

La rivoluzione terapeutica nel **linfoma** e nel **mieloma**

Napoli, Royal Hotel Continental • 14-15 Maggio 2026

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Disclosures of Stefano Rocco

Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other

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Anticorpi Bi-Specifici
Innovazione
Nuove tossicità
Accesso

Approvati in terza recidiva (quarta linea)

Teclistamab

Elranatanab

Talquetamab

Innovazione

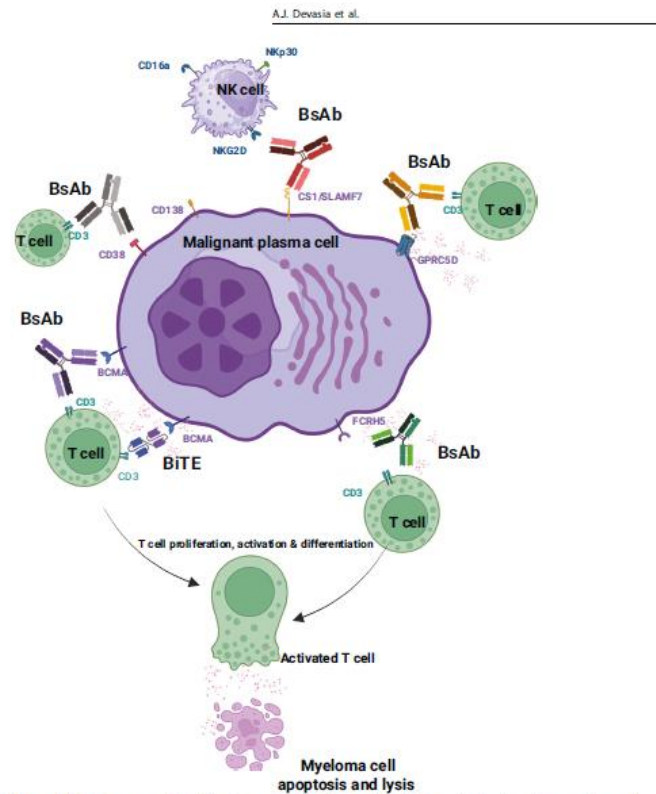


Fig. 1 Bispecific antibodies and their tumour specific antigenic targets on myeloma cells. This figure depicts the various myeloma cell target antigens that have been studied preclinically or clinically, along with the BsAbs constructs used and their associated effector cell antigen targets.

Nuove Tossicità

Supplementary table 1. ASTCT grading for CRS(1)

CRS Parameter	Grade 1	Grade 2	Grade 3	Grade 4
Fever	Temperature $\geq 38^{\circ}\text{C}$	Temperature $\geq 38^{\circ}\text{C}$	Temperature $\geq 38^{\circ}\text{C}$	Temperature $\geq 38^{\circ}\text{C}$
Hypotension	None	Not requiring vasopressors	Requiring one vasopressor with or without vasopressin	Requiring multiple vasopressors (excluding vasopressin)
Hypoxia	None	Requiring low-flow nasal canula ($\leq 6\text{L}/\text{min}$) or blow-by.	Requiring high-flow nasal canula ($> 6\text{L}/\text{min}$), facemask, nonrebreather mask or Venturi mask.	Requiring positive pressure (eg. CPAP, BiPAP, intubation and mechanical ventilation)

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Supplementary table 3. ASTCT grading for ICANS(1)

Neurotoxicity Domain	Grade 1	Grade 2	Grade 3	Grade 4
ICE score	7-9	3-6	0-2	0 (patient is unarousable)
Depressed level of consciousness	Awakens spontaneously	Awakens to voice	Awakens only to tactile stimulus	Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse; stupor or coma
Seizure	N/A	N/A	Any clinical seizure focal or generalized that resolves rapidly or nonconvulsive seizures on EEG that resolve with intervention	Life-threatening prolonged seizure (> 5 mins) or repetitive clinical or electrical seizures without return to baseline in between
Motor findings	N/A	N/A	N/A	Deep focal motor weakness such as hemiparesis or paraparesis
Elevated ICP/cerebral edema	N/A	N/A	Focal/local edema on neuroimaging	Diffuse cerebral edema on neuroimaging; decerebrate or decorticate posturing; or cranial nerve VI palsy; or papilledema; or Cushing's triad

Supplementary table 2. ICE score(1)

Parameter	Score (Points)
Orientation: year, month, city, hospital	4
Naming: ability to name 3 objects (eg, point to clock, pen, button)	3
Following commands: ability to follow simple commands (eg, “show me 2 fingers” or “close your eyes and stick out your tongue”)	1
Writing: ability to write a standard sentence (eg, “our national bird is the bald eagle”)	1
Attention: ability to count backwards from 100 by 10	1

La rivoluzione terapeutica nel linfoma e nel mieloma

Supplementary Table 5. Infections complications reported across the different trials.

	Teclistamab(2) n=165	Elranatamab(3,12) n=123	Alnuctamab(5) n=78 (sc)	ABBV-838 (6) n=118	Talquetamab(7,13) n=288 [0.4-0.8mg/kg]*	Cevostamab(11) n=161	Forimtamig (10) n=57 (SC)
Median FUP (months, m)	14.1 m	10.4 m	11.7 m	4.3 – 8.0m	14.9 – 8.6 m	8.8 m	8.0m
Overall, n (%)	126 (76.4)	82 (66.7)	46 (59)	38 (32)	57.3%-50.3%	45%	26 (45.6)
Grade 3-4, n (%)	74 (44.8)	43 (35)	13 (17)	20 (17)	16.8%-11.7%	ND	15 (26.4)
Bacterial	ND	ND	ND	ND		ND	ND
Fungal	ND	ND	ND	ND		ND	ND
Viral	ND	ND	ND	ND		ND	ND
Opportunistic infections							
PJP	6 pts (3.6%)	6 (4.9)	ND	ND	5(3.5%)–4(2.8%)	ND	ND
CMV	NR (*1 pts with Adenoviral pneumonia)	10 (8.1)	2 pts	None	ND 3 patients		
COVID infections, n (%)							
Overall	29 (17.6)	31 (25.2)	18 (23)	ND	13(9.1) – 16(11)	ND	14 (24.6)
Grade 3-4	20 (12.1)	14 (11.4)	2 (3)	ND	0.7% - 2.1%	ND	2 (3.6)
Infectious death, n (%)	16/27	NR	1 pts	4 pts	3 pts – 2 pts	ND	ND
Hypogammaglobulinemia, n (%)	123 (74.5%)	77/102 (75.5%)	15 (19)	17 (14)	64.3% -67.6%	NR	NR
IVIg replacement, n (%)	65/123 (52.8%)	43.1%	NR	29 (23)	14.7% - 13.1%	NR	NR

SC: subcutaneous, PJP:pneumocistis jirovecci pneumonia. CMV: citomegalovirus. NR: not reported. ND: not disclosed.

*Cohort 0.4mg/kg/weekly and cohort 0.8 mg/kg/every 2 weeks.

La rivoluzione terapeutica nel linfoma e nel mieloma

Supplementary table 7. Results of the electronic questionnaire performed and answered by experts of the IMWG regarding diagnosis, monitoring and management of infections complications in patients treated with bispecific antibodies.

Recommended monitoring	
Test to be performed prior to initiation of therapy	Percentage of experts in agreement
- Cytomegalovirus (CMV) PCR test	31 (62%)
- HIV, Hepatitis B and Hepatitis C serology	47 (94%)
- HIV, Hepatitis B or Hepatitis C PCR testing in patients with a positive serology	45 (90%)
- COVID testing (either SARs-CoV-2 PCR or antigen testing)	29 (58%)
- Nasal multiplex PCR in asymptomatic patients	8 (16%)
- Other viral test such as HHV6 PCR, HHV8, etc	5 (10%)
- Blood cultures	2 (4%)
- Cultures to test for possible carriage of multi-resistant germs	11 (22%)
Test to be performed during therapy in asymptomatic patients as routine monitoring	
- Monitoring of CMV DNA using PCR testing in patients with a baseline negative PCR in absence of any clinical suspicion	2 (4%)
- Monitoring of CMV DNA using PCR testing in patients with a baseline negative PCR when clinically indicated (i.e. fever, cytopenias, liver abnormalities, diarrheas)	31 (62%)
- Monitoring of cytomegalovirus DNA using PCR testing in patients with a baseline positive PCR	46 (92%)
- Recommended frequency of CMV monitoring in patients with a positive baseline PCR: <ul style="list-style-type: none"> ○ Every week ○ Every 2 weeks ○ Every month ○ Depending on viral load 	9 (18%) 12 (24%) 8 (16%) 14 (28%)
- PCR monitoring of hepatitis B or C viral load in patients with positive serology (every 3 months or before if clinically indicated)	32 (64%)

Accesso

Step-up dose

CRS

In/Outpatient

Da dove ripartiamo...

PRESA IN CARICO

- Difficoltà per i piccoli centri a causa del numero ridotto di posti letto. Gli eventuali casi eleggibili a bispecifici vengono demandati a centri più grandi. Questo però si riflette su una mancata esperienza con queste terapie e conseguentemente una mancata esperienza del trattamento «outpatient» che gli permetterebbe di prendere in carico il paziente (circolo vizioso). *SOLUZIONE* (temporanea fino a che non si passa all'outpatient): piattaforma di condivisione delle disponibilità posti letto e/o creazione rete per garantire opportunità terapeutica a tutti i pazienti eleggibili all'anticorpo bispecifico
- Al momento il limite della presa in carico del paziente sono le attese/tempi di ricovero (non c'è abbastanza esperienza nella gestione delle reazioni avverse e quindi nella gestione outpatient). *SOLUZIONE*: gestione outpatient
- La gestione del paziente in emergenza è resa difficoltosa dalla mancanza di strumenti. *SOLUZIONE*: protocollo di gestione del paziente in emergenza ovunque si rechi (disponibilità ovunque di Tocilizumab)

GESTIONE

- Paziente in automonitoraggio che si presenta in ospedale (reperibilità medico, infermiere e posto letto)
SOLUZIONE: protocollo gestione delle reazioni avverse per il paziente/cargiver, per l'infermiere e per il medico non ematologo.
- Condivisione delle esperienze di altre regioni/strutture con verifica dell'esportabilità su altre realtà
- Corretta selezione dei pazienti che possono essere gestiti in outpatient. *SOLUZIONE*: elenco delle condizioni che rendono eleggibili all'outpatient (ad es: condizioni concomitanti/organizzative, caregiver, vicinanza al centro, etc)
- Gestione delle reazioni avverse. *SOLUZIONE*: Team multidisciplinare dedicato soprattutto per le fasi iniziali in acuto

FOLLOW-UP

- Gestione delle tossicità a lungo termine. *SOLUZIONE*: monitoraggio delle infezioni, supporto IgG e tossicità Talquetamab.
- Difficoltà ad avere tutti i consulenti in tutte le realtà nel momento di necessità. *SOLUZIONE*: Team multidisciplinare dedicato

CONSIDERAZIONE E NEXT STEPS

- Posto che esiste la volontà di utilizzare gli anticorpi bispecifici, il gruppo ritiene che per farlo in «sicurezza» devono essere forniti gli strumenti.

Un po' di numeri:
Novembre 2025
Cardarelli/Federico II
17 pazienti/Teclistamab
6 linee mediana di terapia*

Mediana di attesa per ricovero: 29 giorni (17 – 70)

Giorni di ricovero: 14 (10 – 20)

Tocilizumab 41%

PFS 8.8 mesi

Trattati al Cardarelli: 23 (1 outpatient)

3 pazienti in protocollo (prima linea e mantenimento)

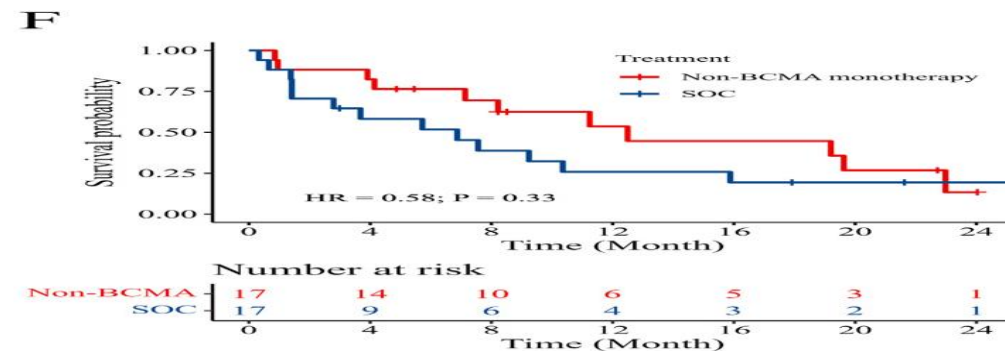
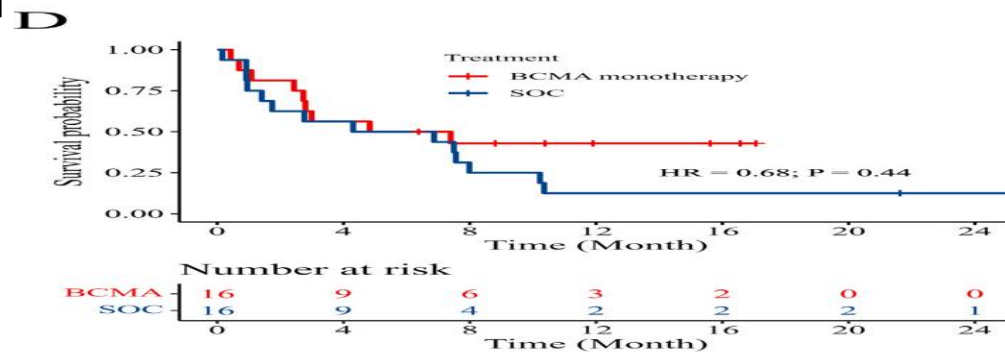
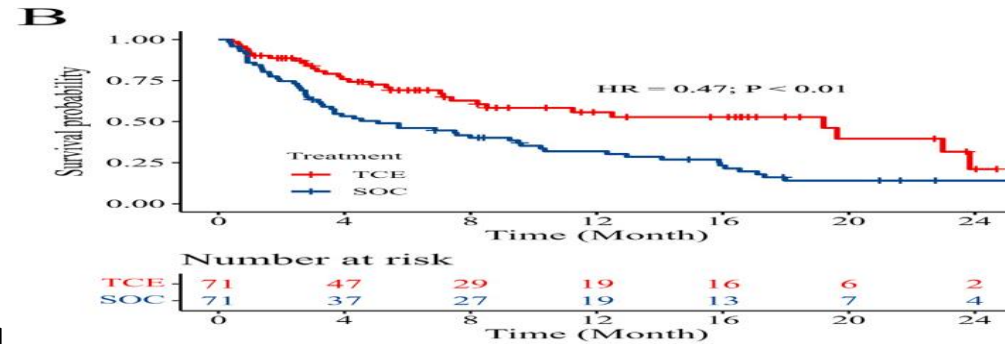
La rivoluzione terapeutica nel linfoma e nel mieloma

Real World data-based case-controlled study
transplantation and cellular Therapy

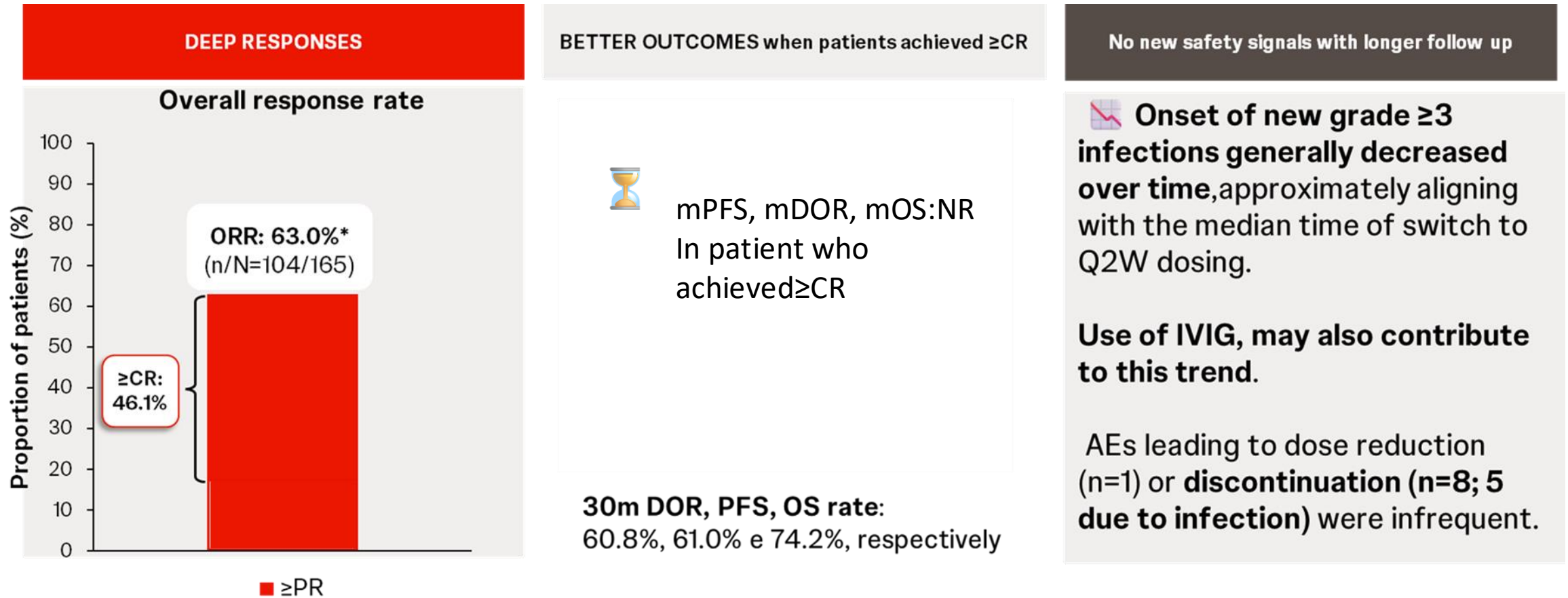
b) Intero gruppo

d) BCMA target therapy

f) Non BCMA target therapy



Deep and Durable Responses Through 2.5 Years of Follow-up in Patients with TCE RMM with Teclistamab¹



Garfall AL, et al. https://doi.org/10.1200/JCO.2024.42.16_suppl.7540; 2

Sustained Remission Following Limited Duration of Bispecific Antibody Therapy in Patients with Relapsed/Refractory Multiple Myeloma

22nd International Myeloma Society Annual Meeting
Toronto, Canada

Methods

Inclusion criteria

- Patients treated with bispecific or multispecific antibodies targeting BCMA and/or GPRC5D (either standard of care or an investigational drug)
- Stopped treatment for reasons other than progression or death
- Remained in remission ≥ 3 months post-discontinuation

Outcomes of interest

- Relapse-free survival
- Relapse and non-relapse mortality
- Cumulative incidence of \geq grade 3
- Kinetics of humoral immunodeficiency (assuming an IgG level of >700 mg/dL as normal)
- Utilization of intravenous immunoglobulin supplementation



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Patient Characteristics

78 out of 720 patients treated with a bispecific antibody were included

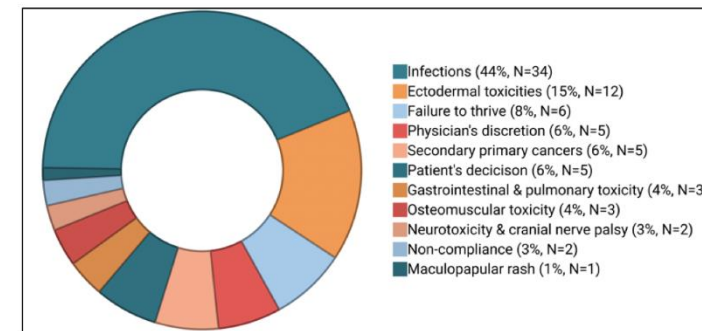
- Median prior lines of therapy: 4 (range 1-9)
- Median total duration of bispecific antibody before treatment discontinuation: 7 (range 1-40) months
- 97% of patients attained a \geq VGPR at treatment discontinuation
- 72% of patients were treated with a BCMA-directed bispecific antibody

Characteristics	N = 78 ¹
Age at initiation of bispecific antibody therapy	70 (26 - 86)
Sex	
Female	43 (55%)
Male	35 (45%)
Race	
Asian	2 (2.9%)
Black	14 (18%)
Caucasian	57 (73%)
Hispanic	3 (3.8%)
Others	2 (2.6%)
Subtype of myeloma	
IgA Kappa	12 (15%)
IgA Lambda	5 (6%)
IgG Kappa	19 (24%)
IgG Lambda	20 (26%)
Kappa light chain	16 (21.3%)
Lambda light chain	6 (7.7%)
High-risk cytogenetics [#]	35 (47%)
Extrasosseous extramedullary disease [#]	6 (8%)

Data is available in 75 patients. High-risk cytogenetics is defined by the presence of any one of these abnormalities on bone marrow FISH studies: t(4;14), t(14;16), t(14;20), gain/amp(1q), del(1p), or del(17p).

Causes For Treatment Discontinuation

The most common reason for treatment discontinuation was infections



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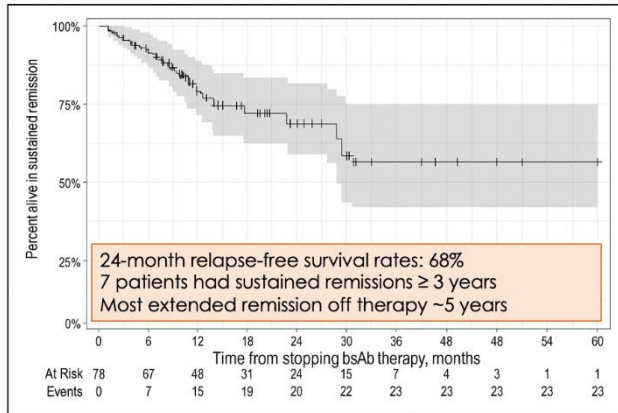


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Relapse-Free Survival and Its Predictive Factors



Factors associated with inferior relapse-free survival

- Presence of EMD (HR = 7.88; 95% CI: 1.95–31.8; $p < 0.004$)
- Higher number of prior lines of therapy (HR = 1.79; 95% CI: 1.32–2.43; $p < 0.001$)
- Partial remission at time of treatment discontinuation (HR = 28.3; 95% CI: 2.03–390; $p = 0.012$)

EMD: extramedullary disease; HR: hazard ratio
 AIC-guided backward model selection was used to select a parsimonious model for predicting relapse-free survival from the following predictors: Age at bispecific antibody (bsAb) initiation, sex, high-risk cytogenetics, EMD at initiation of bsAb, number of prior lines of therapy, number of prior ASCT, target of bsAb, time from myeloma diagnosis to the start of bsAb (grouped), best disease response (grouped), IMWG response at bsAb discontinuation (grouped), and total duration of bsAb therapy (grouped).

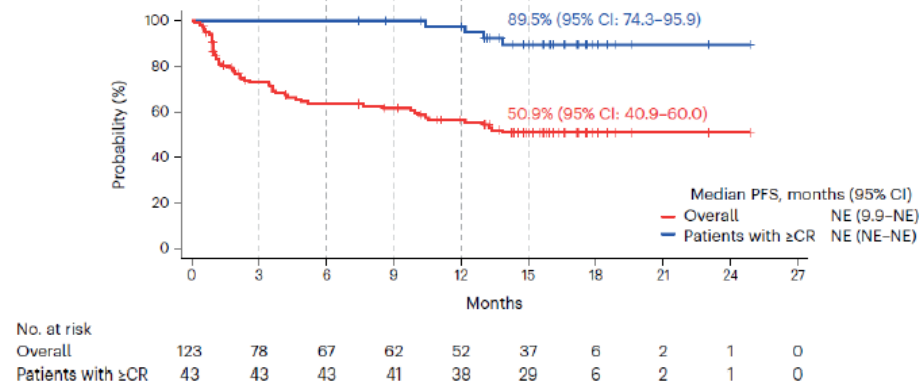
Conclusion

- The 24-month relapse-free survival after stopping the bispecific antibody was 68%, after a finite duration of therapy.
- The 24-month risk of \geq grade 3 infections was 32%, decreasing with time off therapy.
- Serum IgG increased by 13 mg/dL monthly off therapy, along with a reduction in IVIG use.
- Fixed-duration bispecific antibody led to sustained remission off therapy, improving infection risk and immune reconstitution over time.

Secondary Endpoints: PFS and OS*†

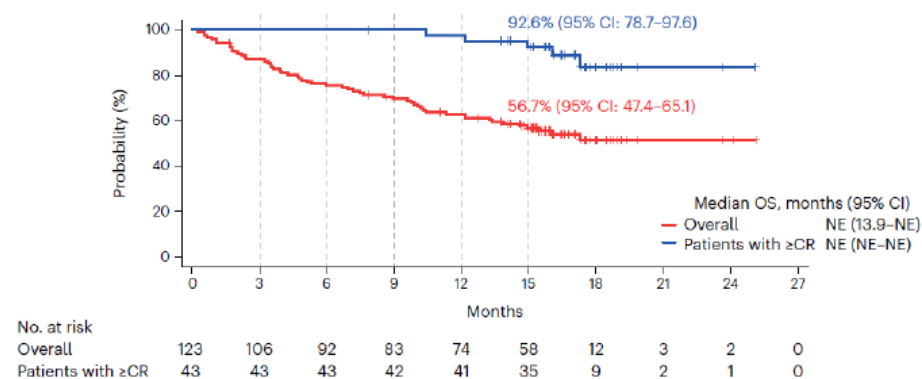
- The median PFS was not reached (95% CI 9.9–NE); 70 (56.9%) patients were censored at data cutoff (**Figure 1**)
- The Kaplan–Meier probability of PFS at 15 months in the overall population was 50.9% (95% CI 40.9–60.0), vs. 89.5% (95% CI 74.3–95.9) in patients with \geq CR

Figure 1: PFS in the Overall Population (n=123) vs. Patients With \geq CR (n=43)‡



- The median OS was not reached (95% CI 13.9–NE) (**Figure 2**)
- The Kaplan–Meier probability of survival at 15 months in the overall population was 56.7% (95% CI 47.4–65.1), vs. 92.6% (95% CI 78.7–97.6) in patients with \geq CR

Figure 2: OS in the Overall Population (n=123) vs. Patients With \geq CR (n=43)‡



Data cutoff: March 14, 2023. *Responses were assessed by BICR, whereas treatment decisions, including switch to Q2W dosing, were made by the investigator. †Time to event outcomes were consistent between BICR and investigator assessment. ‡Tick marks indicate censored data.

\geq CR = complete response or better; CI = confidence interval; NE = not evaluable; OS = overall survival; PFS = progression-free survival. Lesokhin AM, et al. *Nat Med.* 2023;29:2259–2267.

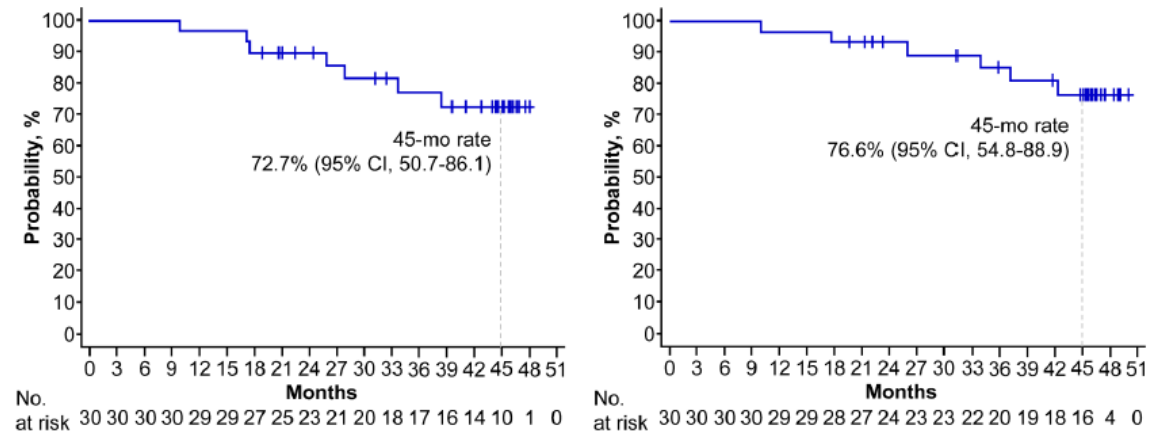
Prolonged Elranatamab Treatment Interruption in Patients With Relapsed or Refractory Multiple Myeloma is Feasible: A Retrospective Analysis From MagnetisMM-3 (6/8)

Lesokhin AM et al. (ASH Poster Presentation)

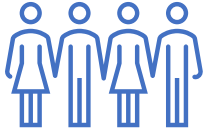
Results: PFS and OS

- Median PFS was not reached (95% CI NE-NE), and the probability of being event-free at 45 months was 72.7% (95% CI 50.7-86.1) (Figure)
- Median OS was not reached (95% CI NE-NE), and the probability of being alive at 45 months was 76.6% (95% CI 54.8-88.9) (Figure)

Figure. PFS and OS



Real-world data reflect everyday practice, including broader patient populations versus clinical trials¹⁻⁴

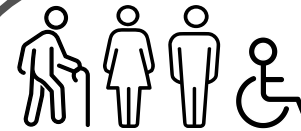


Clinical Trials^{1,2}

- Patients are randomised to treatment or comparator
- Selected patient population with strict inclusion and exclusion criteria
- Randomised treatment allocation ensures that confounding,^a as measured and unmeasured baseline characteristics, is minimised between patients administered different interventions



RWE can inform treatment decisions for patients excluded from RCTs due to comorbidities, age, or other factors₂



RWE studies^{1,3,4}

- Patients are not usually randomly assigned but treated per local clinical practice
- Heterogeneous patient population and unselected populations with few to no exclusion criteria (eg, patients with more comorbidities or older patients)
- Treatment selection is often influenced by patient characteristics, which may result in systemic difference in baseline characteristics of patients administered different interventions

^aConfounding occurs when a variable that predicts the outcome and exposure (ie, treatment status) is unevenly distributed between groups. Confounding is a concern because it may distort the association being measured. RCT, randomised clinical trial; RWE, real-world evidence.

1. Di Maio M, et al. *Oncologist*. 2020;25:e746-e752. 2. Kabisch M, et al. *Dtsch Arztebl Int*. 2011;108:663-668. 3. Villines TC, et al. *Clin Med Insights Cardiol*. 2020;14:1179546820953410. 4. Varga AN, et al. *Stat Med*. 2023;42:487-516.

Teclistamab deep, durable, and rapid responses are also observed in clinical practice¹



Study design

RetrosTECTive¹

Retrospective, multicentre
(N=303)



Patient population

- Patients initiated teclistamab between October 2022 and September 2023 under early access/NPP
- 68.6% (n=208) of patients were IMiD refractory, 64.0% (n=194) were PI refractory, and 54.5% (n=165) were anti-CD38 refractory
- 13.6% (n=41) of patients were BCMA exposed
- Median of 4 prior LOTs



Sites

30 French centres



Median follow-up, mo (range)

11.9 mo
(9.2-14.8)



46.2% of patients in RetrosTECTive were ineligible for MajesTEC-1

Table 1. Patient^a characteristics in IFM 2024-09 real-world study and in MajesTEC-1.^{2,3}

Characteristics	IFM 2024-09 N=303	MajesTEC-1 N=165
Age in years, median (range) >75 years, N (%)	70 (37-88) 90 (29.7)	64 (33-84) 24 (14.4)
Sex, N (%)		
Male	151 (49.9)	96 (58.2)
Female	152 (50.1)	69 (41.8)
Median prior lines of therapy (range)	4 (2-11)	5 (2-14)
Previous autologous transplant, N (%)	171 (56.4)	135 (81.8)
ImiD, N (%)		
exposed	302 (99.7)	165 (100)
refractory	208 (68.6)	152 (92.1)
PI, N (%)		
exposed	303 (100)	165 (100)
refractory	194 (64)	142 (86.1)
Anti-CD38 monoclonal antibody, N (%)		
exposed	295 (97.4)	165 (100)
refractory	165 (54.5)	148 (89.7)
BCMA exposed, N (%)	41 (13.6)	0
ECOG PS >2 at the initiation of teclistamab, N (%)	26 (8.5)	0
Severe renal failure at the initiation of teclistamab, N (%)	30 (9.9)	0
Ineligibility to MajesTEC-1, N (%)	140 (46.2)	0
High-risk cytogenetics, N (%)		
del(17p)	34/179 (19)	23/148 (15.5)
del(17p) and/or TP53 mutation	54/179 (30.2)	NA
t(4;14)	27/188 (14.3)	16/148 (10.8)
t(14;16)	4/97 (4)	4/148 (2.7)
Circulating plasma cells, N (%)	39 (13.8)	NA
EMD, N (%)	34 (11.8)	28 (17)
PMD, N (%)	70 (25.5)	NA
Median follow-up in months (IQR)	11.9 (9.2-14.8)	22 then 30.4

NA: not available; ImiD: immunomodulatory drugs; PI: proteasome inhibitors; BCMA: B-cell maturation antigen; ECOG PS: Eastern Cooperative Group Performance Status; EMD: extramedullary disease; PMD: paramedullary disease; IQR: interquartile range.

Teclistamab deep, durable, and rapid responses are also observed in clinical practice¹



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30 French centres

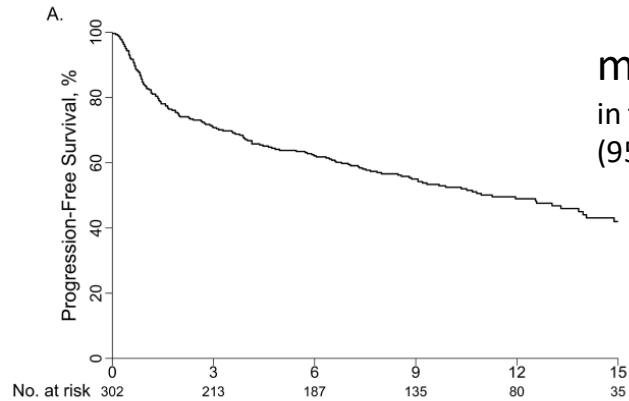
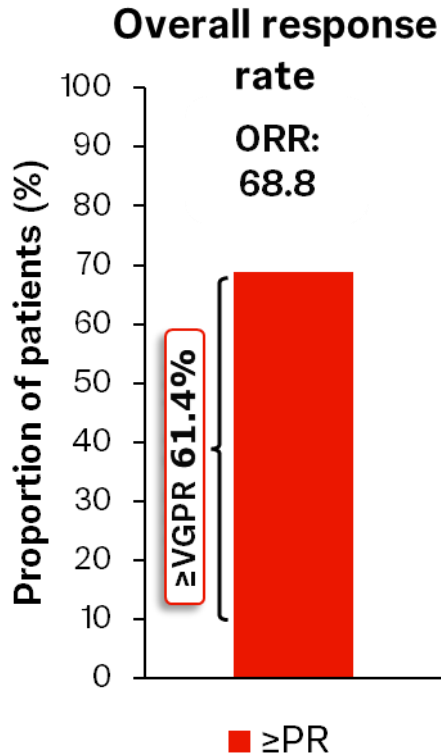


Median follow-up, mo (range)

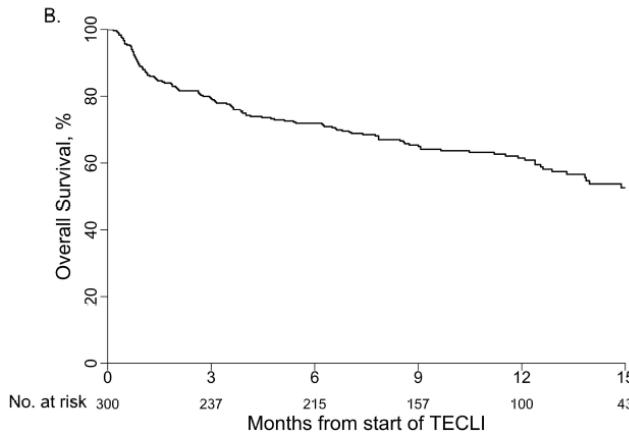
11.9 mo (9.2-14.8)



46.2% of patients in RetrosTECTive were ineligible for MajesTEC-1



mPFS: 11.3 months in the overall population (95%CI 8.9-14.9)*



mOS: 17 months (95%CI, 13.8-NA)

***Among the 175 responding patients, mPFS was 17 months.**

Perrot A, et al. *Haematologica*. 2025;110:990-994.

Real World Efficacy and Safety of Elranatamab, a BCMA Bispecific Antibody for Patients With RRMM: An International Myeloma Working Group Immunotherapy Database Analysis (3/6)

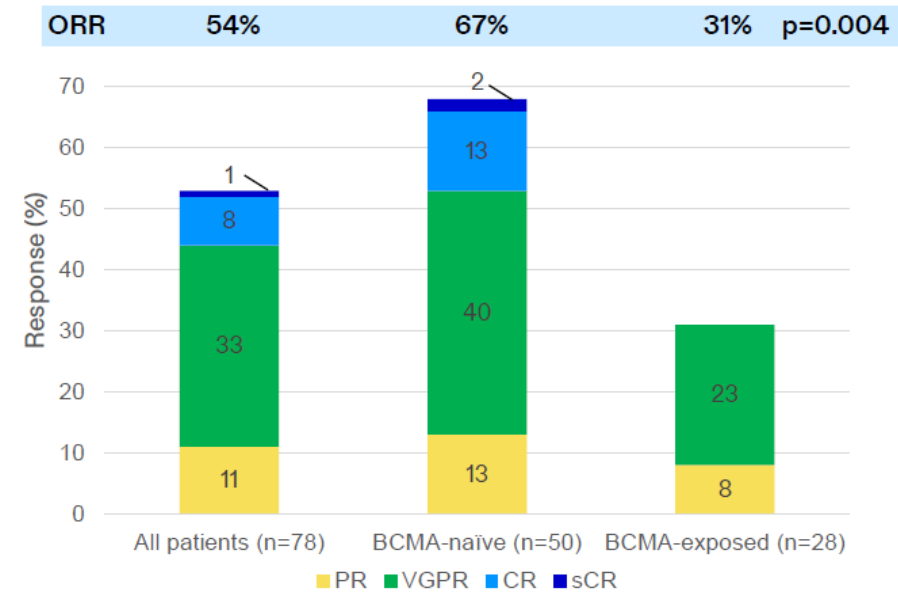
Popat R et al. (ASH Poster Presentation)

Table 1. Estimated Time-to-Event Analysis*

	6-month	12-month
PFS, % (95% CI)	64 (54-77)	52 (40-67)
OS, % (95% CI)	74 (64-85)	58 (45-74)

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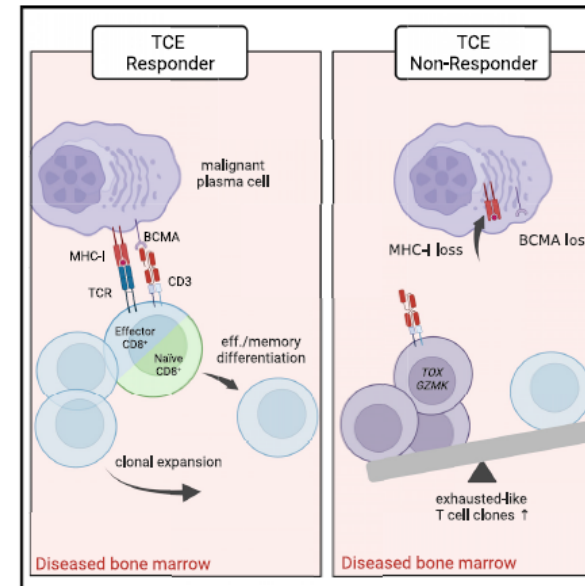
Figure. Response Rate and According to Prior BCMA Exposure



Cancer Cell

The pre-existing T cell landscape determines the response to bispecific T cell engagers in multiple myeloma patients

Graphical abstract



Authors

Mirco J. Friedrich, Paola Neri, Niklas Kehl, ..., Carsten Müller-Tidow, Marc-Steffen Raab, Nizar J. Bahlis

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In brief

Bispecific T cell engagers (TCEs) have shown promise in the treatment of various cancers, but their mode of action in humans is elusive. Providing new insight into immunological mechanisms, Friedrich et al. identify how T cells in multiple myeloma patients respond to TCEs according to their cell state and link inter-individual differences in the immune repertoire to clinical response.

Holding therapy/Bridge Therapy anche prima di bispecifici?

Quale?

Evidenze in vitro per Selinexor

3 casi dopo Melfuflen (+ 1 nostro)

Ask Stefano Rocco

Diverse associazioni in studio

Fasi preliminari

trispecifici

Original Article

Talquetamab plus Teclistamab in Relapsed or Refractory Multiple Myeloma

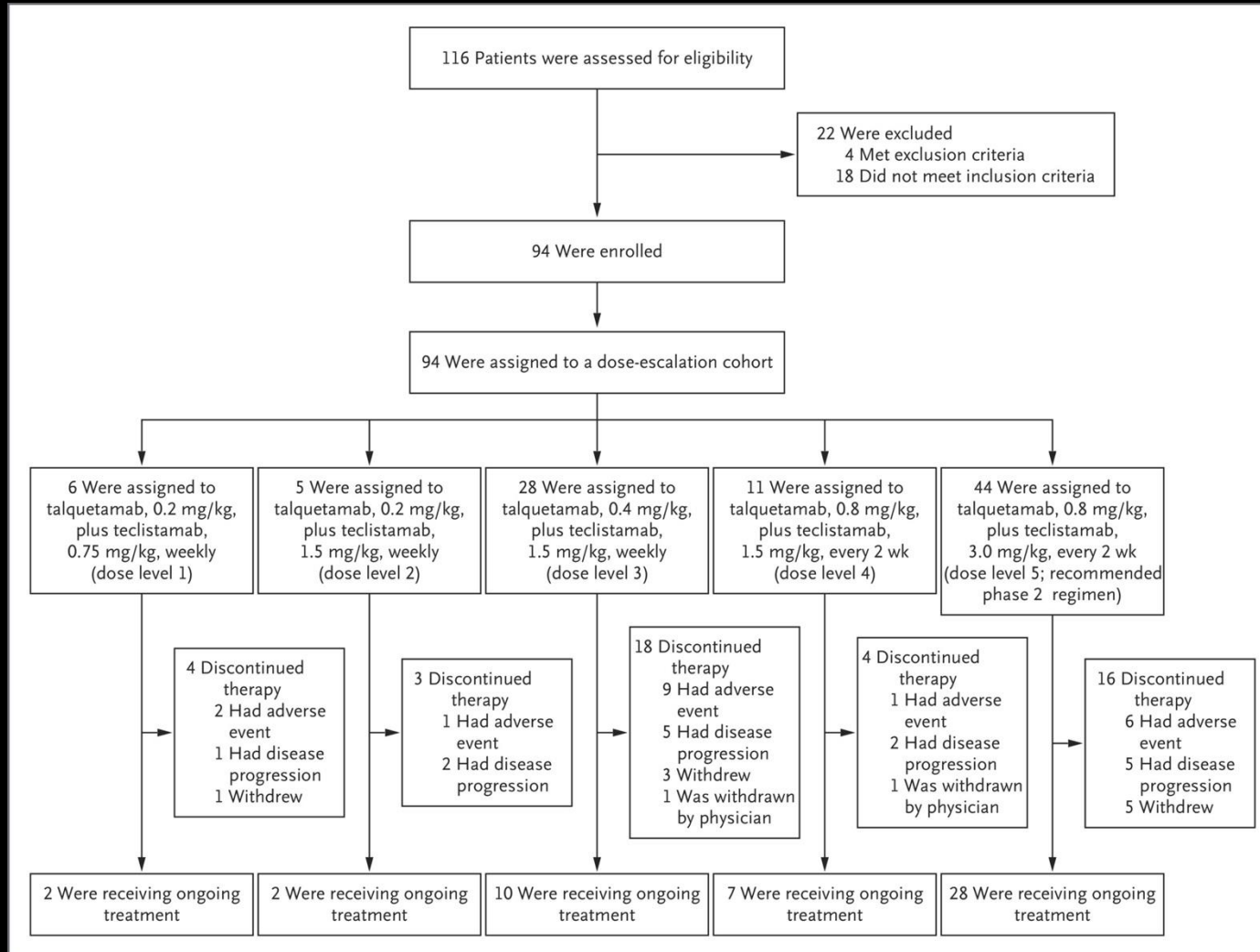
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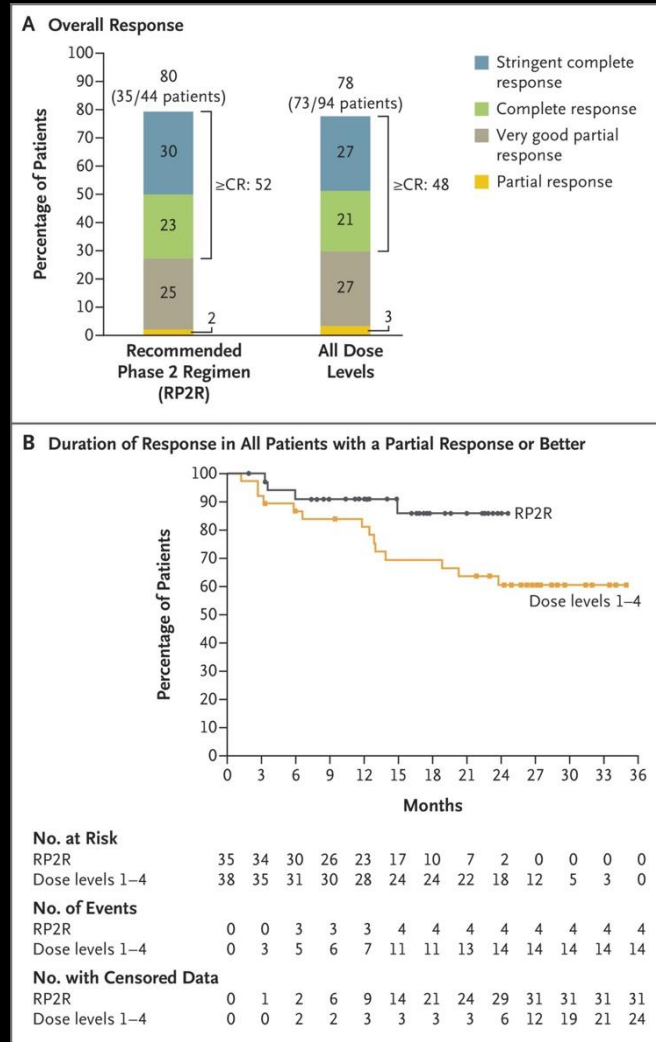
Dose-Cohort Assignment and Follow-up.



Cohen YC et al. N Engl J Med 2025; 392:138-149



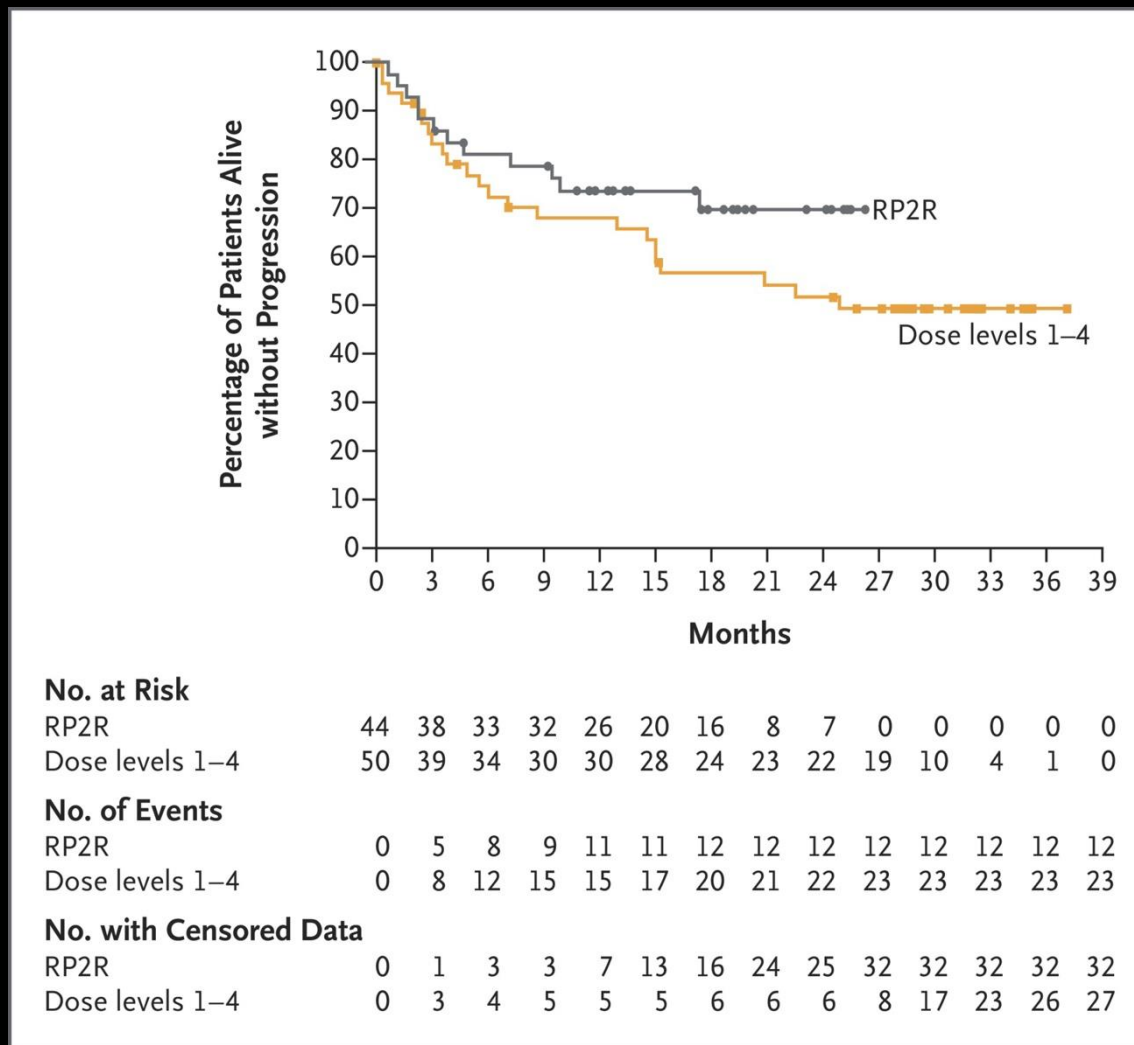
Response to Talquetamab plus Teclistamab in Patients with Relapsed or Refractory Multiple Myeloma.



Cohen YC et al. N Engl J Med 2025;392:138-149



Kaplan–Meier Analysis of Progression-free Survival.



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Conclusions

- The incidence of grade 3 or 4 infections with talquetamab plus teclistamab was higher than has been observed with either therapy alone.
- A response was observed in a high percentage of patients across all dose levels, with durable responses with the recommended phase 2 regimen.



Take Home Message

CAR-t FIRST (Oggi)

Bispecifici da implementare

Domani confronto con associazioni

Outpatient

Identificazione del paziente

Supporto con IG (anche sotto cute)

Necessità di fare rete



5 x 1000

iban



Grazie per
l'attenzione