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Assessing the benefit of incorporating an anti-CD38 monoclonal antibody into second- or third-line systemic treatment for patients with relapsed/refractory multiple myeloma: results from the French real-world EMMY study.

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Keywords: anti-CD38 monoclonal antibodies, relapsed-refractory multiple myeloma, systemic treatment.

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Data-sharing statement

The data assessed in this manuscript will be made available upon reasonable request.

Contributions

TC wrote the manuscript; OD and CH supervised the project;, MM and LV revised the manuscript. All authors approved the manuscript.

To the Editor,

Multiple myeloma (MM) is a malignant disorder characterized by the proliferation of abnormal monoclonal plasma cells. The therapeutic management of patients with MM comprises several sequences of treatments, accompanied by cycles of response to treatments followed by eventual relapse. Over the last few decades several therapies have been developed including proteasome inhibitors (PIs), immunomodulatory drugs (IMiDs), bispecific antibodies, antibody-drug conjugates (ADCs), and anti-CD38 monoclonal antibodies (mAbs)(1). These therapies have improved outcomes. However, optimal sequencing of these treatments, either alone or combined, has not yet been established (2). Real-world data can provide preliminary evidence to assist physicians with therapeutic decisions.

Among the emerging treatments, anti-CD38 mAbs show promise in treating relapsed-refractory MM (RRMM). Evidence suggests that anti-CD38 mAb-based combination therapies improve survival outcomes in RRMM (3). During the years studied (2017-2021), anti-CD38 mAbs available for treating RRMM in France were daratumumab and isatuximab. We designed the non-

interventional, multicenter, longitudinal EMMY study to collect real-world data (during an annual pre-defined three-month period) to assess the evolution of therapeutic management of MM as new therapies emerge in France (4,5). Patients aged 18 years or older with symptomatic MM requiring systemic treatment were eligible. Patients with non-secretory, solitary plasmacytoma, or plasma cell leukemia and those treated in clinical trials were not eligible. Between 2017-2023, patients were annually enrolled in 73 centers during a predefined three-month period. The study was conducted in accordance with the Declaration of Helsinki, and French and European laws and regulations. Ethical approval was not required. Before participating, all patients were informed of study and of their rights concerning the use of their personal data.

In this letter, we report the results concerning patients with RRMM treated with 2nd- or 3rd-line systemic treatment between 2017-2021. We focus on describing the populations of patients treated with and without an anti-CD38 mAb (alone or in combination). Furthermore, we report the time-to-next treatment (TTNT), progression-free survival (PFS), overall survival (OS), and response to treatment in these populations. The TTNT was defined as the interval between treatment initiation (2nd- or 3rd-line) and the initiation of the subsequent line of treatment or death, whichever occurs first. PFS was defined as the time interval between treatment initiation (2nd- or 3rd-line) and either disease progression or death. OS was defined as the time interval between treatment initiation (2nd- or 3rd-line) and death.

Between 2017 and 2021, 1784 patients with RRMM initiating 2nd- or 3rd-line systemic treatment had been enrolled in the EMMY study. Among them, 1128 patients (63.2%) were initiating 2nd-line treatments and 656 (36.8%) 3rd-line. The median age was 72.1 years (with 59.9% patients older than 70 years), and 79.6% of patients had an Eastern Cooperative Oncology Group (ECOG) performance status ≤1. Of the 1784 patients assessed, 822 (46.1%) received an anti-CD38 mAb during 2nd- or 3rd-line systemic treatment and 962 (53.9%) had not. The baseline characteristics were similar between the groups **(Table 1).**

Among the 962 patients treated without an anti CD38 mAb, in the 2nd- or 3rd -line of treatment, 95.5% received a corticosteroid, 77.1% an IMiD, 57.0% a PI, and 28.0% an alkylator. Of the 822 patients treated with an anti-CD38 mAb, 95.9% received a corticosteroid, 71.4% an IMID, 27.1% a proteasome inhibitor, and 7.9% an alkylating agent. Most patients treated with an anti-CD38 mAb received daratumumab (88.8%) **(Table 2)**. Among the 822 patients treated with an anti-CD38 mAb, 49 patients (6.0%) initiated their 2nd- or 3rd -line in 2017, 81 (9.9%) in 2018, 242 (29.4%) in 2019, 211 (25.7%) in 2020, and 239 (29.1%) in 2021.

At analysis, 2nd- or 3rd-line treatment was ongoing (as appropriate) in 19.2% of the patients not treated with an anti-CD38 mAb versus 51.2% of patients treated with an anti-CD38 mAb. Most

(80.8%) of the patients treated without an anti-CD38 mAb had discontinued their 2nd- or 3rd-line of treatment due to disease progression (49.4%), toxicity (14.6%), or completion of the treatment protocol (10.6%). In contrast, most of the 401 patients (48.8%) treated with an anti-CD38 mAb, had discontinued their 2nd- or 3rd-line treatment due to disease progression (35.0%), toxicity (5.5%), or completion of the treatment protocol (4.4%). Overall, 538 patients (55.8%) of the patients without an anti-CD38 mAb had initiated the subsequent treatment line versus 271 (33.0%) of those with an anti-CD38 mAb **(Table 2)**.

At analysis, the median follow-up was 21.0 months (IQR, 10.4-35.7). The median TTNT, PFS, and OS, as well as the annual TTNT, PS, and OS rates were increased in patients treated with 2nd- or 3rd-line anti-CD38 mAb **(Supplementary Table 1)**. Median TTNT was 29.8 months (95% CI, 25.4-33.9) in patients with an anti CD38 mAb versus 15.9 months (95% CI, 14.3-17.7) in those not treated with an anti-CD38 mAb **(Figure 1A)**. Median PFS was 26.3 months (95% CI, 22.7-29.7) in patients treated with an anti-CD38 mAb versus 14.5 months (95% CI, 13.5-16.5) in those not treated with an anti-CD38 mAb **(Figure 1B)**. Median OS was not reached in patients treated with an anti-CD38 mAb versus 46.1 months (95% CI, 39.2-54.8) in those not treated with an anti-CD38 mAb **(Figure 1C)**.

In our study, 57.8% of patients had cytogenetic data. Of these, 27.2% had a high cytogenetic risk. Interestingly, the ICARIA-MM study found that adding the anti-CD38 mAb isatuximab to pomalidomide and dexamethasone benefited all patients with RRMM (in terms of response and PFS), irrespective of the cytogenetic risk (6). To interpret our results, it is important to consider the timing of approvals and availability of the anti-CD38 mAbs daratumumab and isatuximab, for treating patients with RRMM in France. In Europe, daratumumab first received a conditional marketing authorization for treating adults with RRMM on the 20th of May 2016 while isatuximab was only approved by the EMA on the 30th of May 2020 for treating adults with RRMM (3,7). Consequently, in our study, most of the patients treated with an anti-CD38 mAb received daratumumab, with only 11.2% receiving isatuximab. Moreover, the use of an anti-CD38 mAb-based regimen for patients with RRMM gradually increased during the period under study: 49 patients in 2017, 81 in 2018, 242 in 2019, 211 in 2020, and 239 in 2021.

We observed a median PFS of 26.3 months in patients treated with an anti-CD38 mAb. While the median OS in patients treated with an anti-CB38 has not yet been reached (but will exceed the 46.1 months in patients not treated with an anti-CD38 mAb). Our results are consistent with those previously reported (8). The median PFS and OS of 582 patients in the Canadian Myeloma Research Group Database that received daratumumab-based therapies was 23.5 months and 49.1 months, respectively, with daratumumab-based therapies in the 2nd-line (8). The median PFS and OS decreased with daratumumab use in further lines and was 12.8 months and 43.0 months,

respectively, in the 3rd-line and 7.0 months and 20.5 months, respectively, in the 4th- and subsequent lines. Median PFS and OS were extended when daratumumab was combined with bortezomib, lenalidomide, or pomalidomide (compared to monotherapy). Also, several recent systematic reviews and/or meta-analyses have shown that anti-CD38 mAbs (alone or combined) significantly extend survival outcomes in patients with RRMM (9,10).

Currently, there are several emerging therapies that will transform the therapeutic landscape of RRMM. These include chimeric antigen receptor (CAR) T-cell therapies, bispecific antibodies, and ADCs (1,11). Furthermore, now that daratumumab and isatuximab are approved in patients newly diagnosed with MM, anti-CD38 mAbs will be used earlier during MM evolution (12-15).

This study, as with all real-world studies, has limitations; the data collected depended on the completeness, accuracy, and frequency of the data entered in the medical files.

Our results show that incorporating an anti-CD38 mAb into 2nd- or 3rd-line systemic treatment for patients with RRMM extends median TTNT, PFS, and OS.

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TABLE 1 Patient characteristics at baseline, all patients, and according to whether the 2nd- or 3rd-line treatment included an anti-CD38 mAb

	All patients (N=1784)	**Not treated with an anti-CD38 mAb (N=962)**	**Treated with an anti-CD38 mAb (N=822)**
Age (at initiation of treatment line), years			
Median (range)	72.1 (39-99.2)	73.4 (39-99.2)	71.2 (39.5-93)
Age in categories, years, N (%)			
<59	235 (13.2)	111 (11.5)	124 (15.1)
60-69	481 (27.0)	237 (24.6)	244 (29.7)
70-79	693 (38.9)	353 (36.7)	340 (41.4)
≥80	375 (21.0)	261 (27.1)	114 (13.9)
ECOG performance status, N (%)			
0-1	1134 (79.6)	574 (77.9)	560 (81.5)
≥2	290 (20.4)	163 (22.1)	127 (18.5)
Missing data	360	225	135
Refractory to IMiD, N (%)			
Yes	595 (33.4)	317 (33.0)	278 (33.8)
No	1185 (66.4)	643 (66.8)	542 (65.9)
Not determined	4 (0.2)	2 (0.2)	2 (0.2)
ISS classification (at diagnosis), N (%)			
Stage I	257 (25.6)	140 (25.5)	117 (25.6)
Stage II	303 (30.1)	156 (28.4)	147 (32.2)
Stage III	446 (44.3)	254 (46.2)	192 (42.1)
Missing data	778	412	366

Cytogenetic testing performed, N (%)			
Yes	784 (57.8)	423 (57.5)	361 (58.1)
No	573 (42.2)	313 (42.5)	260 (41.9)
Missing data	427	226	201
Patient at high cytogenetic risk[a], N (%)	213 (27.2)	107 (25.3)	106 (29.4)
Fragility score, N (%)			
Not fragile	806 (53.7)	366 (46.1)	440 (62.2)
Fragile	695 (46.3)	428 (53.9)	267 (37.8)
Missing data	283	168	115

ECOG, Eastern Cooperative Oncology Group; mAb, monoclonal antibody; IMiD, immunomodulatory drug; ISS, International Staging System

[a] High cytogenetic risk was defined as having either a t(4 ;14) or a del(17p) genetic anomaly.

TABLE 2 Treatment and disease status according to whether the 2nd- or 3rd-line of treatment included an anti-CD38 mAb

	Not treated with an anti-CD38 mAb (N=962)	**Treated with an anti-CD38 mAb (N=822)**
Prior stem cell transplant, N (%)		
Yes	296 (30.8)	354 (43.1)
No	666 (69.2)	468 (56.9)
Details concerning 2nd- or 3rd-line of treatment, N (%)		
Corticosteroids	919 (95.5)	788 (95.9)
Anti-CD38 mAb, alone or combined	0	822 (100)
Daratumumab	0	730 (88.8)
Isatuximab	0	92 (11.2)
IMiD, alone or combined	742 (77.1)	587 (71.4)
Lenalidomide	495 (51.5)	373 (45.4)
Pomalidomide	241 (25.1)	212 (25.8)
Thalidomide	6 (0.6)	2 (0.2)
Proteasome inhibitors, alone or combined	548 (57.0)	223 (27.1)
Bortezomib	258 (26.8)	173 (21.0)
Ixazomib	121 (12.6)	4 (0.5)
Carfilzomib	169 (17.6)	46 (5.6)
Alkylators	269 (28.0)	65 (7.9)
Other cytotoxic agents	40 (4.2)	9 (1.1)
Anti-BMCA	2 (0.2)	0
Treatment combinations, N (%)		

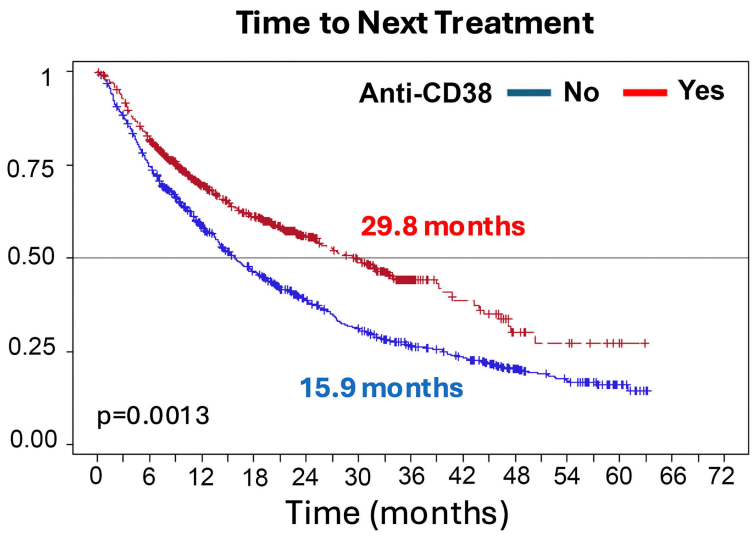
anti-CD38 mAb, alone or combined	0 (0.0)	822 (100.0)
IMiD and IP, alone or combined	367 (38.1)	0 (0.0)
IMiD, alone or combined	375 (39.0)	0 (0.0)
IP, alone or combined	181 (18.8)	0 (0.0)
Other combination	39 (4.1)	0 (0.0)
Treatment status, N (%)		
Ongoing	185 (19.2)	421 (51.2)
Discontinued	777 (80.8)	401 (48.8)
Due to disease progression	475 (49.4)	288 (35.0)
Due to toxicity	140 (14.6)	41 (5.0)
Treatment protocol completed	102 (10.6)	36 (4.4)
Due to 2nd cancer	4 (0.4)	1 (0.1)
Unknown reason	56 (5.8)	35 (4.3)
Initiated next line of treatment, N (%)	538 (55.8)	271 (33.0)
Primary refractory, N (%)		
Yes	165 (17.2)	112 (13.6)
No	700 (72.9)	664 (80.8)
Not applicable	96 (9.9)	46 (5.6)
Missing data	2	0
Secondary refractory, N (%)		
Yes	239 (25.1)	123 (15.1)
No	284 (29.9)	141 (17.3)
Not applicable	428 (45.0)	551 (67.6)
Missing data	11	7

mAb, monoclonal antibody; IMiD, immunomodulatory drug; PI, proteasome inhibitor; BMCA, B-cell maturation antigen.

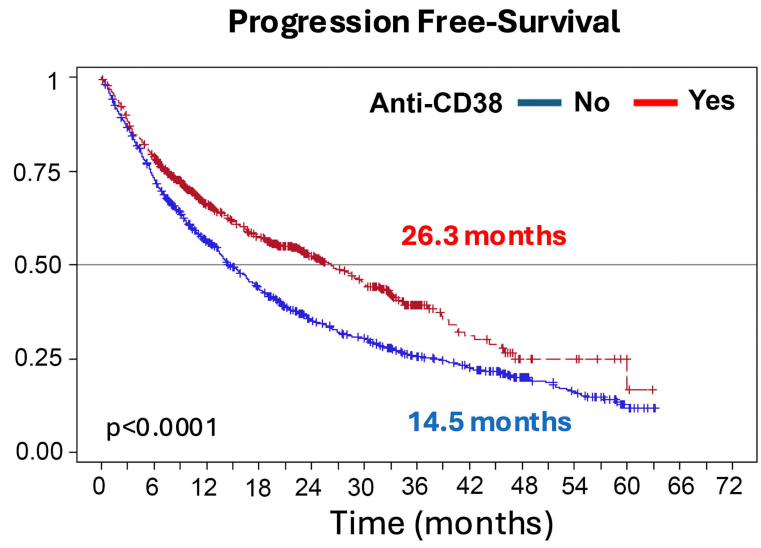
LEGENDS

FIGURE 1: results according to whether the 2nd- or 3rd-line of treatment included an anti-CD38 mAb. Analysis of time-to-next treatment (A), progression-free survival (B) and overall survival (C).

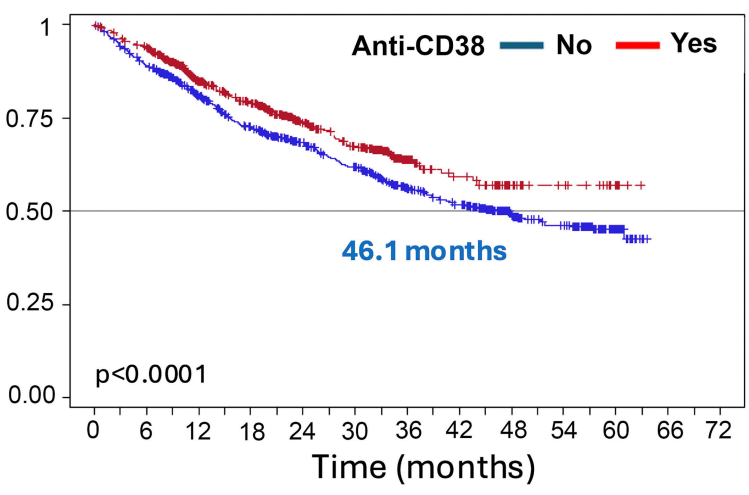
A


Time to Next Treatment
Anti-CD38 No Yes
29.8 months
15.9 months
p=0.0013
1
0.75
0.50
0.25
0.00
0 6 12 18 24 30 36 42 48 54 60 66 72
Time (months)

B


Progression Free-Survival
Anti-CD38 No Yes
26.3 months
14.5 months
p<0.0001
1
0.75
0.50
0.25
0.00
0 6 12 18 24 30 36 42 48 54 60 66 72
Time (months)

C


Overall Survival
Anti-CD38 No Yes
46.1 months
p<0.0001
1
0.75
0.50
0.25
0.00
0 6 12 18 24 30 36 42 48 54 60 66 72
Time (months)

Supplementary Table 1 Summary of efficacy according to whether the 2nd- or 3rd-line of treatment included an anti-CD38 mAb

	Not treated with an anti-CD38 mAb (N=962)	**Treated with an anti-CD38 mAb (N=822)**
Analysis of time-to-next treatment		
Median (95% CI), months	15.9 (14.3-17.7)	29.8 (25.4-33.9)
Time-to-next treatment rates, % (95% CI)		
At 6 months	74.6 (71.9-77.4)	82.1 (79.5-84.8)
At 1 year	58.6 (55.4-61.8)	69.3 (66-72.6)
At 2 years	38.8 (35.5-42.1)	56 (52.1-59.9)
At 3 years	26.4 (23.3-29.5)	44.1 (39.4-48.9)
At 4 years	20.2 (17.2-23.2)	30 (22.2-37.9)
At 5 years	16.2 (13-19.3)	27.3 (18.6-36.1)
Analysis of progression-free survival		
Median (95% CI), months	14.5 (13.5-16.5)	26.3 (22.7-29.7)
Progression-free survival rates, % (95% CI)		
At 6 months	73.1 (70.2-75.9)	78.9 (76.1-81.7)
At 1 year	56.2 (53-59.4)	66.1 (62.7-69.4)
At 2 years	35.1 (31.9-38.3)	52.2 (48.3-56.1)
At 3 years	25.5 (22.5-28.6)	39.3 (34.5-44)
At 4 years	20.1 (17.1-23.1)	25 (18-32)
At 5 years	11.8 (8.1-15.5)	16.7 (2.5-30.8)
Analysis of overall survival		

Median (95% CI), months	46.1 (39.2-54.8)	NR (NR-NR)
Overall survival rates, % (95% CI)		
At 6 months	89 (87.0-91.0)	93.8 (92.2-95.5)
At 1 year	80.7 (78.1-83.3)	84.8 (82.2-87.3)
At 2 years	68.4 (65.3-71.5)	73.5 (69.9-77)
At 3 years	55.9 (52.4-59.4)	63.6 (59.1-68.2)
At 4 years	49.4 (45.7-53.1)	57 (50.8-63.2)
At 5 years	45 (40.9-49.1)	57 (50.8-63.2)

CI, confidence interval; mAb, monoclonal antibody; NR, not reached.