364 Impact of Minimal Residual Disease on Progression-Free Survival in Patients with Newly Diagnosed Multiple Myeloma Treated with Isatuximab, Lenalidomide, Bortezomib and Dexamethasone Induction Therapy in the Phase 3 GMMG-HD7 Trial

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Hematology Disease Topics & Pathways:
Research, Clinical trials, Combination therapy, Adult, Clinical Research, Plasma Cell Disorders, Diseases, Lymphoid Malignancies, Study Population, Human, Measurable Residual Disease

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Abstract

Background:

Minimal residual disease negativity (MRDneg) in the bone marrow is associated with improved survival outcomes in patients (pts) with newly diagnosed multiple myeloma (NDMM). The randomized, multicenter phase 3 GMMG-HD7 trial (NCT03617731) demonstrated that addition of anti-CD38 monoclonal antibody isatuximab (Isa) to standard of care treatment lenalidomide, bortezomib, and dexamethasone (RVd) in pts with transplant-eligible NDMM significantly increased MRDneg rates 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*.). Here we present landmark analyses exploring the impact of MRDneg and continued MRDneg on progression-free survival (PFS).

Methods:

Pts with transplant-eligible NDMM were stratified by Revised International Staging System (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 10 mg/kg IV, cycle 1: d 1, 8, 15, 22, 29; cycles 2-3: d 1, 15, 29 was added. Following induction therapy, pts underwent stem cell collection, high-dose melphalan therapy (200 mg/m^2) and autologous hematopoietic stem cell transplant. 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. MRDneg from bone marrow samples was assessed by next-generation flow cytometry (sensitivity 10^{-5}) independent of International Myeloma Working Group response rates. Continued MRDneg status was defined as MRDneg persisting from post induction to post intensification. PFS was defined as time from respective landmark to

progression or death from any cause, whichever occurred first. Data cut-off for the present analyses 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. PFS results from first randomization are reported separately.

At this respective PFS landmark analyses post induction and post intensification, higher proportions of patients in the Isa-RVd arm vs. RVd arm had improved rates of MRDneg and continued MRDneg. PFS analyses from end of induction therapy comprised 282 MRDneg pts (Isa-RVd: 166/55% and RVd:116/41%) and 304 MRD positive (MRDpos) pts (Isa-RVd: 136/45% and RVd: 168/59%). PFS was significantly longer in pts achieving MRDneg (HR 0.38, 95% CI 0.26-0.55; p<0.001) with 3-year PFS rates from end of induction therapy of 88% (95% CI 85–92) for MRDneg pts and 71% (95% CI 66–77) for MRDpos pts. Among MRDneg pts, PFS was similar in the Isa-RVd and RVd arms (HR 1.12, 95% CI 0.60-2.11, p=0.72). In MRDpos pts, PFS was significantly longer with Isa-RVd vs. RVd (HR 0.64, 95% CI 0.43-0.96; p=0.03). Analyses of the impact of continued MRDneg on PFS from start of maintenance therapy included 227 pts with continued MRDneg (Isa-RVd: 138/53% and RVd:89/38%) and 267 without continued MRDneg (Isa-RVd: 122/47% and RVd: 145/62%). PFS was significantly prolonged in pts with continued MRDneg compared with those without continued MRDneg (HR 0.41, 95% CI 0.25-0.65; p<0.001). 3-year PFS rates from start of maintenance therapy were 90% (95% CI 86-94) in pts with continued MRDneg and 77% (95% CI 72–83) in pts without continued MRDneg. Pts in the Isa-RVd and RVd arm with continued MRDneg had similar PFS (HR 1.13, 95% CI 0.49-2.61; p=0.77). Among pts without continued MRDneg, PFS was longer in the Isa-RVd arm vs. the RVd arm (HR 0.68, 95% CI 0.41-1.13; p=0.14).

Multivariable analyses including induction treatment arm, key baseline patient characteristics and disease risk factors confirmed the significant prognostic impact of MRDneg on PFS from end of induction therapy (HR 0.37, 95% CI 0.26-0.55; p<0.001) and continued MRDneg on PFS from start of maintenance therapy (HR 0.44, 95% CI 0.27-0.72; p=0.001).

Conclusions:

More pts achieved MRDneg and continued MRDneg with Isa-RVd vs. RVd, while the PFS benefit after obtaining MRDneg and continued MRDneg was similar in both arms. For pts who have MRDpos and continued MRDpos, the addition of Isa to RVd is associated with a favorable PFS vs. RVd alone.

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