Venetoclax, MLN9708 (Ixazomib Citrate) and Dexamethasone for the Treatment of Relapsed or Refractory Light Chain Amyloidosis

NCT04847453

Status	RECRUITING
Phase	Phase 1
Sponsor	National Cancer Institute (NCI)
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (40)

- Histologically-proven systemic anti-light chain amyloidosis (AL) confirmed by positive Congo red staining with green birefringence on polarized light microscopy and evidence of a measurable clonal disease that requires active treatment. An underlying plasma cell disorder can be identified by one of the following: clonal plasma cells in the bone marrow (BM), monoclonal protein in the serum or urine, or abnormal free light chain ratio. For patients who are African-American or males \>= 70 years with isolated cardiac involvement, mass spectrometry must be performed to confirm subtyping
- Presence of t(11;14) by fluorescence in situ hybridization (FISH) on bone marrow biopsy, either confirmed at screening or documented with a prior biopsy
- Patient requires therapy, as determined by the treating physician, following at least one line of treatment (No limit on the number of prior treatments)
- Age \>= 18 years. Because no dosing or adverse event data are currently available on the use of venetoclax in combination with MLN9708 (ixazomib citrate) and dexamethasone in patients \< 18 years of age, children are excluded from this study
- Eastern Cooperative Oncology Group (ECOG) performance status =\< 2 (Karnofsky \>= 60%)

... and 35 more (see full listing online)

Exclusion (17)

- Patients who have had major surgery or radiotherapy within 14 days prior to entering the study. If the involved radiotherapy field is small, 7 days will be considered a sufficient interval between treatment and administration of the MLN9708 (ixazomib citrate)
- Patients who have had anti-plasma cell therapy within 4 weeks (6 weeks for nitrosoureas or mitomycin C) prior to entering the study
- Patients who have not recovered from adverse events due to prior anti-cancer therapy (i.e., have residual toxicities \> grade 1) with the exception of alopecia
- Patients who are receiving any other investigational agents, within 30 days of the start of this trial and throughout the duration of this trial
- Patients with central nervous system involvement

... and 12 more (see full listing online)

Locations (16 total)

City of Hope Comprehensive Cancer Center, Duarte, California, United States
University of California Davis Comprehensive Cancer Center, Sacramento, California, United States
Emory University Hospital/Winship Cancer Institute, Atlanta, Georgia, United States
... and 13 more locations

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