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Long-Term Outcomes From the Phase 3 OCEAN (OP-103) Study: Melphalan Flufenamide (Melflufen) and Dexamethasone Versus Pomalidomide and Dexamethasone in Relapsed Refractory Multiple Myeloma

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CONCLUSIONS

- Long-term results of the OCEAN study reported here were consistent with previous analyses[1]
- Overall survival (OS) outcomes continued to be more favorable with melflufen + dexamethasone (dex) in patients with no prior autologous stem cell transplant (ASCT) or with time to progression (TTP) >36 months after ASCT (defined as the target population)
  - OS in the intention-to-treat (ITT) population, however, trended in favor of pomalidomide (pom) + dex
- No new safety signals were reported
  - The safety of melflufen + dex primarily consisted of hematologic adverse events that were manageable with dose modifications, which is consistent with previous reports[1-4]
- This long-term follow-up of OCEAN confirms the favorable safety and overall survival outcomes of melflufen + dex in the target population and supports its continued use as a treatment choice for patients with relapsed refractory multiple myeloma (RRMM)

BACKGROUND

- Melphalan flufenamide (melflufen) is a first-in-class peptide-drug conjugate that utilizes increased peptidase expression to selectively release potent alkylating agents inside tumor cells[5-9] (**Suppl Fig 1**)
- Based on results of the phase 2 HORIZON study and supported by the phase 3, randomized, controlled OCEAN study,[1,4] melflufen was approved in Europe for use in patients with triple-class refractory multiple myeloma with ≥3 prior lines of therapy (LoTs) and without prior ASCT or with a TTP >36 months after prior ASCT
- In the OCEAN study, melflufen + dex showed superior progression-free survival (PFS) compared with pom + dex (6.8 vs 4.9 months; hazard ratio [HR]: 0.79; *P*=0.032)
  - PFS benefit in the melflufen + dex arm was mainly driven by patients who had not received prior ASCT
- OS in the ITT population was not different between the melflufen and pom arms (19.8 vs 25.0 months; HR: 1.10; *P*=0.47) at a median follow-up of 19.8 vs 18.6 months[1]
  - However, OS trended in favor of melflufen + dex in patients without prior ASCT and favored pom + dex in patients with prior ASCT[1]
- Post-hoc analyses of OCEAN and HORIZON demonstrated that a TTP <36 months after prior ASCT was a negative prognostic factor for OS with melflufen + dex[10]

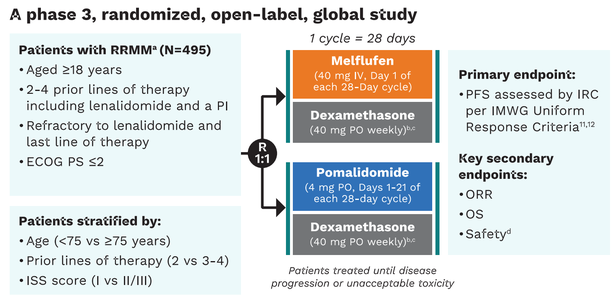
OBJECTIVE

- Here, we present long-term OS and safety data (2-year follow-up from the initial data cut) from the final analysis of the OCEAN study (OP-103; NCT03151811) in patients with RRMM treated with melflufen + dex or pom + dex

METHODS

- The OCEAN study was a randomized phase 3, head-to-head study of melflufen + dex compared with pom + dex in patients with RRMM who had disease refractory to lenalidomide and last line of therapy (**Figure 1**)
  - Patients must have received 2-4 prior LoTs including lenalidomide and a proteasome inhibitor
- Patients were randomized 1:1 (stratified by age, number of prior LoTs, and International Staging System score) to receive either
  - 28-day cycles of melflufen 40 mg intravenously on day 1 OR pom 4 mg orally daily on days 1 to 21
  - All patients received dex 40 mg (20 mg for patients ≥75 years) orally on days 1, 8, 15, and 22
- Analyses were performed in
  - The ITT population: all patients assigned to treatment
  - The safety analysis set: all patients who received at least 1 dose of melflufen, pom, or dex
  - The target population: patients without a prior ASCT or TTP >36 months after an ASCT

Figure 1. OCEAN Study Design



[a]Select inclusion criteria. Other criteria apply. [b]Days 1, 8, 15, and 22 of each 28-day cycle. [c]The starting dexamethasone dose will be reduced to 20 mg in patients aged ≥75 years. [d]An independent data safety monitoring committee will monitor the risk-benefit ratio at regular intervals, as previously described by Schjesvold et al.[1]
ECOG PS, Eastern Cooperative Oncology Group performance status; IMWG, International Myeloma Working Group; IRC, independent review committee; ISS, International Staging System; IV, intravenously; ORR, overall response rate; PI, proteasome inhibitor; PO, orally; R, randomization.

RESULTS

PATIENTS

- As of the data cutoff date of February 3, 2023, 228 of 246 (93%) patients randomized to the melflufen arm, and 246 of 249 (99%) patients randomized to the pom arm, received at least 1 dose of study drug, and were included in the safety analysis (**Suppl Fig 2**)
  - In both arms, the most frequent reasons for treatment discontinuation were progressive disease (57% and 69%) and adverse events (AEs, 21% and 16%)
  - In both arms, the most frequent reasons for study discontinuation were death (73% and 68%) and study terminated by sponsor (18% and 22%)
- Baseline characteristics are shown in **Table 1**
  - The median age was 68 years (range, 39-91)
  - Patients had received a median of 3 prior LoTs

Table 1. Baseline Patient Characteristics

Characteristics	Melflufen + Dex (n=246)	Pom + Dex (n=249)
Age, median (range), years	68 (41-91)	68 (39-87)
<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, n (%)[a]	83 (34)	86 (35)
EMD at study entry, n (%)	31 (13)	31 (12)
Previous lines of therapy, median (range)	3 (2-4)	3 (2-4)
2 vs 3 or 4, %	46/54	45/55
Previous ASCT, n (%)	125 (51)	120 (48)

Data cutoff date: February 3, 2023.
[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.
ASCT, autologous stem cell transplant; dex, dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; EMD, extramedullary disease; ISS, International Staging System; melflufen, melphalan flufenamide; pom, pomalidomide.

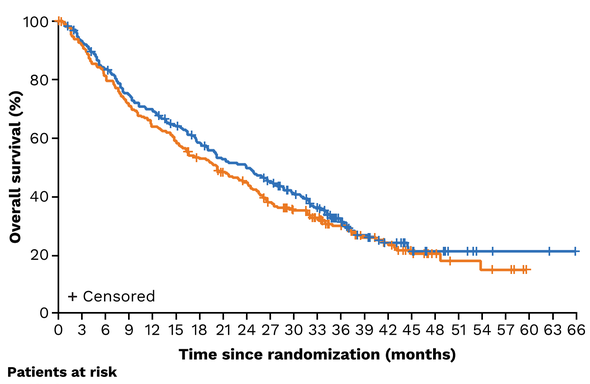
EFFICACY

OVERALL SURVIVAL

- ITT population: Median OS in the ITT melflufen and pom populations was 20.2 vs 24.0 months (HR, 1.09 [95% CI, 0.88-1.35]), at a median follow-up of 40.3 and 38.1 months, respectively (**Figure 2**)
  - Target population: Median OS in patients without a prior ASCT or TTP >36 months after an ASCT was 23.6 vs 19.1 months (HR, 0.88 [95% CI, 0.67-1.16]) in the melflufen and pom groups, respectively (**Figure 3A**)
  - Non-target population: Median OS in patients with TTP <36 months after ASCT was 15.7 vs 27.5 months (HR, 1.60 [95% CI, 1.15-2.21]) in the melflufen and pom groups, respectively (**Figure 3B**)

Figure 2. OS in the ITT Population

	Events, n (%)	Median (95% CI), months	HR (95% CI)[a]	*P*-value[b]
Melflufen + dex (N=246)	180 (73)	20.2 (15.8-24.1)	1.09 (0.88-1.35)	0.4088
Pom + dex (N=249)	169 (68)	24.0 (18.9-27.9)		

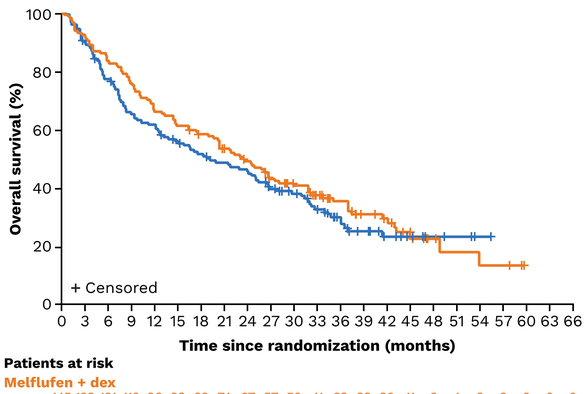


Data cutoff date: February 3, 2023.
[a]HR (and associated 95% CI) and *P*-value are calculated using a Cox proportional hazards regression model stratified by randomization strata: age (<75, >75), number of lines of prior therapy (2, 3-4), and ISS Score (1, ≥2). [b]Log-rank test stratified by randomization strata: age (<75, >75), number of lines of prior therapy (2, 3-4), and ISS Score (1, ≥2).
Dex, dexamethasone; HR, hazard ratio; ISS, International Staging System; ITT, intention-to-treat; OS, overall survival; pom, pomalidomide.

Figure 3. OS in Patients (A) Without ASCT or TTP >36 Months After ASCT and (B) With TTP <36 Months After ASCT

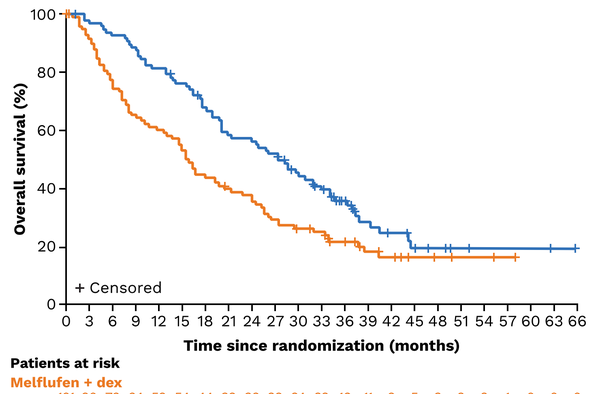
A

	Events, n (%)	Median (95% CI), months	HR (95% CI)[a]	*P*-value[b]
Melflufen + dex (N=145)	101 (70)	23.6 (18.9-28.0)	0.88 (0.67-1.16)	0.3606
Pom + dex (N=148)	101 (68)	19.1 (12.6-26.5)		



B

	Events, n (%)	Median (95% CI), months	HR (95% CI)[a]	*P*-value[b]
Melflufen + dex (N=101)	79 (78)	15.7 (11.9-20.5)	1.60 (1.15-2.21)	0.0045
Pom + dex (N=101)	68 (67)	27.5 (20.1-33.0)		



Data cutoff date: February 3, 2023.
[a]HR (and associated 95% CI) and *P*-value are calculated using a Cox proportional hazards regression model. [b]Unstratified log-rank test.
ASCT, autologous stem cell transplant; dex, dexamethasone; HR, hazard ratio; OS, overall survival; pom, pomalidomide; TTP, time to progression.

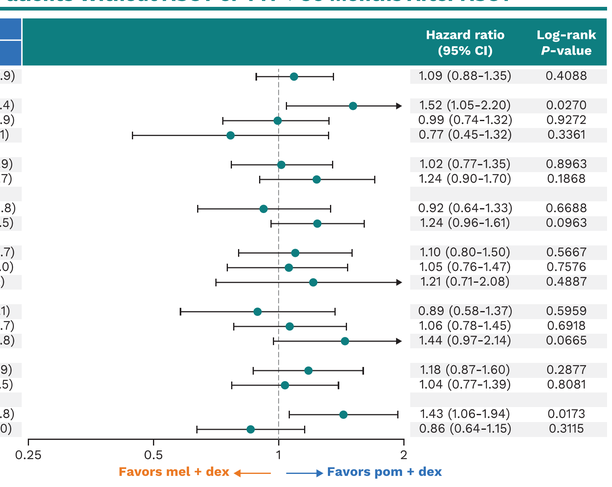
RESULTS

- Although OS in the ITT population was higher for most subgroups in the pom arm, with notable exception for patients >75 years and patients without a previous ASCT (**Figure 4A**), it was generally in favor of melflufen when compared with pom in the target population (**Figure 4B**)

Figure 4. OS by Subgroup in (A) the ITT Population and (B) in Patients Without ASCT or TTP >36 Months After ASCT

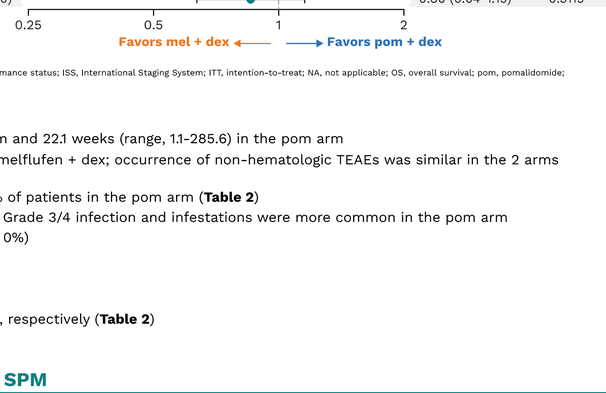
A

	Melflufen + dex		Pom + dex		Hazard ratio (95% CI)	Log-rank *P*-value
	Events/Patients	Median	Events/Patients	Median		
Overall	180/246	20.2 (15.8-24.1)	169/249	24.0 (18.9-27.9)	1.09 (0.88-1.35)	0.4088
Age						
<65	67/96	16.2 (11.9-24.5)	48/85	32.0 (21.3-37.4)	1.52 (1.05-2.20)	0.0270
65-74	85/113	21.1 (16.3-25.5)	94/125	20.2 (17.0-25.9)	0.99 (0.74-1.32)	0.9272
≥75	28/37	23.0 (14.6-33.6)	27/39	17.5 (7.2-32.1)	0.77 (0.45-1.32)	0.3361
Sex						
Male	101/139	20.3 (16.7-25.3)	96/140	21.7 (15.5-27.9)	1.02 (0.77-1.35)	0.8963
Female	79/107	16.4 (12.7-26.2)	73/109	24.8 (19.1-31.7)	1.24 (0.90-1.70)	0.1868
ECOG PS						
0	58/90	27.2 (20.3-35.0)	57/92	28.7 (20.2-33.8)	0.92 (0.64-1.33)	0.6688
1-2	122/156	14.8 (11.4-18.9)	112/157	20.1 (15.0-26.5)	1.24 (0.96-1.61)	0.0963
ISS						
I	78/119	26.0 (21.8-34.0)	77/124	30.1 (25.0-34.7)	1.10 (0.80-1.50)	0.5667
II	72/94	16.3 (11.8-23.0)	68/94	18.7 (12.9-24.0)	1.05 (0.76-1.47)	0.7576
III	30/33	7.1 (4.3-9.0)	24/31	7.9 (5.3-9.3)	1.21 (0.71-2.08)	0.4887
Creatinine clearance						
<60	36/50	16.3 (10.1-26.5)	51/68	16.4 (9.2-20.1)	0.89 (0.58-1.37)	0.5959
60-90	86/119	20.3 (14.6-26.5)	74/112	24.7 (15.9-28.7)	1.06 (0.78-1.45)	0.6918
≥90	57/76	21.8 (16.6-25.7)	44/69	31.7 (24.8-36.8)	1.44 (0.97-2.14)	0.0665
BSA						
Below median	82/116	18.9 (13.1-26.2)	84/128	26.1 (18.7-31.9)	1.18 (0.87-1.60)	0.2877
Above median	94/126	20.3 (16.3-25.3)	82/117	21.4 (17.0-27.5)	1.04 (0.77-1.39)	0.8081
Stem cell transplant						
Yes	95/125	16.7 (13.8-24.1)	79/120	28.7 (21.3-33.8)	1.43 (1.06-1.94)	0.0173
No	85/121	22.2 (16.4-26.7)	90/129	17.5 (12.1-25.0)	0.86 (0.64-1.15)	0.3115



B

	Melflufen + dex		Pom + dex		Hazard ratio (95% CI)	Log-rank *P*-value
	Events/Patients	Median	Events/Patients	Median		
Overall	101/145	23.6 (18.9-28.0)	101/148	19.1 (12.6-26.5)	0.88 (0.67-1.16)	0.3606
Age						
<65	22/41	35.0 (10.2-NA)	16/30	35.9 (7.3-NA)	0.98 (0.51-1.87)	0.9500
65-74	51/69	23.4 (17.5-28.0)	58/80	18.2 (12.5-25.0)	0.90 (0.62-1.31)	0.5728
≥75	28/35	21.6 (14.4-31.7)	27/38	16.4 (7.2-30.9)	0.80 (0.47-1.38)	0.4294
Sex						
Male	51/75	24.3 (19.6-31.8)	59/83	15.7 (8.2-25.3)	0.76 (0.52-1.11)	0.1499
Female	50/70	23.2 (11.8-33.6)	42/65	22.8 (14.6-32.1)	1.04 (0.69-1.57)	0.8585
ECOG PS						
0	33/54	32.1 (23.6-44.8)	29/45	24.4 (12.0-36.8)	0.69 (0.42-1.14)	0.1439
1-2	68/91	14.8 (11.0-25.7)	72/103	15.7 (10.3-25.3)	1.04 (0.75-1.45)	0.8260
ISS						
I	38/64	36.9 (24.3-44.8)	39/62	26.6 (17.0-34.2)	0.76 (0.49-1.20)	0.2383
II	45/60	19.6 (11.0-27.5)	43/63	18.2 (12.1-27.9)	1.01 (0.66-1.53)	0.9703
III	18/21	8.7 (5.7-20.2)	19/23	7.3 (4.0-9.3)	0.85 (0.45-1.63)	0.6231
Creatinine clearance						
<60	28/38	17.9 (9.0-26.7)	36/50	13.7 (7.3-19.1)	0.82 (0.50-1.34)	0.4293
60-90	53/78	26.0 (18.9-36.9)	47/68	19.8 (11.2-27.9)	0.84 (0.56-1.24)	0.3736
≥90	19/28	24.0 (14.3-44.8)	18/30	32.6 (24.4-41.3)	1.10 (0.57-2.10)	0.7819
BSA						
Below median	56/81	23.6 (14.4-31.7)	53/78	19.1 (14.6-31.7)	0.94 (0.64-1.37)	0.7360
Above median	42/61	24.3 (17.3-35.0)	46/68	19.8 (7.9-26.7)	0.82 (0.54-1.25)	0.3574
Stem cell transplant						
Yes	16/24	29.8 (10.0-48.7)	11/19	33.8 (11.2-NA)	1.02 (0.47-2.24)	0.9527
No	85/121	22.2 (16.4-26.7)	90/129	17.5 (12.1-25.0)	0.86 (0.64-1.15)	0.3115



Data cutoff date: February 3, 2023.
ASCT, autologous stem cell transplant; BSA, body surface area; dex, dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System; ITT, intention-to-treat; NA, not applicable; OS, overall survival; pom, pomalidomide; TTP, time to progression.

SAFETY

- The median treatment duration was 25.2 weeks (range, 4.1-257.1) in the melflufen arm and 22.1 weeks (range, 1.1-285.6) in the pom arm
- Hematologic treatment-emergent adverse events (TEAEs) were more common with melflufen + dex; occurrence of non-hematologic TEAEs was similar in the 2 arms (**Suppl Table 1**)
- Grade 3/4 TEAEs were experienced by 90% of patients in the melflufen arm and 76% of patients in the pom arm (**Table 2**)
  - Grade 3/4 hematologic toxicity was more common in the melflufen arm, whereas Grade 3/4 infection and infestations were more common in the pom arm
    - Thrombocytopenia (78% vs 13%; occurring with Grade 3/4 hemorrhage in 1% vs 0%)
    - Neutropenia (64% vs 50%; occurring with Grade 3/4 infections in 4% vs 7%)
    - Anemia (43% vs 19%)
    - Infection and infestations (14% vs 24%)
- In the melflufen and pom arms, serious TEAEs occurred in 43% and 50% of patients, respectively (**Table 2**)
- Fatal TEAEs were similar in the melflufen and pom arms (14% vs 15%) (**Table 2**)

Table 2. Most Common Grade 3/4, Serious AEs, Fatal AEs, and SPM

Adverse event, n (%)	Safety Analysis Set		Target Population	
	Melflufen + Dex (n=228)	Pom + Dex (n=246)	Melflufen + Dex (n=137)	Pom + Dex (n=147)
Grade 3/4 AEs	204 (90)	187 (76)	122 (89)	108 (73)
Thrombocytopenia[a]	177 (78)	32 (13)	99 (72)	18 (12)
Concomitant with Grade 3/4 bleeding[b]	2 (1)	0 (0)	2 (2)	0 (0)
Neutropenia[c]	147 (64)	122 (50)	91 (66)	75 (51)
Concomitant with Grade 3/4 infection	8 (4)	16 (7)	4 (3)	9 (6)
Infection	31 (14)	58 (24)	21 (15)	36 (24)
Anemia[d]	99 (43)	46 (19)	58 (42)	28 (19)
Serious AEs[e]	99 (43)	124 (50)	63 (46)	75 (51)
Pneumonia	14 (6)	23 (9)	8 (6)	14 (10)
COVID-19 pneumonia	12 (5)	14 (6)	8 (6)	10 (7)
Anemia	8 (4)	6 (2)	5 (4)	6 (4)
Thrombocytopenia	11 (5)	3 (1)	6 (4)	1 (1)
Atrial fibrillation	1 (0.4)	9 (4)	0 (0)	5 (3)
Fatal AEs[f]	32 (14)	37 (15)	19 (14)	27 (18)
COVID-19 pneumonia	8 (4)	5 (2)	4 (3)	4 (3)
Pneumonia	4 (2)	4 (2)	2 (1)	4 (3)
Multiple organ dysfunction syndrome	2 (1)	2 (1)	1 (1)	2 (1)
Cardiac arrest	2 (1)	2 (1)	2 (1)	2 (1)
Renal failure	2 (1)	2 (1)	0 (0)	1 (1)
Second primary malignancy	5 (2)	5 (2)	3 (2)	4 (3)

Data cutoff date: February 3, 2023.
[a]Events of special interest represent grouped terms, or Standardised MedDRA Queries (SMQ). For thrombocytopenia, the preferred terms from hematopoietic thrombocytopenia (SMQ) were combined. [b]Bleeding = hemorrhage. [c]For neutropenia, the preferred terms from neutropenia, febrile neutropenia, neutrophil count decreased, neutropenic sepsis, neutropenic infection, cyclic neutropenia, band neutrophil count decreased, band neutrophil percentage decreased, agranulocytosis, granulocyte count decreased, and granulocytopenia were counted. [d]For anemia, the preferred terms under hematopoietic erythropenia (SMQ) were combined. For hemorrhages, the preferred terms from hemorrhage terms (excluding laboratory terms; SMQ) and hemorrhage laboratory terms (SMQ) narrow were combined. [e]For SPM, the preferred terms from the high-level term myelodysplastic syndromes or any term in malignant or unspecified tumors (SMQ) but will exclude high-level group term plasma cell neoplasm were combined. [e]Serious AEs presented are those occurring in ≥2% (10 patients) of the total safety population. [f]Fatal AEs presented are those occurring in 4 or more patients.
AE, adverse event; dex, dexamethasone; pom, pomalidomide; SPM, second primary malignancy.

- TEAEs led to dose reductions in 52% of melflufen-treated vs 28% of pom-treated patients, most frequently due to thrombocytopenia (32% vs 2%) and neutropenia (12% vs 8%) (**Suppl Table 2**)
- TEAEs led to permanent discontinuation in 30% of melflufen-treated vs 24% of pom-treated patients (**Suppl Table 2**)
- TEAEs led to dose delays in 68% of patients receiving melflufen vs 51% of patients receiving pom (**Suppl Table 2**)
- In the safety population, deaths occurred in 74% vs 68% of patients in the melflufen and pom arms (**Suppl Table 3**)
  - AEs were the primary cause of death ≤30 days after last dose in 8% and 11% of patients, respectively, followed by progressive disease (3% in each arm)

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