769 Isatuximab, Lenalidomide, Bortezomib and Dexamethasone Induction Therapy for Transplant-Eligible Patients with Newly Diagnosed Multiple Myeloma: Final Progression-Free Survival Analysis of Part 1 of an Open-Label, Multicenter, Randomized, Phase 3 Trial (GMMG-HD7)

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Hematology Disease Topics & Pathways:
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Abstract

Background:

In patients (pts) with newly diagnosed multiple myeloma (NDMM), anti-CD38 monoclonal antibodies (CD38-mAb) increase efficacy of standard-of-care regimens. Addition of the CD38-mAb isatuximab (Isa) to lenalidomide, bortezomib, and dexamethasone (RVd) in pts with transplant-eligible NDMM met the primary endpoint of minimal residual disease (MRD) negativity in the bone marrow after induction therapy (Isa-RVd 50% vs. RVd 36%, OR 1.82, 95% CI 1.33-2.48, p<0.001; Goldschmidt H et al., 2022, *Lancet Haematol.*; NCT03617731). The present analysis compared the effect of induction therapy with Isa-RVd vs. RVd on secondary endpoint of progression-free survival (PFS).

Methods:

Pts with transplant-eligible NDMM at 67 sites in Germany were stratified by Revised International Staging System (R-ISS; Palumbo A et al., 2015, *J Clin Oncol*) and equally randomized to receive three 42-day cycles of RVd (lenalidomide 25 mg/d po, d1-14 and d22-35; bortezomib 1.3 mg/m^2 SC d1, 4, 8, 11, 22, 25, 29, 32; dexamethasone 20 mg/d po, d1-2, 4-5, 8-9, 11-12, 15, 22-23, 25-26, 29-30, 32-33). In the Isa-RVd arm, Isa was added as follows: 10 mg/kg IV, cycle 1: d 1, 8, 15, 22, 29; cycles 2-3: d 1, 15, 29. Following induction therapy, pts underwent cyclophosphamide-based stem cell collection and subsequently proceeded to high-dose melphalan (200 mg/m^2) and autologous hematopoietic stem cell transplant (ASCT).

Second ASCT was recommended if pts achieved less than complete response (CR) after first ASCT or in case of high-risk cytogenetics. Pts were then randomized to receive maintenance with either lenalidomide alone (10 mg/d po continuously) or in combination with Isa (10 mg/kg IV, cycle 1: d 1, 8, 15, 22; cycles 2-3: d 1, 15; cycles 4-39: d 1) for up to 36 months. Cytogenetic risk status was defined as presence (high-risk) or absence (standard risk) of deletion17p, t(4;14), and/or t(14;16). PFS was defined as time from first randomization to progression or death from any cause, whichever occurred first. Weighted risk set estimator analyses accounting for second randomization (maintenance therapy) were applied to analyze PFS comparing Isa-RVd with RVd induction followed by lenalidomide maintenance. Data cut-off for the present analysis was January 31, 2024.

Results:

Between Oct 2018 and Sep 2020, 662 pts were included in the trial. The intention-to-treat analysis comprised 660 pts (Isa-RVd: 331 and RVd: 329). Baseline characteristics were well balanced. 225 (68%)/79 (24%) pts in the Isa-RVd arm and 179 (54%)/99 (30%) pts in the RVd arm received a single or tandem ASCT, respectively.

After a median follow up of 47 months (95% CI 46-48), 179 PFS events occurred. Isa-RVd induction therapy significantly prolonged PFS compared with RVd (HR 0.70, 95% CI 0.52-0.94; stratified log-rank p=0.0184). 3-year PFS rates in the Isa-RVd and RVd arms were 83% (95% CI 79-87) and 75% (95% CI 70-80). The PFS benefit for Isa-RVd vs. RVd arm was confirmed on multivariable analysis, including R-ISS, age, sex, performance status, and renal insufficiency (HR 0.64, 95% CI 0.47-0.86; p=0.004). Subgroup analyses found a consistent PFS benefit for Isa-RVd vs. RVd induction among clinically relevant baseline subgroups (female and male sex, good performance status, ISS stages I, II, and III, normal and elevated LDH, standard risk cytogenetics). Patients with poor performance status (WHO grade >1, HR 1.09, 95% CI 0.47-2.52), and high-risk cytogenetics (HR 1.09, 95% CI 0.63-1.91) did not see benefit at this point.

Weighted risk set estimator PFS analyses accounting for second randomization confirmed a significant benefit for Isa-RVd vs. RVd induction followed by lenalidomide maintenance (HR 0.63, 95% CI 0.38-1.07; stratified weighted log-rank p=0.016). Estimated, weighted 3-year PFS rates for Isa-RVd and RVd followed by lenalidomide maintenance were 84% (95% CI 79-89) and 73% (95% CI 67-79).

OS was not mature with median OS not reached in either arm, and 3-year OS rates of 88% (95% CI 85-92) and 89% (95% CI 86-93) in the Isa-RVd vs. RVd arm.

Conclusions:

Addition of Isa to RVd during 18 weeks of induction therapy, followed by ASCT, resulted in a significant and clinically meaningful PFS benefit, regardless of the maintenance therapy strategy. The present analysis of the GMMG-HD7 trial supports the MRD negativity benefit reported previously. The trial is ongoing and will evaluate the addition of Isa to lenalidomide during maintenance after a re-randomization (part 2).

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OffLabel Disclosure: Isatuximab is not approved for upfront treatment in patients with newly-diagnosed multiple myeloma.