A Study of Daratumumab-Based Therapies in Participants With Amyloid Light Chain (AL) Amyloidosis

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Cohort 1: Cardiac involvement (amyloid light chain \[AL\] amyloidosis Mayo Cardiac Stage II and Stage IIIa) with or without other organ(s) involved; Cohort 2: One or more organs impacted by systemic AL amyloidosis according to consensus guidelines * Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0, 1 or 2 * A female participant of childbearing potential must have a negative serum or urine test at screening and within 72 hours of the first dose of study treatment and must agree to further serum or urine pregnancy tests during the study * A male participant must agree not to donate sperm for the purpose of reproduction during the study and for a minimum of 6 months after receiving the last dose of cyclophosphamide or 100 days after discontinuation of daratumumab, whichever is longer * Cohort 2 only: self-identified racial and ethnic minorities, including Black or African American * Measurable disease at screening defined by one of the following: Difference between iFLC and uninvolved FLC (dFLC) \>= 40mg/L per central laboratory Serum involved free light chain (iFLC) \>= 40 mg/L with an abnormal kappa:lambda ratio Serum M-protein \>= 0.5 g/dL

Exclusion Criteria:

* Prior therapy for systemic AL amyloidosis or multiple myeloma including medications that target cluster of differentiation 38 (CD38), with the exception of 160 milligrams(mg) dexamethasone or equivalent corticosteroid maximum exposure prior to randomization/enrollment * Previous or current diagnosis of symptomatic multiple myeloma, including the presence of lytic bone disease, plasmacytomas, \>=60% plasma cells in the bone marrow, or hypercalcemia related to myeloma. * Participant received any of the following therapies: 1. treatment with an investigational drug or used an invasive investigational medical device within 14 days or at least 5 half-lives, whichever is less; 2. vaccinated with an investigational vaccine (except for COVID-19) live, attenuated or replicating viral vector vaccines less than (\<) 4 weeks prior to randomization/enrollment. Participants who are taking strong Cytochrome P450 3A4(CYP3A4) inducers must discontinue their use at least 5 half-lives prior to the first dose of bortezomib * Stem cell transplantation -Planned stem cell transplant during the first 9 cycles of protocol therapy are excluded. Stem cell collection during the first 9 cycles of protocol therapy is permitted * Grade 2 sensory or Grade 1 painful peripheral neuropathy

Conditions & Interventions

Interventions:
DRUG: Daratumumab, DRUG: Cyclophosphamide, DRUG: Bortezomib, DRUG: Dexamethasone
Conditions:
Amyloidosis

More Information

Contact(s): Study Contact - Participate-In-This-Study1@its.jnj.com
Principal Investigator:
Phase: PHASE2
IRB
Number:
System ID: NCT05250973
