overall survival (OS). Key secondary endpoints tested with a closed test procedure. Safety data included treatment emergent adverse events (TEAE), hematological, and biochemistry results for all patients. Interim efficacy analysis is planned once 65% of total expected PFS events are observed.

Results: 302 patients (Isa-Kd: 179, Kd: 123) were randomized. Median age 64 (33–90) years; R-ISS I, II, III was 25.8%, 59.6%, 7.9% respectively; 44%, 33% and 23% had 1, 2 and ≥3 prior lines respectively; 90% and 78% had prior proteasome inhibitor and IMiD respectively; 24% had high-risk cytogenetics. At a median follow-up of 20.7 months and with 103 PFS events per IRC, median PFS was not reached for Isa-Kd vs. 19.15 months Kd; HR 0.531 (99% CI 0.318–0.889), one-sided $p = 0.0007$. Thus, the pre-specified efficacy boundary ($p = 0.005$) was crossed. PFS benefit was consistent across subgroups. ORR (≥PR) was 86.6% Isa-Kd vs. 82.9% Kd, one-sided $p = 0.1930$. ≥VGPR rate was 72.6% Isa-Kd vs. 56.1% Kd, $p = 0.0011$. CR rate was 39.7% Isa-Kd vs. 27.6% Kd. MRD negativity-rate (10–5) in ITT was 29.6% (53/179) Isa-Kd vs. 13.0% (16/123) Kd, descriptive $p = 0.0004$. OS was immature (events 17.3% Isa-Kd vs. 20.3% Kd). 52.0% Isa-Kd vs. 30.9% Kd pts remain on treatment. Main reasons for treatment discontinuation were disease progression (29.1% Isa-Kd vs. 39.8% Kd) and AEs (8.4% Isa-Kd vs. 13.8% Kd). Grade ≥3 TEAEs were observed in 76.8% Isa-Kd vs. 67.2% Kd. Treatment-emergent SAEs (59.3% vs. 57.4%) and fatal TEAEs were similar in Isa-Kd and Kd (3.4% vs. 3.3%,) and Infusion reactions were reported in 45.8% (0.6% grade 3–4) Isa- Kd and 3.3% (0% grade 3–4) Kd. Grade ≥3 respiratory infections (grouping): 32.2% Isa-Kd vs. 23.8% Kd. Grade ≥3 cardiac failure (grouping): 4.0% Isa-Kd vs. 4.1% Kd. As per lab results, grade 3–4 thrombocytopenia and neutropenia were reported in 29.9% Isa-Kd vs. 23.8% Kd and 19.2% Isa-Kd vs. 7.4% Kd, respectively.

Conclusion: Addition of Isa to Kd provided superior, statistically-significant improvement in PFS with clinically meaningful improvement in depth of response. Isa-Kd was well tolerated with manageable safety and favourable benefit-risk profile, and represents a possible new standard of care treatment in patients with relapsed MM. Data first presented at EHA 2020 virtual meeting, June 11–21st. Study sponsored by Sanofi.

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Relapse of multiple myeloma presenting as extramedullary plasmacytoma surrounding the aorta: a rare case report

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Objective: Extramedullary plasmacytoma (EMP) defines soft tissue tumors that are characterized by plasma cell infiltration and develop secondary to hematogenous spread, in an anatomical site distant from the bone marrow (usually liver, skin, central nervous system, pleura, kidneys, lymph nodes, and pancreas) (3,4). The prevalence of EMP in MM patients is approximately 6–8% at diagnosis and approaches 10–30% during the course of the disease. Here, we present a case of relapsed MM concomitant with a large EMP surrounding the aorta, which is an extremely rare pattern of involvement.

Case report: A 66-year-old male patient presented to our clinic with back pain and weakness in the legs. The patient had been diagnosed with IgG kappa multiple myeloma six years ago. In the initial diagnosis, he had been evaluated as an ISS stage-II, transplant eligible based on clinical and laboratory findings. He had received monthly zoledronic acid, two courses of VAD and two courses of VD regimens. Subsequent to complete response, he had undergone aHSCT with high-dose melphalan for the purpose of consolidation. The patient had achieved complete remission under follow-up after aHSCT. The disease had relapsed approximately 4 years after the first aHSCT, and the patient had undergone another aHSCT with high-dose chemotherapy after a VCD chemotherapy regimen, and had been in complete remission under follow-up. He presented with the complaints stated above 18 months after the second transplantation. On physical examination, bilateral lower extremities showed weakness and impaired sensation. Spinal vertebrae were examined with MRI in consideration of the history of MM. On MRI examination, there were diffuse lytic lesions involving all spinal segments and the sternum, and a soft tissue lesion that involved the aorta-vascular structures in the retrocrural space at the level of T7-L1 and extended to the spinal canal and involved the spinal cord at the level of T8-10. An imaging-guided trucut biopsy was taken from the mass and the diagnosis was confirmed as plasma cell myeloma based on histopathological and immunohistochemical findings. Although the patient underwent 2 courses of Len-Dex, and subsequently, 2 courses of VRD, there was no reduction in the size of the plasmacytoma, and the patient was considered non-responsive. As a more aggressive regimen, a combination of VDT-PACE was administered. A very good partial response was obtained after two courses. The patient was not suitable for allogeneic HSCT because of poor performance status. The patient and his relatives were consulted, and it was decided to continue the treatment with chemotherapy agents.

Conclusion: In conclusion, EMPs, although infrequently, are encountered during the course of multiple myeloma and its relapse. EMPs can be found in very rare localizations. Symptoms vary depending on the anatomical localization of the masses or the dysfunctions that result from the direct mass effect or organ involvement. In this regard, radiological, laboratory, and histopathological evaluation of massive lesions during follow-up is important. Particularly, MRI can be effective as an imaging method in the diagnosis and close follow-up of patients with symptoms associated with extramedullary plasmacytomas.

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