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TeclistAMY (EMN40): A Phase 2 Trial of Teclistamab in Patients With Previously Treated Light-Chain Amyloidosis

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Overview

- TeclistAMY (EMN40) is an ongoing, international, phase 2 study that is evaluating the efficacy and safety of teclistamab monotherapy in patients with previously treated AL amyloidosis
- TeclistAMY (EMN40) aims to provide data on the use of teclistamab in patients with relapsed/refractory AL amyloidosis, for which there is currently no approved treatment regimen
- ClinicalTrials.gov Identifier: NCT06649695

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Poster

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Acknowledgments

This study is sponsored by EMN in collaboration with Johnson & Johnson. Medical writing and editorial support were provided by Laura Ganser, PhD, of Lumanity Communications Inc., and funded by Johnson & Johnson.

Disclosures

MR served in a consulting role for GSK, Johnson & Johnson, and Pfizer; received research funding from Johnson & Johnson and Sanofi; and received honoraria from Amgen, Bristol Myers Squibb, Johnson & Johnson, and Takeda.

Introduction

- Systemic amyloid light-chain (AL) amyloidosis is a rare disorder that is characterized by the deposition of misfolded monoclonal immunoglobulin (Ig) light chains as insoluble amyloid fibrils in various tissues and organs, which leads to serious and life-threatening organ dysfunction[1,2]
- Treatment mostly targets plasma cells to stop the production of the amyloid-forming light chains[3]
- Daratumumab, a human IgGκ monoclonal antibody targeting CD38, in combination with bortezomib, cyclophosphamide, and dexamethasone, is the first and only regimen indicated both in the United States and Europe for the treatment of newly diagnosed AL amyloidosis and has demonstrated high rates of hematologic and organ responses[4-6]
- Most patients with AL amyloidosis relapse or are refractory to initial therapy; however, there is no currently approved treatment regimen for patients with relapsed/refractory disease[7]
- Teclistamab (Tec) is a first-in-class B-cell maturation antigen (BCMA) × CD3 bispecific antibody that is approved for triple-class–exposed relapsed/refractory multiple myeloma[8]
- BCMA is widely expressed on both multiple myeloma and amyloid plasma cells; in vivo data confirm that soluble BCMA levels positively correlate with involved free light chain levels in patients with AL amyloidosis[9,10]
- Two recent retrospective case series suggest that Tec may induce rapid and deep hematologic responses in patients with heavily pretreated AL amyloidosis, with no unexpected adverse events[11,12]

Methods

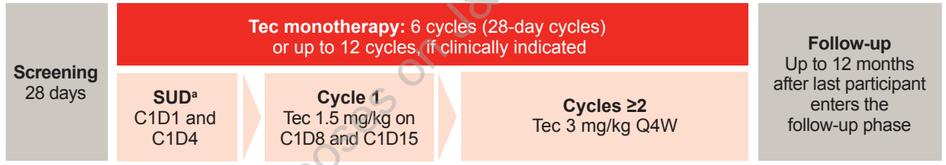
Study design and patients

- TeclistAMY (EMN40) is an ongoing, international, multicenter, open-label, single-arm, phase 2 study that is evaluating the safety and efficacy of Tec monotherapy in patients with previously treated AL amyloidosis (**Figure 1**)
- This study will enroll approximately 30 patients at 10 sites across 6 countries (Australia, France, Germany, Greece, Italy, and The Netherlands; **Figure 2**)
- A safety analysis will be performed by an independent data monitoring committee after 6 patients have completed ≥1 cycle of treatment; if no safety signals are observed, the trial will continue as planned

Statistical analysis

- Continuous and categorical variables will be summarized using descriptive statistics
- Time-to-event variables will be evaluated using the Kaplan-Meier method

Figure 1: TeclistAMY (EMN40) study design



Key eligibility criteria

- ≥18 years of age
- Histologic diagnosis of systemic AL amyloidosis (affecting ≥1 organ)
- ECOG PS score of 0-2
- Mayo stage I-IIIA cardiac disease at screening
- Measurable hematologic disease
- CrCl ≥20 mL/min
- Absence of symptomatic multiple myeloma
- ≥1 prior line of treatment (including daratumumab and bortezomib)
- Wash-out period of ≥14 days from date of last administration of any previous antitumor therapy or investigational treatment for AL amyloidosis

Endpoints

Primary endpoint

- Hematologic CR rate after 3 cycles

Secondary endpoints

- Hematologic ORR and ≥VGPR
- Duration and time to hematologic response
- Rate and depth of organ response
- Hematologic PFS
- MOD-PFS
- MOD-EFS
- TST
- OS
- Safety/tolerability
- MRD after 3 cycles
- QOL

[a]0.06 mg/kg on C1D1 and 0.3 mg/kg on C1D4.
AL, amyloid light-chain; C, Cycle; CR, complete response; CrCl, creatinine clearance; D, Day; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; EMN, European Myeloma Network; MOD, major organ deterioration; MRD, minimal residual disease; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; Q4W, every 4 weeks; QOL, quality of life; SUD, step-up dosing; Tec, teclistamab; TST, time to subsequent therapy; VGPR, very good partial response.

Figure 2: Countries planned for participation in TeclistAMY (EMN40)

EMN, European Myeloma Network.

Current Status

- TeclistAMY (EMN40) is being conducted at 10 sites across 6 countries and is actively recruiting
- The first patient was enrolled on July 2, 2025
- As of October 7, 2025, 5 of the 10 sites have been activated, with 15 patients screened, 8 enrolled, and 7 treated

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Presented by Murielle Roussel at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition; December 6-9, 2025; Orlando, FL, USA