Pomalidomide and Dexamethasone (Pom-Dex) With or Without Daratumumab (DARA) in Patients (Pts) With Relapsed or Refractory Multiple Myeloma (RRMM): a Multicenter, Randomized, Phase 3 Study (APOLLO)

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OBJECTIVE

To evaluate the efficacy and safety of DARA SC + Pom-Dex versus Pom-Dex alone in patients with RRMM who received PI prior treatment with both lenalidomide and a PI

METHODS

Key Eligibility Criteria

18+ years of age
Eastern Cooperative Oncology Group performance status of 0–2
Responded to prior treatment with lenalidomide and a PI and documented evidence of progressive disease
Patients who received only 1 prior treatment must have demonstrated progressive disease ≤60 days after completing the lenalidomide-containing regimen
Creatinine clearance ≥80 mL/min

CONCLUSIONS

APOLLO is a phase 3, randomized, open-label, multicenter trial evaluating the efficacy and safety of Pom-Dex in combination DARA SC in patients with RRMM

This study is currently enrolling patients

REFERENCES


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DISCLOSURES

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Study endpoints and evaluations

Primary

± PFS

Secondary

± Overall response rate and rates of very good partial response and complete response
± Minimal residual disease negativity rate
± Time to response
± Duration of response
± Time to next therapy
± Overall survival
± Safety
± European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) Core 30 and EORTC QLQ Multiple Myeloma Module 20 scale and domain scores
± European Quality of Life Dimensions Questionnaire health utility values
± Immunomodulatory effects of DARA on T cells
± DARA serum concentration and immunogenicity

Study design

- Pom-Dex
- Pom-Dex with DARA
- Pom-Dex alone in patients with RRMM who received PI prior treatment with both lenalidomide and a PI
- Approximately 302 patients will be randomized 1:1 to receive either DARA + Pom-Dex or Pom-Dex alone in patients with RRMM who received ≥1 prior treatment with both lenalidomide and a PI
- Three cycles of agent administration ± DARA
- A safety run-in phase for both regimens
- Patients will receive treatment until disease progression or unacceptable toxicity
- Disease evaluation will occur monthly
- Safety evaluation: monthly
- Follow-up: 12 weeks after last treatment

CONCLUSIONS

To mitigate potential infusion-related reactions, all patients will receive pre-infusion medications, including DEX, acetaminophen, diphenhydramine, and an optional leukostat inhibitor
- Patients with a higher risk of respiratory complications will receive post-infusion medications, including diphenhydramine, a short-acting β2-adrenergic receptor agonist, and lung disease control medications
- A total of 302 patients are expected to enroll in sites that span 12 countries (Figure 4)

Figure 4. APOLLO clinical sites.