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INTRODUCTION

Multiple myeloma (MM) is a heterogeneous hematologic malignancy

Daratumumab, an anti-CD38 antibody is approved within both triplet (DRd) and more recently, quadruplet (DVRd) in new-diagnosed MM (NDMM).

Generating real world evidence remains key to show how effective treatments are outside of clinical trials, and to help guide everyday clinical practice

AIM

This retrospective real-world (RW) analysis describes patients characteristics and outcomes associated with DRd (daratumumab, lenalidomide, dexamethasone) and DVRd (daratumumab, bortezomib, lenalidomide, dexamethasone) use in frontline transplant eligible and ineligible patient populations

METHOD

Sub-analysis of the EMMY cohort.

- EMMY is a non-interventional, retrospective, multicenter cohort of adults with symptomatic MM starting a new line of therapy in 70 French centers. Data were extracted annually from medical records up to January 2025, death or data cut-off.
- Inclusion criteria: all patients starting L1 therapy between September and December of 2021, 2022 or 2023.

Demographic, clinical and cytogenetic¹ characteristics were described. PFS and OS were estimated using the Kaplan–Meier method

¹ With the following high risk cytogenetic status definition : at least one of the following abnormalities t(4 ;14), del(17p), gain(1q), del(1p).

RESULTS

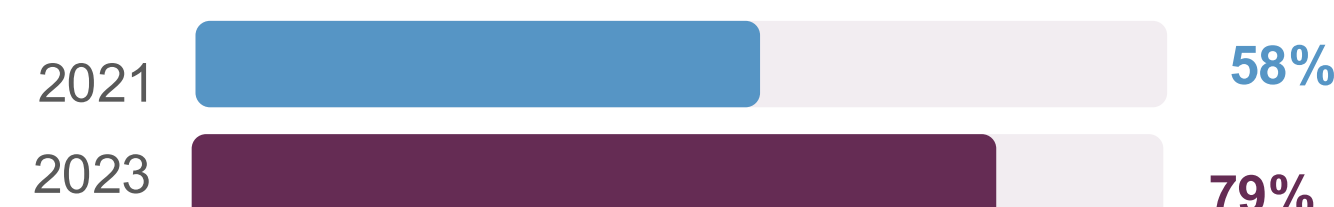
1 | GENERAL DISPOSITION

Among **1,291 patients** starting first-line (L1) treatment between September and December 2021–2023, **325** were transplanted and **966** were not.

Daratumumab-based regimens were used in **99%** of transplanted and **90%** of non-transplanted patients.

2 | TRANSPLANTED POPULATION (n=325)

DVRd use increased by 21% over the analysis period establishing it as the most frequently used regimen.



Patients treated with DVRd were young (median age **61 years**) and fit: **87.2%** had an ECOG performance status of 0-1, **89.0%** had 1 comorbidity or less. When cytogenetics were tested, **43.2%** of patients were classified as high risk (HR) (see Table 1).

At 24 months, PFS was **91.0%** (95% CI, 86.2–95.9) (see Figure 1) and OS was **98.4%** (95% CI, 96.2–100.0).

Among patients with sufficient follow-up (those initiating treatment in 2021 or 2022), maintenance therapy was widely adopted, with **87.5%** initiating maintenance therapy during the study period.

3 | NON-TRANSPLANTED POPULATION (n=966)

In the non-transplanted population, DRd remained the most frequently prescribed regimen, with DVRd use increasing by 13%



Patients treated with DRd were older than patients treated with DVRd (median **77 vs 67 years**) and more often frail (approximately two-thirds vs one-third). DVRd was more often used in patients with HR cytogenetics (**50.5%* vs 31.4%***) (see Table 1).

The median follow-up of patients treated with DRd was 19.1 months and 7.7 months for patients treated with DVRd.

For patients treated with DRd, the 24-months PFS was **67.1%** (95% CI, 62.2–71.9) (see Figure 2) and OS **85.6%** (95% CI, 82.3–89.0). As comparison, the 30-months PFS of the pivotal study MAIA, which included patients younger and fitter than this RW cohort, was 71%.

Longer follow-up is awaited to assess effectiveness outcomes with DVRd.

*among patients with available HR cytogenetics results

Table 1 – Patients characteristics*

		L1T DVRd (n=219)	L1NT DVRd (n=160)	L1NT DRd (n=610)
Sex	Male	130 (59.4%)	89 (55.6%)	309 (50.7%)
	Female	89 (40.6%)	71 (44.4%)	301 (49.3%)
Age (years)	Median	61	67	76,9
ECOG	0-1	171 (87.2%)	105 (78.4%)	391 (74.6%)
	> = 2	25 (12.8%)	29 (21.6%)	133 (25.4%)
	Missing	23	26	86
Comorbidities	0-1	195 (89.0%)	120 (75.0%)	440 (72.1%)
	> = 2	24 (11.0%)	40 (25.0%)	170 (27.9%)
Frailty score	Frail	33 (16.8%)	50 (36.8%)	354 (63.4%)
	Not frail	163 (83.2%)	86 (63.2%)	204 (36.6%)
	Missing	23	24	52
HR cytogenetics	Yes	64 (43.2%)	49 (50.5%)	83 (31.4%)
	No	84 (56.8%)	48 (49.5%)	181 (68.6%)
	Missing or not done	71	63	346
ISS stages	I	64 (36.8%)	27 (21.1%)	108 (22.4%)
	II	54 (31.0%)	35 (27.3%)	185 (38.4%)
	III	42 (24.1%)	51 (39.8%)	139 (28.8%)
	II-III**	14 (8.0%)	15 (11.7%)	50 (10.4%)
	Missing	45	32	128

*Percentages were calculated among patients with available data, unless otherwise specified.

** ISS stage was derived from serum β 2-microglobulin and albumin levels when not documented in the medical record (II-III : β 2-microglobulin <5.5 mg/L and albumin <35 g/L)

Figure 1 – PFS for L1 transplanted population, treated with DVRd

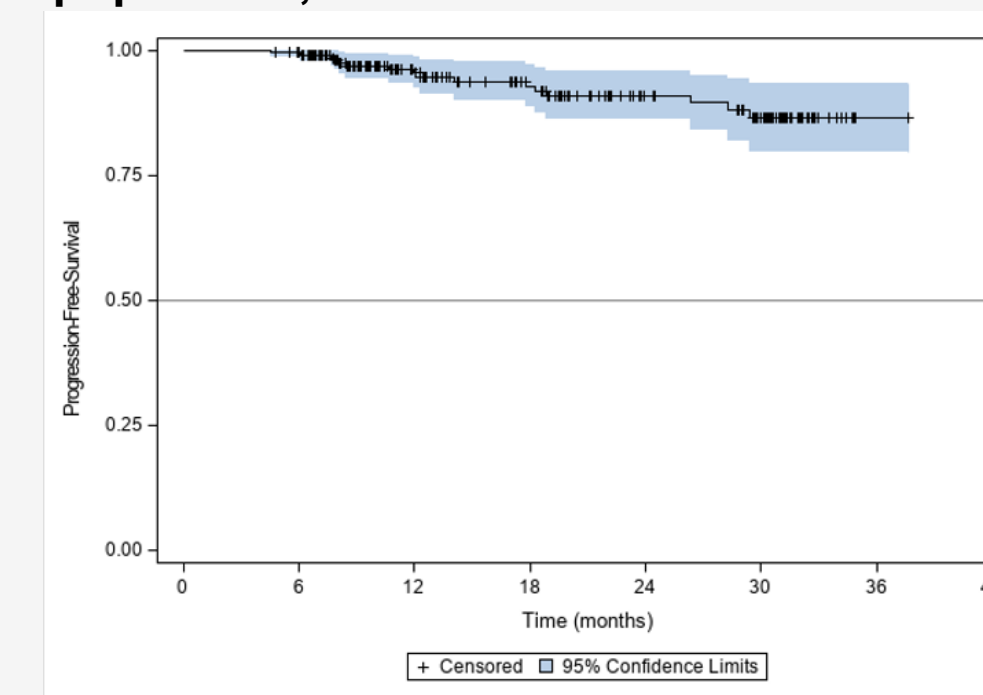
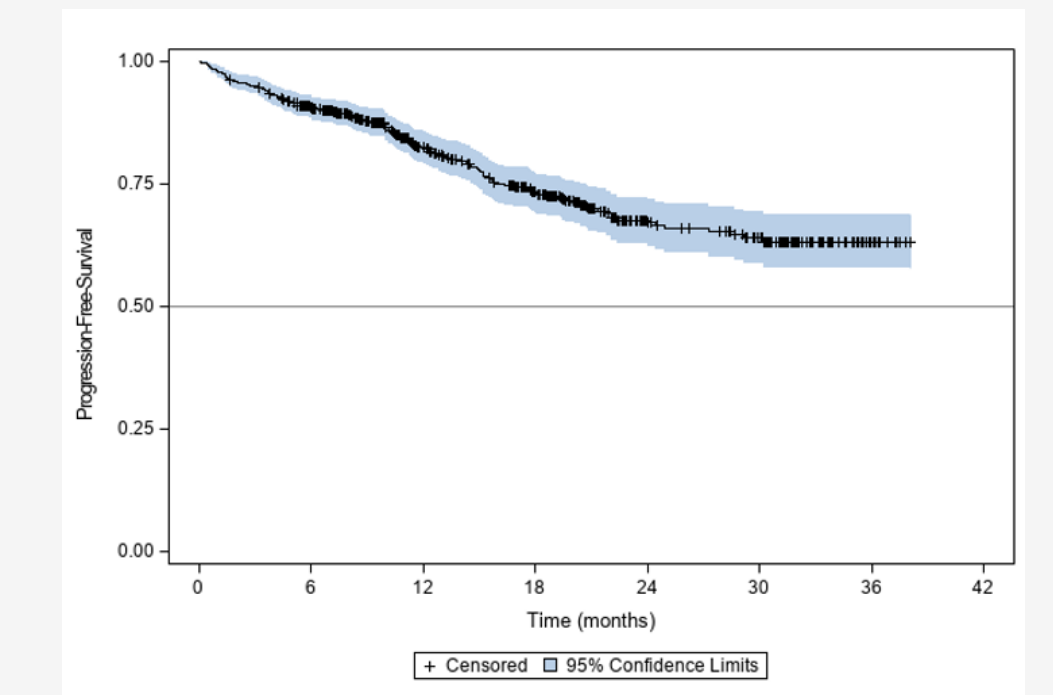


Figure 2 – PFS for L1 non-transplanted population, treated with DRd



CONCLUSIONS

Daratumumab-based regimens: DRd and DVRd are standards of care first-line MM treatment in France, and regimens can be selected in a tailored approach based on patient fitness and disease risk.

This real world analysis shows the increasing role of DVRd in 1L treatment choice. Real world effectiveness outcomes of patients receiving DRd were comparable to those reported in pivotal clinical trials, despite the inclusion of an older and more frail patient population.

REFERENCES

Facon T *et al.* Daratumumab plus Lenalidomide and Dexamethasone for Untreated Myeloma. N Engl J Med. 2019 May 30;380(22):2104-2115

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