (SGC)

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Country	NCT04249947 GO46335 P-PSMA-101-001

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:

A Phase 1 Dose Escalation and Expanded Cohort Study of P-PSMA-101 in Subjects With Metastatic Castration-Resistant Prostate Cancer (mCRPC) and Advanced Salivary Gland Cancers (SGC)

Trial Summary:

An open-label, multi-center, single and cyclic ascending dose study of P-PSMA-101 autologous CAR-T cells in patients with mCRPC and SGC.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT04249947 GO46335 P-PSMA-101-001
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Subjects #18 years of age
- Must have a confirmed diagnosis of mCRPC or SGC
- Must have measurable disease by RECIST 1.1 or bone only metastases with measurable PSA (#1 ng/mL) (mCRPC subjects only)

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- Must have progressed by PCWG3 and/or RECIST 1.1 (mCRPC subjects only)
- Must be willing to practice birth control from screening and for 2 years after the last administration of P-PSMA-101
- Must have adequate vital organ function within pre-determined parameters
- Must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1

Exclusion Criteria:

- Has inadequate venous access and/or contraindications to leukapheresis
- Has an active second malignancy in addition to mCRPC or SGC, excluding low-risk neoplasms such as non-metastatic basal cell or squamous cell skin carcinoma
- Has a history of or active autoimmune disease
- Has a history of significant central nervous system (CNS) disease, such as stroke or epilepsy
- Has an active systemic (viral, bacterial or fungal) infection
- Has received anti-cancer medications (excluding GnRH targeted therapies) within 2 weeks of the time of initiating conditioning chemotherapy
- Has received immunosuppressive medications (including anti-cancer medications) within 2 weeks of initiating leukapheresis and/or expected to require them while enrolled in the study
- Has received systemic corticosteroid therapy within 2 weeks of either the required leukapheresis or is expected to require it during the course of the study
- Has CNS metastases or symptomatic CNS involvement
- Has a history of significant ocular disease
- Has a history of significant liver disease or active liver disease
- Has liver metastases (<5 lesions and maximum diameter </= 2.5 cm permitted)
- Has a history of or known predisposition to HLH or MAS

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