OCEAN (OP-103): A Phase 3, Randomized, Global, Head-to-Head Comparison Study of Melflufen and Dexamethasone Versus Pomalidomide and Dexamethasone in Relapsed Refractory Multiple Myeloma

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FDA Regulatory Update

- Melphalan flufenamide (referred to hereinafter as “melflufen”) plus dexamethasone received **accelerated approval** by the US FDA (under trade name Pepaxto®) for the treatment of adult patients with RRMM who have received ≥4 prior lines of therapy and whose disease is refractory to ≥1 proteasome inhibitor, ≥1 immunomodulatory drug, and ≥1 anti-CD38 monoclonal antibody[1,2]
- In the confirmatory OCEAN trial, melflufen plus dexamethasone was superior compared with pomalidomide plus dexamethasone in terms of PFS (primary endpoint), but not OS (key secondary endpoint) in the ITT population[3]
- The US FDA issued a **partial clinical hold** based on the differences in the frequency and management of adverse events between the melflufen plus dexamethasone arm and the pomalidomide plus dexamethasone arm and the OS data in favour of the pomalidomide plus dexamethasone arm (HR, 1.104) for the ITT population[3,4]
- On 28 July, the US FDA issued a safety alert regarding an increased risk of death associated with melflufen in OCEAN[3,4]
- The US FDA has recently announced that a public advisory committee meeting of the **Oncologic Drugs Advisory Committee** discussing safety findings from OCEAN, will be held on **28 October 2021[5]**
- Oncopeptides is cooperating with the US FDA as OCEAN data are evaluated[3]

FDA, Food and Drug Administration; ITT, intention-to-treat; OS, overall survival; PFS, progression-free survival; RRMM, relapsed/refractory multiple myeloma.

1. Oncopeptides. Press Release, 28 July 2021. https://www.oncopeptides.com/en/media/press-releases/regulatory-update-from-us-food-and-drug-administration. 2. PEPAXTO® (melphalan flufenamide). Prescribing Information. Oncopeptides; 2021. 3. Oncopeptides. Press Release, 8 July 2021. https://www.oncopeptides.com/en/media/press-releases/updated-results-from-phase-3-ocean-study-shows-melflufen-met-primary-endpoint-of-superior-pfs--overall-survival-data-lead-to-partial-clinical-hold. 4. US Food and Drug Administration. FDA Drug Alert, 28 July 2021. https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-about-clinical-trial-results-showing-increased. 5.US FDA. Oncologic Drug Advisory Committee. https://public-inspection.federalregister.gov/2021-19024.pdf Accessed 2 September 2021.

Disclosures

Fredrik Schjesvold, MD, PhD

- **Consulting/Advisory**: Amgen, Celgene/Brystol Myers Squibb, Janssen, Novartis, Oncopeptides, Sanofi
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- **Stocks**: Nordic Nanovector, Oncopeptides
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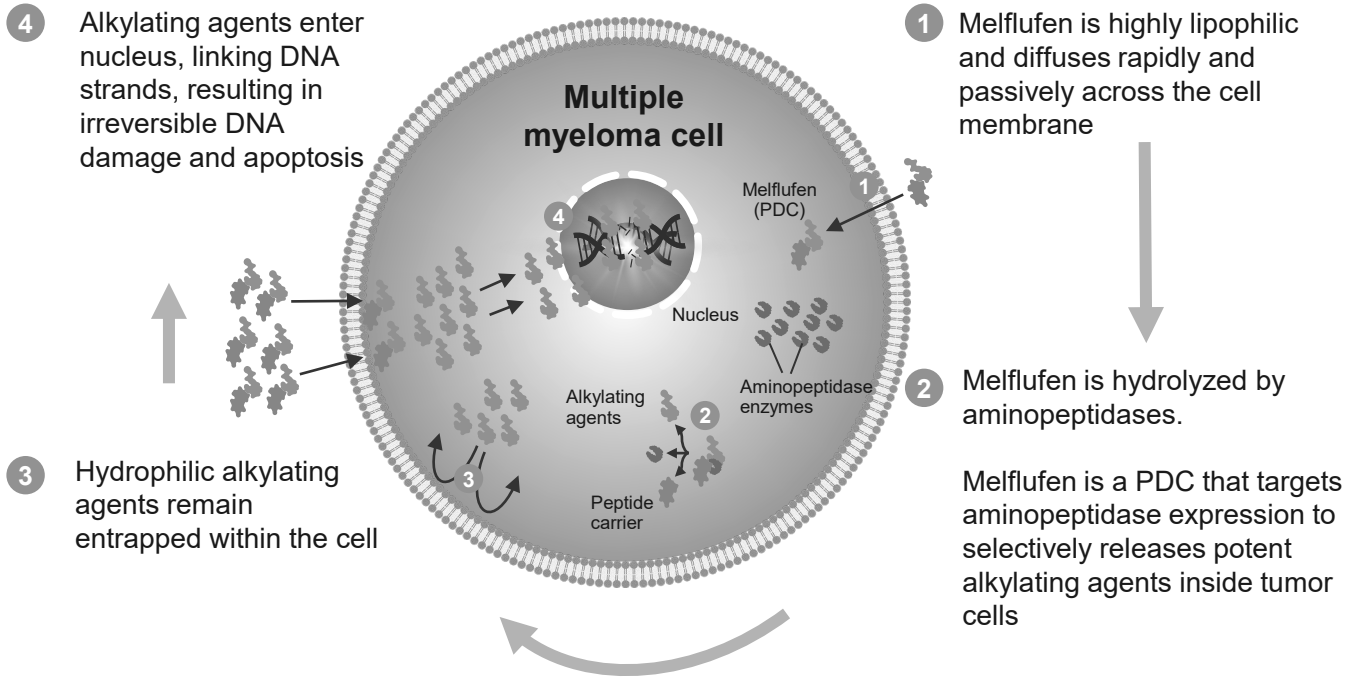
Melflufen in Relapsed/Refractory Multiple Myeloma



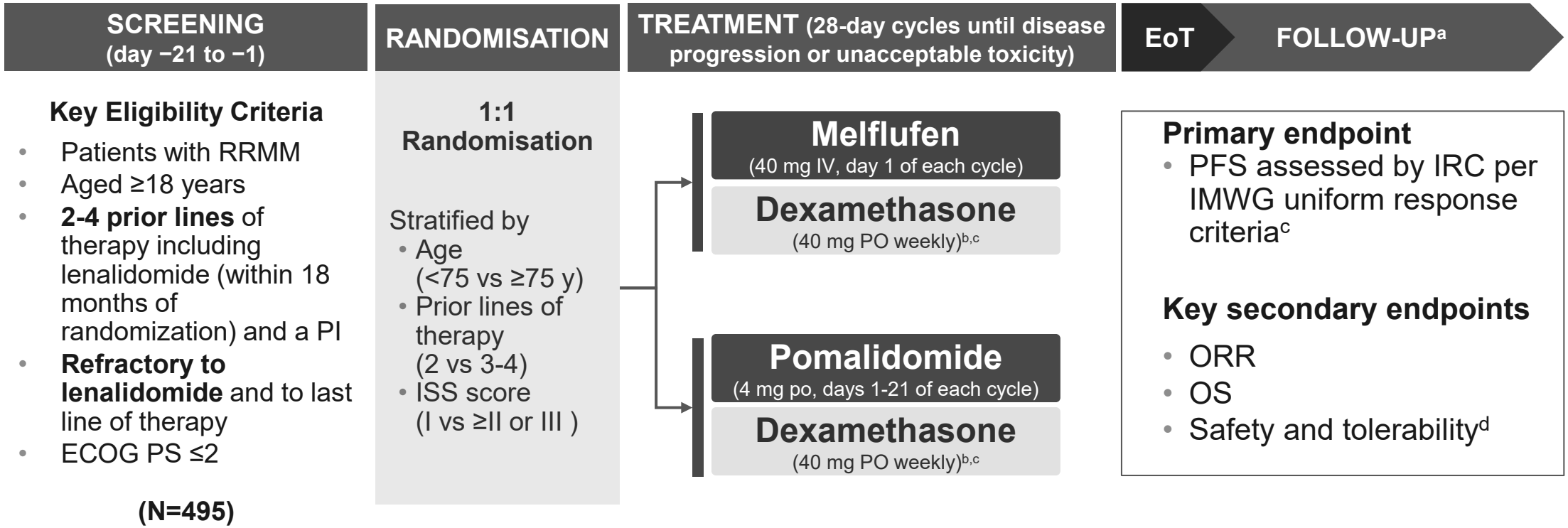
Melphalan flufenamide (melflufen) is a first-in-class peptide-drug conjugate (PDC) that targets aminopeptidases and thereby rapidly releases alkylating agents inside tumor cells.[1-6]

[a]Refractory to ≥1 proteasome inhibitor, ≥1 immunomodulatory drug, and ≥1 anti-CD38 monoclonal antibody.

1. PEPAXTO (melphalan flufenamide). [package insert]. Waltham, MA: Oncopeptides (publ); 2021. 2. Chauhan D, et al. *Clin Cancer Res*. 2013;19:3019-3031. 3. Wickström M, et al. *Oncotarget*. 2017;8:66641-66655. 4. Wickström M, et al. *Biochem Pharmacol*. 2010;79:1281-1290. 5. Gullbo J, et al. *J Drug Target*. 2003;11:355-363. 6. Ray A, et al. *Br J Haematol*. 2016;174:397-409.

OCEAN (OP-103): Study Design and Key Eligibility Criteria

Phase 3, Randomised, Open-Label, Controlled, Head-to-Head, Comparison Study



ECOG, Eastern Cooperative Oncology Group; EoT, end of treatment; IMWG, International Myeloma Working Group; IRC, independent review committee; ISS, International Staging System; IV, intravenous; melflufen, melphalan flufenamide; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; PO, orally; PS, performance status; RRMM, relapsed/refractory multiple myeloma.

[a]PFS follow-up every month until progressive disease; OS follow-up every 3 months for up to 24 months. [b]The starting dexamethasone dose was reduced to 20 mg in patients aged ≥75 years. [c]The study was powered to measure superiority using a log-rank test to determine the *P* value for the treatment comparison, and noninferiority (ie, if the upper limit of the 95% CI for the hazard ratio was below 1.2). [d]An independent data safety monitoring committee monitored the benefit-risk ratio at regular intervals.

Patient Characteristics

Characteristics	Melflufen + Dex (N=246)	Pom + Dex (N=249)
Age, median (IQR), years	68 (60-72)	68 (61-72)
<65 years, n (%)	96 (39)	85 (34)
65 to <75 years, n (%)	113 (46)	125 (50)
≥75 years, n (%)	37 (15)	39 (16)
Male sex, n (%)	139 (57)	140 (56)
ECOG PS (0 / 1 / 2), %	37 / 53 / 11	37 / 55 / 8
ISS score (I / II / III) at study entry, %	48 / 38 / 13	50 / 38 / 12
High-risk cytogenetics at study entry[a]	83 (34)	86 (35)
EMD at study entry	31 (13)	31 (12)
Previous lines of therapy, median (IQR), n	3 (2-3)	3 (2-3)
2 vs 3 or 4, %	46 / 54	45 / 55
Previous ASCT, n (%)	125 (51)	120 (48)
Refractory to previous line of therapy, n (%)		
Alkylator	78 (32)	75 (30)
Lenalidomide	245 (>99)	248 (>99)
Lenalidomide in last line of therapy	213 (87)	217 (87)
Proteasome inhibitor	163 (66)	163 (65)
Anti-CD38 monoclonal antibody	48 (20)	39 (16)
Triple-class–refractory disease[b]	39 (16)	30 (12)
Last line of therapy[c]	245 (>99)	247 (99)

ASCT, autologous stem cell transplant; dex, dexamethasone; ECOG, Eastern Cooperative Oncology Group; EMD, extramedullary disease; IQR, interquartile range; ISS, International Staging System; melflufen, melphalan flufenamide; pom, pomalidomide; PS, performance status.

[a]Defined as t(4;14), t(14;16), t(14;20), del(17p), gain(1q21), or gain 1q(+1q) by fluorescence in situ hybridization. [b]Refractory to ≥1 immunomodulatory drug, ≥1 proteasome inhibitor, and ≥1 anti-CD38 monoclonal antibody. [c]Failure to achieve at least a minimal response or progression on therapy within 60 days of the last dose of treatment.

Data cut-off date: 3 Feb. 2021

Melflufen Had a Numerically Higher Response Rate Compared With Pomalidomide

Key secondary endpoint

	Melflufen + Dex (N=246)	Pomalidomide + Dex (N=249)
ORR, % (95% CI)[a]	**33 (27-39)**	**27 (22-33)**
CBR, % (95% CI)[b]	50 (43-56)	41 (35-47)
Best confirmed response[c], n (%)		
Stringent complete response	0 (0)	0 (0)
Complete response	7 (3)	3 (1)
Very good partial response	23 (9)	18 (7)
Partial response	50 (20)	46 (18)
Minimal response	42 (17)	35 (14)
Stable disease	68 (28)	72 (29)
Progressive disease	36 (15)	60 (24)
Not evaluable	20 (8)	15 (6)
Time to best response, median (IQR), months	2.1 (1.1-3.7)	2.0 (1.1-2.9)

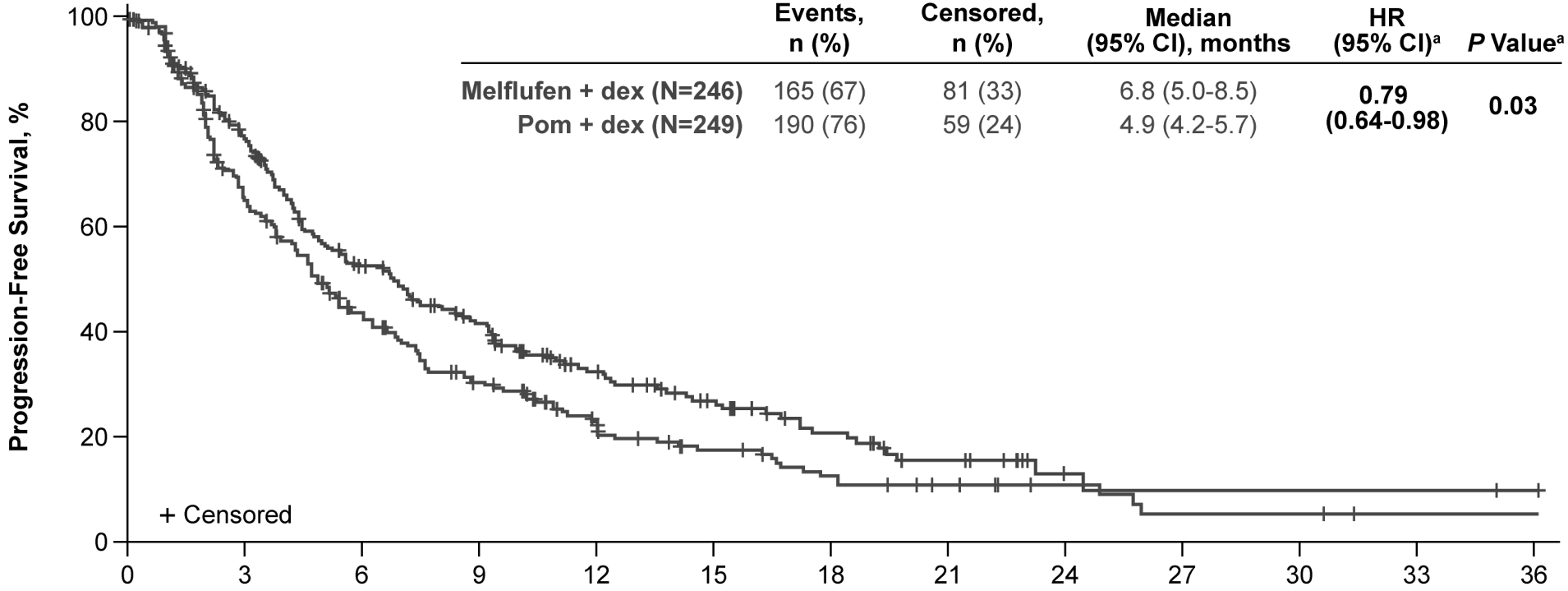
CBR, clinical benefit rate; dex, dexamethasone; IQR, interquartile range; melflufen, melphalan flufenamide; ORR, overall response rate.

[a]Defined as the proportion of patients with a partial response or better. [b]Defined as the proportion of patients with a minimal response or better. [c]Assessed by an independent review committee per the International Myeloma Working Group Uniform Response Criteria. All response categories required 2 consecutive assessments.

Data cut-off date: 3 Feb. 2021

Melflufen Met the Primary Endpoint of Superior PFS as Assessed by the IRC

Primary endpoint



	Events, n (%)	Censored, n (%)	Median (95% CI), months	HR (95% CI)[a]	*P* Value[a]
Melflufen + dex (N=246)	165 (67)	81 (33)	6.8 (5.0-8.5)	**0.79 (0.64-0.98)**	**0.03**
Pom + dex (N=249)	190 (76)	59 (24)	4.9 (4.2-5.7)		

Patients at risk, n

Melflufen + dex	246	168	109	80	50	34	22	13	5	3	3	3	2
Pom + dex	249	150	90	58	37	23	15	10	6	3	3	1	1

Median follow-up: 15.5 months (melflufen + dex) vs 16.3 months (pom + dex).

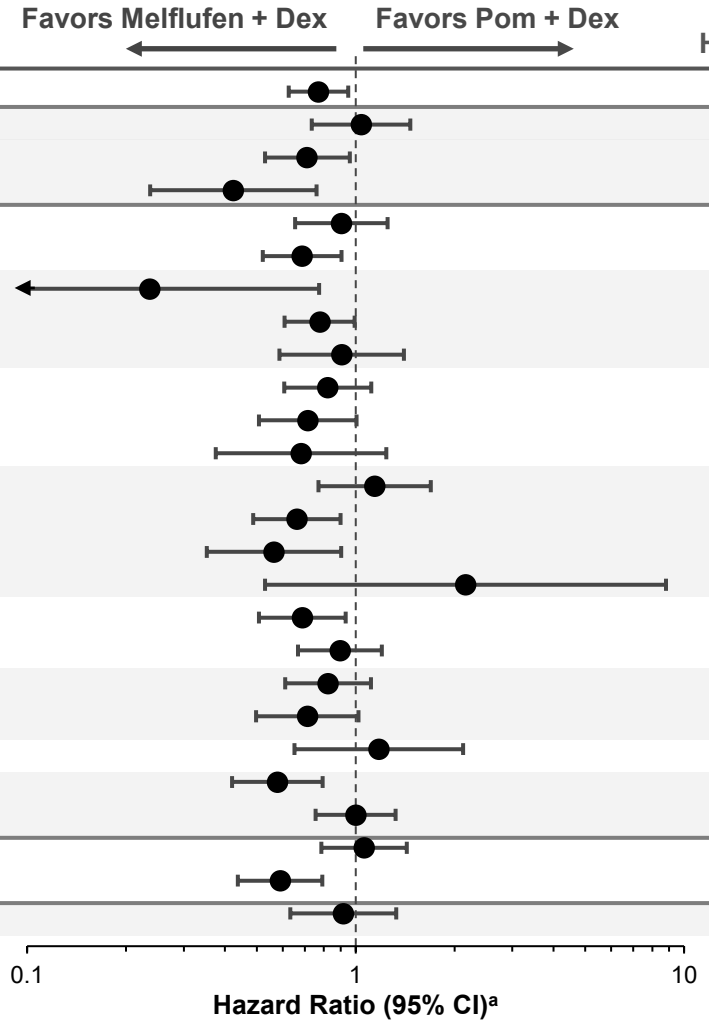
dex, dexamethasone; HR, hazard ratio; IRC, independent review committee; melflufen, melphalan flufenamide; pom, pomalidomide; PFS, progression-free survival.
[a]Stratified hazard ratio. [b]Log-rank *P* value.

Data cut-off date: 3 Feb. 2021

PFS was Generally in Favor of Melflufen in Subgroups

Prespecified analysis

Subgroup		Melflufen+ Dex, n	Pom + Dex, n	Hazard Ratio (95% CI)[a]	*P* Value[b]
Overall		**246**	**249**	**0.77 (0.63-0.95)**	**0.014**
Age category, years	<65	96	85	1.04 (0.74-1.47)	0.83
	65-74	113	125	0.71 (0.53-0.96)	0.03
	≥75	37	39	0.43 (0.24-0.76)	<0.01
Sex	Female	107	109	0.90 (0.65-1.25)	0.55
	Male	139	140	0.69 (0.52-0.91)	<0.01
Region	USA	11	15	0.24 (0.07-0.77)	0.01
	Europe	180	176	0.78 (0.61-0.99)	0.04
	ROW	55	58	0.91 (0.59-1.40)	0.66
ISS score	I	112	119	0.82 (0.61-1.12)	0.21
	II	88	95	0.72 (0.51-1.01)	0.05
	III	28	29	0.68 (0.38-1.24)	0.21
Creatinine clearance (mL/min)	≥90	76	69	1.14 (0.77-1.69)	0.51
	≥60 to <90	119	112	0.66 (0.49-0.90)	<0.01
	≥45 to <60	44	58	0.56 (0.35-0.90)	0.02
	<45	6	10	2.16 (0.53-8.80)	0.27
Median body surface area	≤1.855 m^2	116	128	0.69 (0.51-0.93)	0.02
	>1.855 m^2	126	117	0.90 (0.67-1.20)	0.46
Cytogenetic risk group	Standard	128	130	0.82 (0.61-1.11)	0.21
	High[c]	83	86	0.71 (0.50-1.02)	0.06
EMD at baseline		30	26	1.18 (0.65-2.12)	0.59
Number of prior regimens	2	114	111	0.58 (0.42-0.79)	<0.001
	3-4	132	138	1.00 (0.76-1.32)	1.00
Previous ASCT	Yes	125	120	1.06 (0.79-1.43)	0.69
	No	121	129	0.59 (0.44-0.79)	<0.001
Refractory to prior alkylator		78	75	0.92 (0.63-1.33)	0.65



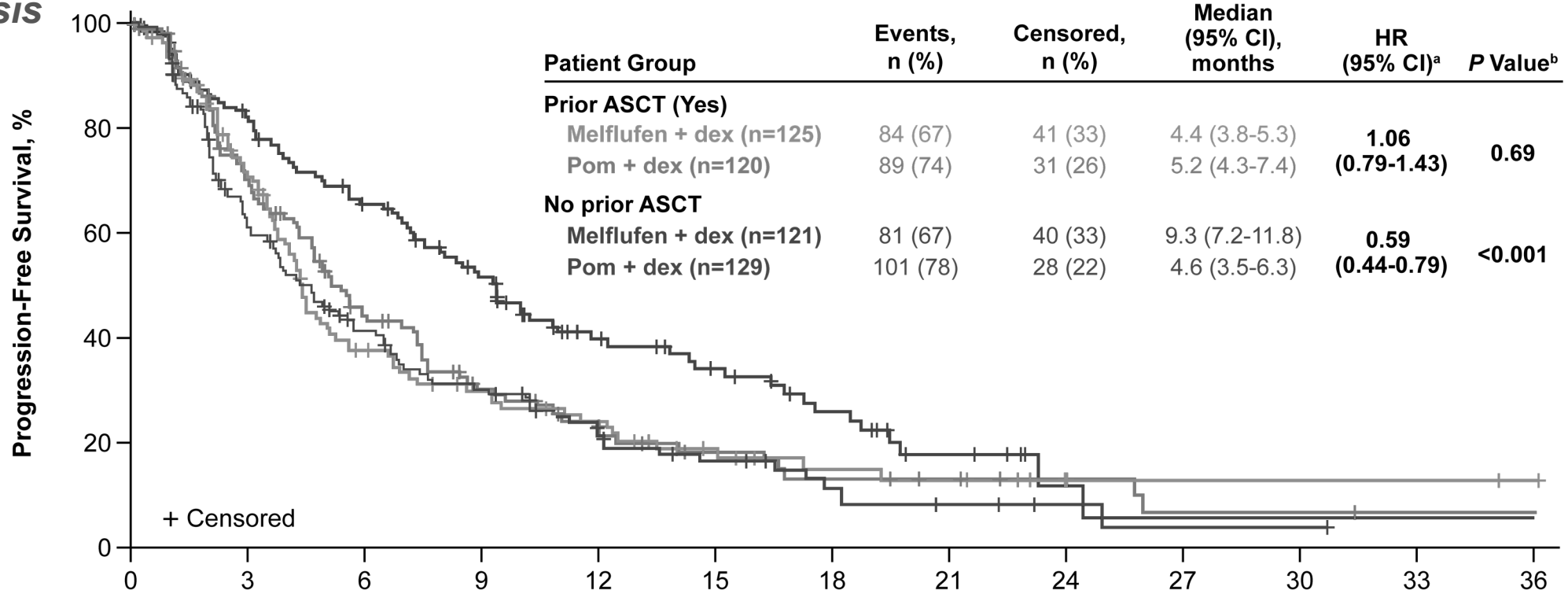
ASCT, autologous stem cell transplant; dex, dexamethasone; EMD, extramedullary disease; ISS, International Staging System score; melflufen, melphalan flufenamide; pom, pomalidomide; ROW, rest of world, USA, United States of America.

[a]Unstratified hazard ratio. [b]Log-rank *P* value. [c]High-risk defined as t(4;14), t(14;16), t(14;20), del(17p), gain(1q21), or gain 1q(+1q) by fluorescence in situ hybridization.

Data cut-off date: 3 Feb. 2021

PFS Benefit in the Melflufen Arm Mainly Driven by Patients Who Had Not Received a Prior ASCT

Post-hoc analysis



Patient Group	Events, n (%)	Censored, n (%)	Median (95% CI), months	HR (95% CI)[a]	*P* Value[b]
Prior ASCT (Yes)					
Melflufen + dex (n=125)	84 (67)	41 (33)	4.4 (3.8-5.3)	**1.06 (0.79-1.43)**	**0.69**
Pom + dex (n=120)	89 (74)	31 (26)	5.2 (4.3-7.4)		
No prior ASCT					
Melflufen + dex (n=121)	81 (67)	40 (33)	9.3 (7.2-11.8)	**0.59 (0.44-0.79)**	**<0.001**
Pom + dex (n=129)	101 (78)	28 (22)	4.6 (3.5-6.3)		

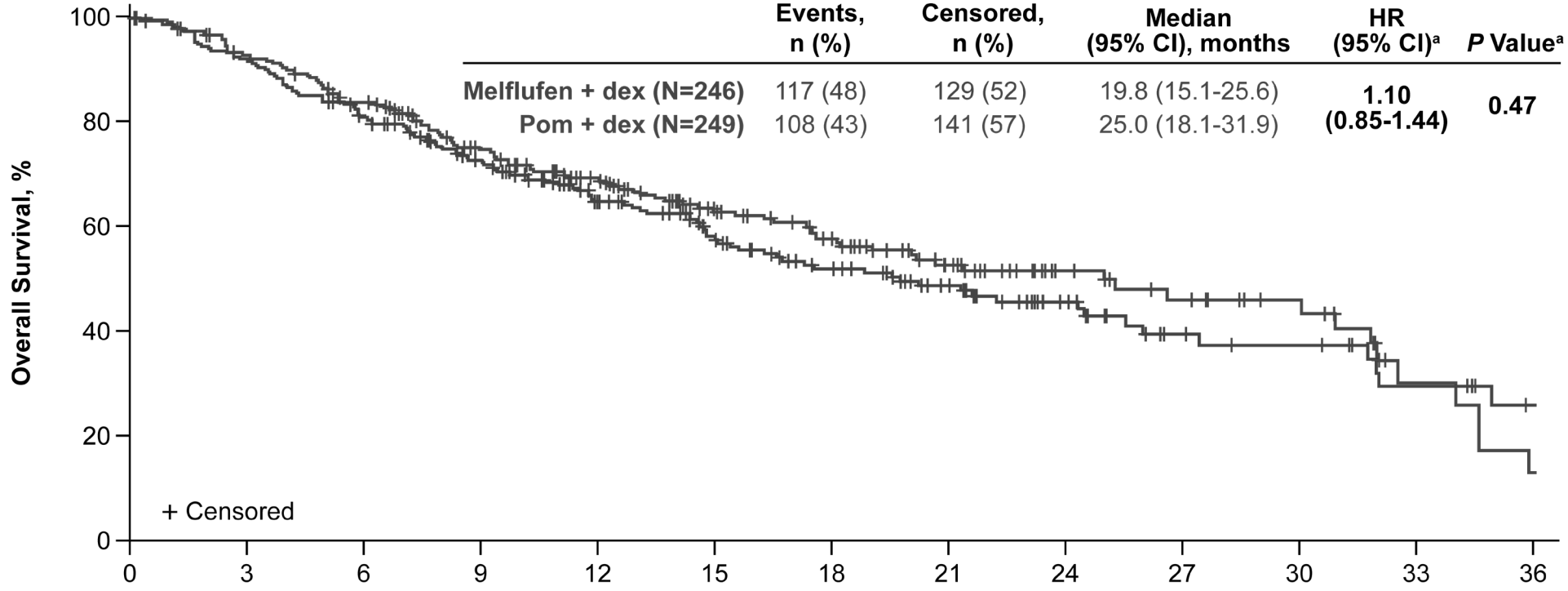
Patients at risk, n													
Prior ASCT (Yes)													
Melflufen + dex	74	36	26	19	11	7	6	3	2	2	2	1	0
Pom + dex	77	45	26	18	11	8	6	4	2	2	1	1	1
No prior ASCT													
Melflufen + dex	94	73	54	31	23	15	7	2	1	1	1	1	0
Pom + dex	73	45	32	19	12	7	4	2	1	1	0	0	0

ASCT, autologous stem cell transplant; dex, dexamethasone; HR, hazard ratio; melflufen, melphalan flufenamide; PFS, progression-free survival; pom, pomalidomide.
[a]Unstratified HR. [b]Log-rank *P* value.

Data cut-off date: 3 Feb. 2021

Overall Survival by Treatment Group

Key secondary endpoint



	Events, n (%)	Censored, n (%)	Median (95% CI), months	HR (95% CI)[a]	*P* Value[a]
Melflufen + dex (N=246)	117 (48)	129 (52)	19.8 (15.1-25.6)	**1.10 (0.85-1.44)**	**0.47**
Pom + dex (N=249)	108 (43)	141 (57)	25.0 (18.1-31.9)		

Patients at risk, n

Melflufen + dex	246	223	192	160	119	91	70	53	34	20	17	11	6
Pom + dex	249	225	196	157	129	95	75	53	31	24	18	7	3

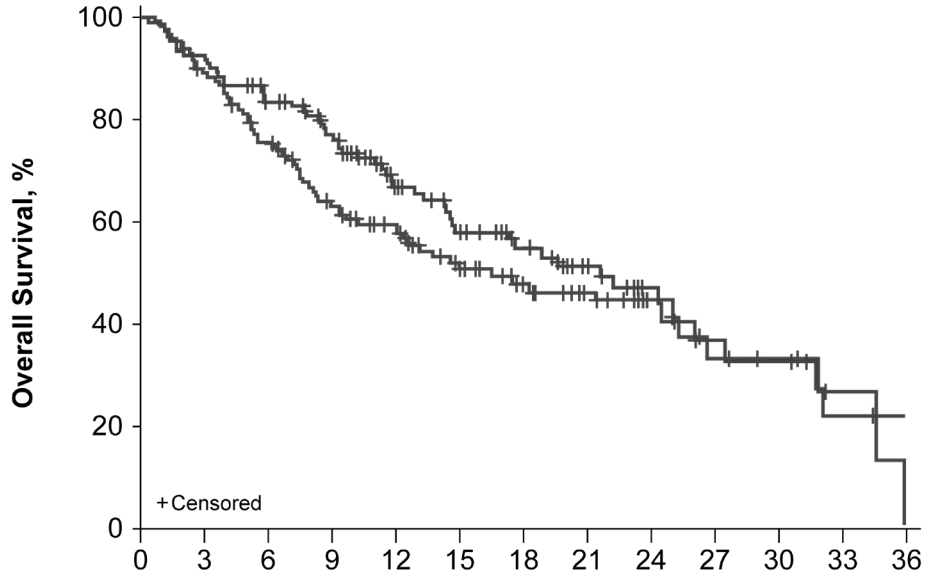
dex, dexamethasone; HR, hazard ratio; melflufen, melphalan flufenamide; pom, pomalidomide.
[a]Stratified hazard ratio. [b]Log-rank *P* value.

Data cut-off date: 3 Feb. 2021

OS Trended in Favor of Melflufen in Patients Without a Prior ASCT, and Favored Pom in Patients With a Prior ASCT

Post-hoc analysis

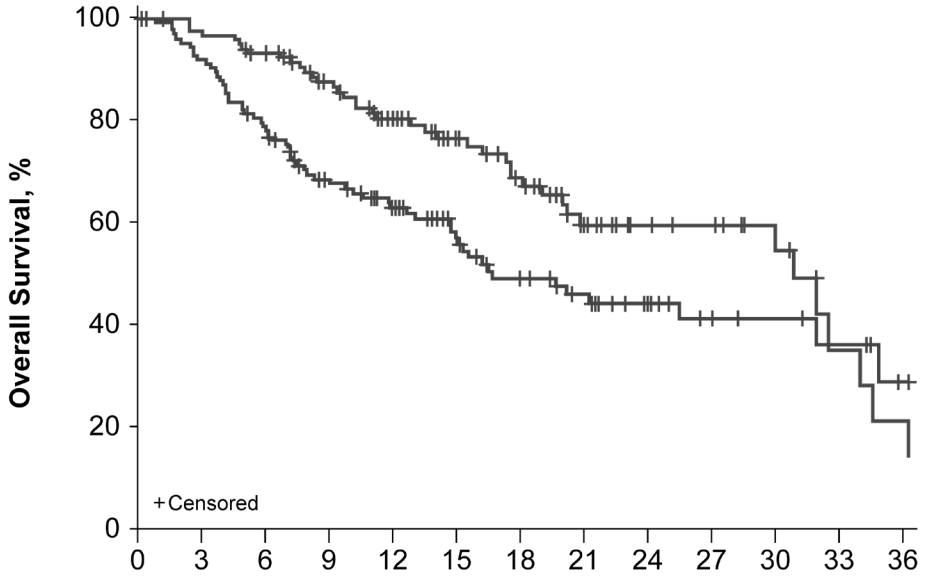
No Prior ASCT



Patients at risk, n													
Melflufen + dex	121	111	97	84	55	45	34	25	14	9	8	4	3
Pom + dex	129	112	91	70	59	43	32	24	13	8	6	2	0

No Prior ASCT	Patients, n: Events	Patients, n: Censored	Median (95% CI), months	HR (95% CI)[a]; *P* Value[b]
Melflufen + dex (n=121)	56	65	21.6 (14.6-26.0)	0.78 (0.55-1.12) *P*=0.1766
Pom + dex (n=129)	67	62	16.5 (10.3-25.3)	

Prior ASCT (Yes)



Patients at risk, n													
Melflufen + dex	125	112	95	76	64	46	36	28	20	11	9	7	3
Pom + dex	120	113	105	87	70	52	43	29	18	16	12	5	3

Prior ASCT (Yes)	Patients, n: Events	Patients, n: Censored	Median (95% CI), months	HR (95% CI)[a]; *P* Value[b]
Melflufen + dex (n=125)	61	64	16.7 (14.8-32.0)	1.61 (1.09-2.40) *P*=0.0170
Pom + dex (n=120)	41	79	31.0 (20.2-34.1)	

ASCT, autologous stem cell transplant; dex, dexamethasone; HR, hazard ratio; melflufen, melphalan flufenamide; pom, pomalidomide.
[a]Unstratified HR. [b]Log-rank *P* value.

Data cut-off date: 3 Feb. 2021

Deaths on Study

		Melflufen + Dex	Pom + Dex
Patients randomized (intention-to-treat population), n		**246**	**249**
Total number of deaths in the intention-to-treat population, n (%)		117 (48)	108 (43)
Patients randomized and who received ≥1 dose of study drug (safety population), n		**228**	**246**
Total of deaths in the safety population, n (%)		106 (46)	106 (43)
Death ≤30 days after last dose, n (%)		23 (10)	33 (13)
Primary cause of death (death ≤30 days after last dose), n (%)	Adverse event	16 (7)	23 (9)
	Progressive disease	7 (3)	8 (3)
	Unknown	0	2 (1)
Death >30 days after last dose, n (%)		83 (36)	73 (30)
Primary cause of death (death >30 days after last dose), n (%)	Progressive disease	53 (23)	46 (19)
	Other	11 (5)	11 (4)
	Unknown	13 (6)	13 (5)
	Adverse event	6 (3)	3 (1)
Deaths attributed to COVID-19, n (%)		7 (3)	4 (2)

dex, dexamethasone; melflufen, melphalan flufenamide; pom, pomalidomide.

Data cut-off date: 3 Feb. 2021

Treatment-Emergent Adverse Events of Special Interest

Treatment-Emergent Adverse Events of Special Interest, n (%)[a]	Melflufen + Dex (n=228)	Pom + Dex (n=246)
Thrombocytopenia	198 (87)	58 (24)
Grade 3/4	174 (76)	31 (13)
Haemorrhage	36 (16)	16 (7)
Grade 3/4 haemorrhage and concomitant grade 3/4 thrombocytopenia	2 (1)	0
Neutropenia	161 (71)	135 (55)
Grade 3/4	147 (64)	121 (49)
Infection	114 (50)	137 (56)
Grade 3/4	30 (13)	53 (22)
Grade 3/4 infection and concomitant grade 3/4 neutropenia	7 (3)	16 (7)
Infective pneumonia	38 (17)	60 (24)
Grade 3/4	12 (5)	30 (12)
Grade 3/4 infective pneumonia and concomitant grade 3/4 neutropenia	2 (1)	8 (3)
Febrile neutropenia	6 (3)	4 (2)
Anaemia	153 (67)	93 (38)
Second primary malignancy	3 (1)	6 (2)
Myelodysplastic syndromes or acute myeloid leukaemia	1 (<1)	1 (<1)

dex, dexamethasone; melflufen, melphalan flufenamide; pom, pomalidomide.

[a]Treatment-emergent adverse events of special interest are categorized by standardized MedDRA query (SMQ); anaemia includes Haematopoietic erythropenia (SMQ); neutropenia includes neutropenia, febrile neutropenia, neutrophil count decreased, neutropenic sepsis, neutropenic infection, cyclic neutropenia, band neutrophil count decreased, band neutrophil percentage decreased, neutrophil percentage decreased, agranulocytosis, granulocyte count decreased, and granulocytopenia; thrombocytopenia includes haematopoietic thrombocytopenia (SMQ); haemorrhages includes haemorrhage terms (excl laboratory terms) (SMQ) and haemorrhage laboratory terms (SMQ) narrow were combined; second primary malignancy includes the high level term myelodysplastic syndromes or any term in malignant or unspecified tumours (SMQ), but will exclude high level group term plasma cell neoplasm; and myelodysplastic syndromes includes the high level term myelodysplastic syndromes.

Data cut-off date: 3 Feb. 2021

Safety Overview

Treatment-Emergent Adverse Events (TEAEs), n (%)	Melflufen + Dex (n=228)	Pom + Dex (n=246)
Any TEAE	226 (99)	241 (98)
Any grade ≥3 TEAE	206 (90)	189 (77)
Non-haematologic grade 3/4 TEAEs occurring in ≥2% of patients overall		
Pneumonia	10 (4)	20 (8)
Muscular weakness	5 (2)	5 (2)
Hyperglycaemia	4 (2)	7 (3)
Asthenia	4 (2)	6 (2)
COVID-19 pneumonia	4 (2)	4 (2)
Hypertension	4 (2)	4 (2)
Bronchitis	3 (1)	5 (2)
Acute kidney injury	2 (1)	6 (2)
Any treatment-related TEAE	216 (95)	209 (85)
Any serious TEAE	95 (42)	113 (46)
Any serious treatment-related TEAE	42 (18)	52 (21)
Any TEAE leading to dose modifications of melflufen or pom	178 (78)	144 (59)
Dose delays	137 (60)	109 (44)
Reductions[a]	107 (47)	37 (15)
Permanent discontinuation	60 (26)	54 (22)

dex, dexamethasone; melflufen, melphalan flufenamide; pom, pomalidomide.

[a]Dose reductions of melflufen were allowed for drug-related toxicities from 40 mg to 30 mg or 20 mg. Treatment was discontinued in patients unable to tolerate the 20-mg dose. Dose reductions of pomalidomide were also allowed for drug-related toxicities from 4 mg to 3 mg to 2 mg. Treatment was discontinued in patients unable to tolerate the 2-mg dose.

Data cut-off date: 3 Feb. 2021

Conclusions

- The phase 3 OCEAN study enabled a direct head-to-head comparison of melflufen plus dexamethasone versus pomalidomide plus dexamethasone in RRMM
- Melflufen plus dexamethasone was superior to pomalidomide plus dexamethasone for the primary endpoint of PFS
- OS trended in favour of melflufen plus dexamethasone in patients without a prior ASCT, and favoured pomalidomide plus dexamethasone in patients with a prior ASCT
- The safety of melflufen plus dexamethasone primarily consisted of haematologic adverse events that were manageable with dose modifications, which is consistent with previous reports[1-3]
- Results from OCEAN suggest that melflufen plus dexamethasone may become a potential treatment for patients with lenalidomide-refractory RRMM who have received 2-4 previous lines of therapy and who have not received a prior ASCT

ASCT, autologous stem cell transplant; melflufen, melphalan flufenamide; OS, overall survival; PFS, progression-free survival; RRMM, relapsed/refractory multiple myeloma.

1. Richardson PG, et al. *Lancet Haematol*. 2020;7:e395-e407. 2. Bringhen S, et al. *Br J Haematol*. 2021;193:1105-1109. 3. Richardson PG, et al. *J Clin Oncol*. 2021;39:757-767.

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