A Study of JNJ-68284528, a Chimeric Antigen Receptor T Cell (CAR-T) Therapy Directed Against B-cell Maturation Antigen (BCMA) in Participants With Multiple Myeloma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Cohort A: Received a minimum of 1 to a maximum of 3 prior lines of therapy including a proteasome inhibitor (PI) and immunomodulatory therapy (IMiD), and lenalidomide refractory per International Myeloma Working Group (IMWG) guidelines * Cohort B: Received one line of prior therapy including a PI and an IMiD, and disease progression per IMWG criteria less than or equal to (\<=) 12 months after treatment with autologous stem cell transplantation (ASCT) or \<=12 months from the start of anti-myeloma therapy for participants who have not had an ASCT * Cohort C: Previously treated with a PI, an IMiD, an anti-CD38 monoclonal antibody and B-cell maturation antigen (BCMA)-directed therapy * Cohort D: Newly diagnosed multiple myeloma per IMWG with a history of 4 to 8 total cycles of initial therapy, including induction, high-dose therapy, and ASCT with or without consolidation * Cohort E: Have newly diagnosed multiple myeloma without prior therapy (one cycle of prior therapy before enrollment is acceptable) and classified as high risk defined as either: 1) International Staging System (ISS) stage III criteria, Beta 2 microglobulin greater than or equal to (\>=) 5.5 milligrams per liter (mg/L) (via local or central laboratory assessment) or 2) high risk cytogenetic features del(17/17p), t (14;16), t(14;20), 1q amplification (at least 4 total copies) in at least 20 percent (%) of the total plasma cell population * Cohort F: * Participant must have a documented efficacy response of very good partial response (VGPR) or better, without progressive disease prior to enrollment, as assessed per IMWG 2016 criteria * Received initial therapy as specified below. The dose/schedule of cycles administered will be as per standard of care. It is acceptable for up to 1 cycle of the protocol-specified regimens to be missing one of the listed agents (example, held due to toxicity). Acceptable combinations include: At least 5 to 8 cycles of initial therapy with daratumumab, bortezomib, lenalidomide and dexamethasone (D-VRd). The dose/schedule of cycles administered will be as per standard of care or; at least 4 to 8 cycles of initial therapy with daratumumab, lenalidomide and dexamethasone (D-Rd) or; at least 4 to 8 cycles of initial therapy with a carfilzomib-based triplet or quadruplet regimen * Cohort G: Not considered for high-dose chemotherapy with autologous stem cell transplantation (ASCT) due to: a) Ineligibility due to advanced age; or b) Ineligibility due to presence of comorbid condition(s) likely to have a negative impact on tolerability of high-dose chemotherapy with ASCT; or c) Subject refusal of high-dose chemotherapy with ASCT as initial treatment * Cohort H: Considered a candidate for high-dose chemotherapy with ASCT as initial treatment * Cohorts A, B, C, E, G, H: * Serum monoclonal paraprotein (M-protein) level greater than or equal to (\>=) 1.0 gram per deciliter (g/dL) or urine M-protein level \>=200 milligrams (mg)/24 hours * Light chain multiple myeloma in whom only measurable disease is by serum free light chain (FLC) levels in the serum: Serum immunoglobulin FLC \>=10 mg/dL and abnormal serum immunoglobulin kappa lambda FLC ratio * Cohort A: For participants with neither serum nor urine measurable disease, baseline positron emission tomography/ computed tomography (PET/CT) or whole -body magnetic resonance imaging (MRI) may be used to satisfy the measurable disease criteria. A minimum of one lesion with a bi-dimensional measurement of at least 1 centimeter (cm)*1 cm is required * Cohorts B, C: For participants with neither serum nor urine measurable disease, baseline positron emission tomography/ computed tomography (PET/CT) or whole body magnetic resonance imaging (MRI) may be used to satisfy the measurable disease criteria * Cohorts A, B, C, D, E, F, G, H: Eastern Cooperative Oncology Group (ECOG) performance status grade of 0 or 1

Exclusion Criteria:

* Cohorts A, B, D, F: Any therapy that is targeted to BCMA * Cohorts A, B, C, D, F: Prior treatment with chimeric antigen receptor T (CAR-T) therapy directed at any target * Cohorts A, B, C, D, F: * Ongoing toxicity from previous anticancer therapy must resolve to baseline levels or to Grade 1 or less except for alopecia or peripheral neuropathy * Received a cumulative dose of corticosteroids equivalent to \>=70 mg of prednisone within the 7 days (Cohort A, B, C, F) or 14 days (Cohort D) prior to apheresis * Serious underlying medical condition, such as (a) evidence of active viral or bacterial infection requiring systemic antimicrobial therapy, or uncontrolled systemic fungal infection; (b) active autoimmune disease or a history of autoimmune disease within 3 years; (c) overt clinical evidence of dementia or altered mental status; (d) any history of Parkinson's disease or other neurodegenerative disorder * Cohorts A, B, C, D, E, F: Known active, or prior history of central nervous system (CNS) involvement or exhibits clinical signs of meningeal involvement of multiple myeloma * Cohorts F, G, and H: Active malignancies (that is, progressing or requiring treatment change in the last 24 months) other than the disease being treated under study. The only allowed exceptions are: a) non-muscle invasive bladder cancer treated within the last 24 months that is considered completely cured; b) skin cancer (non-melanoma or melanoma) treated within the last 24 months that is considered completely cured; c) non-invasive cervical cancer treated within the last 24 months that is considered completely cured; d) localized prostate cancer (N0M0): with a Gleason score of greater than or equal to (=\>)6, treated within the last 24 months or untreated and under surveillance, with a Gleason score of 3+4 that has been treated more than 6 months prior to full study screening and considered to have a very low risk of recurrence, or history of localized prostate cancer and receiving androgen deprivation therapy and considered to have a very low risk of recurrence, e) breast cancer: adequately treated lobular carcinoma in situ or ductal carcinoma in situ, or history of localized breast cancer and receiving antihormonal agents and considered to have a very low risk of recurrence; f) malignancy that is considered cured with minimal risk of recurrence * Cohorts E, G, and H: Frailty index of \>= 2 according to Myeloma Geriatric Assessment score

Conditions & Interventions

Interventions:
DRUG: JNJ-68284528, DRUG: Lenalidomide, DRUG: Daratumumab, DRUG: Bortezomib, DRUG: Dexamethasone
Conditions:
Multiple Myeloma
Keywords:
Cellular Therapy, CAR-T Therapy, BCMA CAR-T

More Information

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Phase: PHASE2
IRB
Number:
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