Teclistamab-Daratumumab in AL Amyloidosis

NCT07110844

Status	RECRUITING
Phase	Phase 2
Sponsor	Suzanne Lentzsch, MD
Enrollment	25 participants

Key Eligibility Criteria

Inclusion (19)

- Age \>18 years and able to sign Informed Consent Form (ICF). If the individual being considered for participation in this study is unable to provide informed consent due to medical, cognitive, or other conditions, a legally authorized representative (LAR) may consent on their behalf.
- Ability to comply with the study protocol, in the investigator's judgment.
- Confirmed histopathological diagnosis of systemic AL amyloidosis by mass spectrometry or immunohistochemistry (IHC) or Immunofluorescence (IF) on a tissue biopsy that is positive for Congo Red.
- Patient must not have received any prior plasma cell clone-directed therapy.
- Measurable hematologic disease, defined as one of the following:

... and 14 more (see full listing online)

Exclusion (14)

- Prior therapy for AL amyloidosis or multiple myeloma with the exception of 160 mg dexamethasone (or equivalent corticosteroid) maximum exposure prior to C1D0.
- Patients meeting criteria for symptomatic multiple myeloma by any one of the following: (a) Lytic lesions on imaging (Skeletal survey, whole body CT or MRI, or PET/CT) (b) Plasmacytoma, (c) Hypercalcemia without any alternate etiology, (d) Bone marrow plasma cell infiltrate of greater than 60%.
- Patients with involved/uninvolved serum FLC ratio\>100 as the sole myeloma-defining event will be allowed.
- Evidence of significant cardiovascular conditions as specified below:
- NT-Pro BNP \> 8500 pg/mL, and/or

... and 9 more (see full listing online)

Locations (1 total)

Columbia University Irving Medical Center, New York, New York, United States