MultipleMyelomaHub

Relapsed/refractory patients

Update from the phase III COLUMBA (MMY3012) study

Emily Smith | Feb 28, 2019

The randomized, open-label, parallel assignment phase III COLUMBA (MMY3012) study (NCT03277105) investigated the impact of either subcutaneous (SC) or intravenous (IV) administration of daratumumab (Darzalex®) on response rates in patients with relapsed/refractory multiple myeloma (RRMM).

The study found that daratumumab, co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), administered subcutaneously is non-inferior to IV administration.

- Patients (N = 522) were randomized to either:
  - SC daratumumab: 1800 mg with rHuPH20 2000 U/mL (N = 263)
  - IV daratumumab: 16 mg/kg (N = 259)
- Both were administered:
  - Once-weekly in cycles 1 and 2
  - Every two weeks in cycles 3–6
  - Every four weeks in cycle 7
  - Continued until disease progression, unacceptable toxicity or study end
- Co-primary endpoints:
  - Overall response rate (ORR)
  - Maximum trough of daratumumab (C_{trough})
    - Daratumumab serum pre-dose concentration on day 1 of cycle 3
- ORR:
  - SC daratumumab: 41.1% (N = 263)
  - IV daratumumab: 37.1% (N = 259)
- Mean C_{trough} rate
  - SC daratumumab: 499 mg/mL (N = 149)
  - IV daratumumab: 463 mg/mL (N = 146)

No additional safety concerns were raised. The pharmaceutical company expected to present the data at an upcoming medical conference, publish in a peer-reviewed journal, and consider a regulatory submission for this formulation.

Providing daratumumab subcutaneously may result in a benefit to patients owing to the quicker and more convenient method of administration.

References

1. OncLive. Subcutaneous daratumumab succeeds in phase III myeloma trial. https://www.onclive.com/web-exclusives/subcutaneous-daratumumab-succeeds-in-phase-iii-myeloma-trial [Accessed 2019 Feb 26]