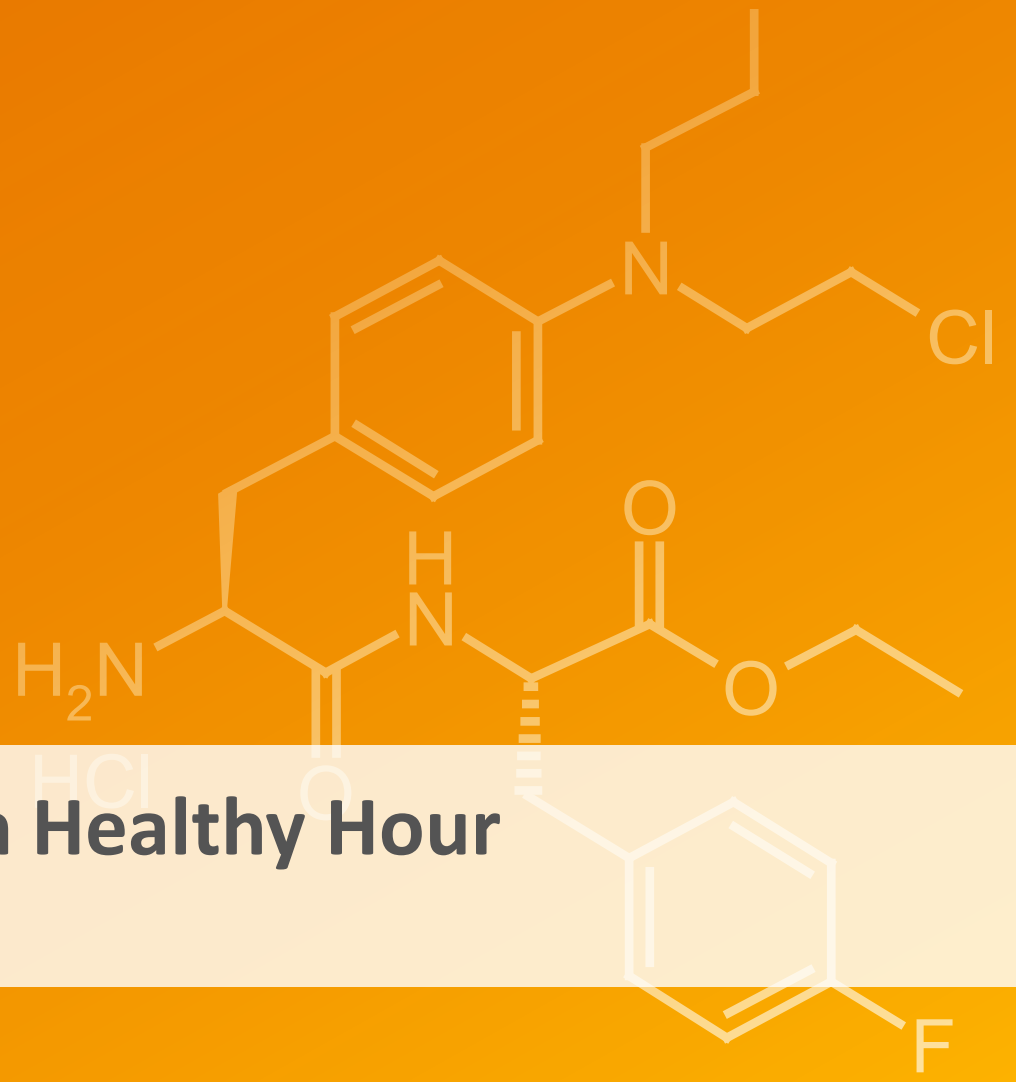

Presentation Handelsbanken Healthy Hour

September 15, 2021

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Disclaimer

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On 26 February 2021, the U.S. Food and Drug Administration ("FDA") approved PEPAXTO® (melphalan flufenamide, also known as melflufen), in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. This indication has been granted under accelerated approval based upon data from the HORIZON study. Melflufen is not approved by any other registration authorities.

Melflufen is an abbreviated form of the international non-proprietary name (INN) melphalan flufenamide

The Information contains forward-looking statements. All statements other than statements of historical fact included in the Information are forward-looking statements. Forward-looking statements give the Company's current expectations and projections relating to its financial condition, results of operations, plans, objectives, future performance and business. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors beyond the Company's control that could cause the Company's actual results, performance or achievements to be materially different from the expected results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Company's present and future business strategies and the environment in which it will operate in the future.

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Agenda

- Introduction – Marty J Duvall, CEO
- Presentation of OCEAN data – Klaas Bakker, MD, PhD
- Presentation of data from PORT – Klaas Bakker
- Financials – Anders Martin-Löf, CFO
- Closing remarks – Marty J Duvall
- Q&A

Key messages

- Q2 - first full quarter with revenue
  - Q2 net sales of SEK 66.4 M ($7.2M) and YTD net sales of SEK 85.7 M ($10.2M) since launch in mid-March
  - Double-digit demand growth on a month-to-month basis
  - Difficult to predict future sales due to FDA issue
- Data presented at IMW encouraging
  - OCEAN phase 3 study
  - PORT phase 2 study
- Near-term focus is to reach an agreement with the FDA
  - ODAC meeting to be held on October 28
  - Various outcomes from FDA review possible
- Regulatory process with the EMA proceeding according to plan

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PEPAXTO strategy - Two-pronged approach

Becoming a foundational treatment in RRMM

Driving change in today's RRMM treatment paradigm where drug classes are "recycled"

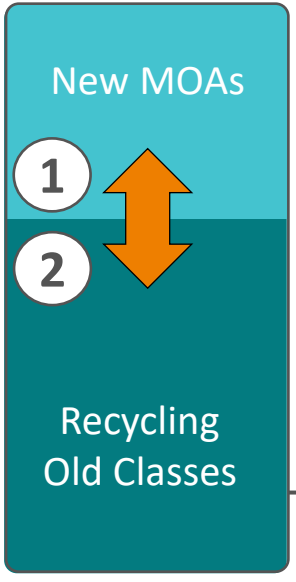
Existing classes

IMIDs
- Thalidomide (1999)
- Lenalidomide (2003)
- Pomalidomide (2013)

PIs
- Bortezomib (2003)
- Carfilzomib (2012)
- Ixazomib (2015)

CD-38
- Daratumumab (2015)
- Isatuximab (2020)

Today



Future

New classes/MoA

PEPAXTO (2021)

Belantamab (2020)

Selinexor (2019)

Abecma (2021)

1 Become the treatment of choice for appropriate and indicated patients

2 Expand market for new MOAs and minimize "recycling" of failed drug classes

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PEPAXTO off to a strong start through the first full quarter

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PEPAXTO gaining on key competitors in 5L+ MM

US quarterly net revenue

Product key revenue drivers

	PEPAXTO	Blenrep	Xpovio
5L+ MM doublet/SA approval	✓	✓	✓
Earlier lines MM doublet/SA approval		✓	✓
MM triplet approval			✓
Approval outside MM			✓
Price	$$	$$$	$$$

5L+ new patient share
Among key competitors

Three months total
(March – June 2021)

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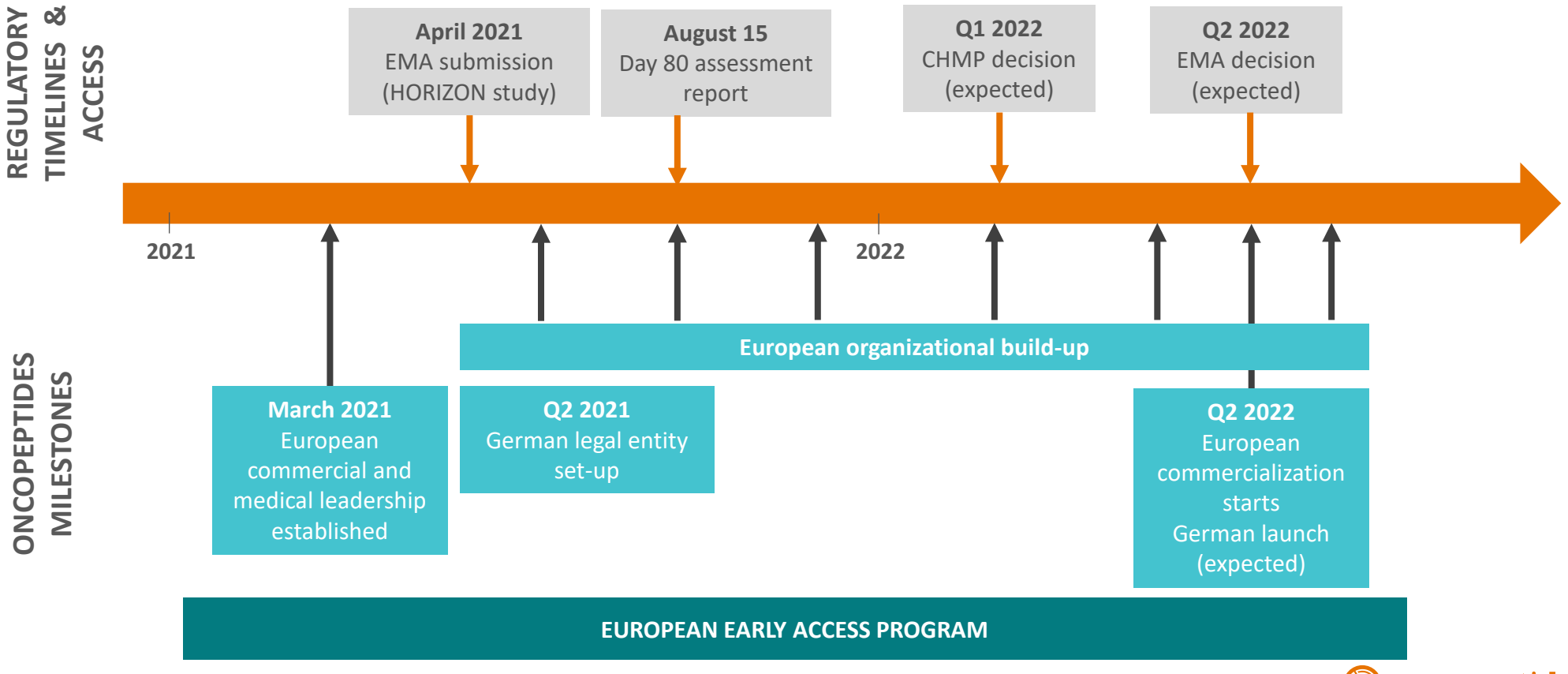
European commercialization start in Q2 2022 on track



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OCEAN results

OCEAN (OP-103): Study design and key eligibility criteria

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

SCREENING (day −21 to −1) | **RANDOMISATION** | **TREATMENT** (28-day cycles until disease progression or unacceptable toxicity) | **EoT** | **FOLLOW-UP**[a]

Key Eligibility Criteria

- Patients with RRMM
- Aged ≥18 years
- **2-4 prior lines** of therapy including lenalidomide (within 18 months of randomization) and a PI
- **Refractory to lenalidomide** and to last line of therapy
- ECOG PS ≤2

(N=495)

1:1 Randomisation

Stratified by
- Age (<75 vs ≥75 y)
- Prior lines of therapy (2 vs 3-4)
- ISS score (I vs ≥II or III)

Melflufen
(40 mg IV, day 1 of each cycle)
+
Dexamethasone
(40 mg PO weekly)[b,c]

Pomalidomide
(4 mg po, days 1-21 of each cycle)
+
Dexamethasone
(40 mg PO weekly)[b,c]

Primary endpoint
- PFS assessed by IRC per IMWG uniform response criteria[c]

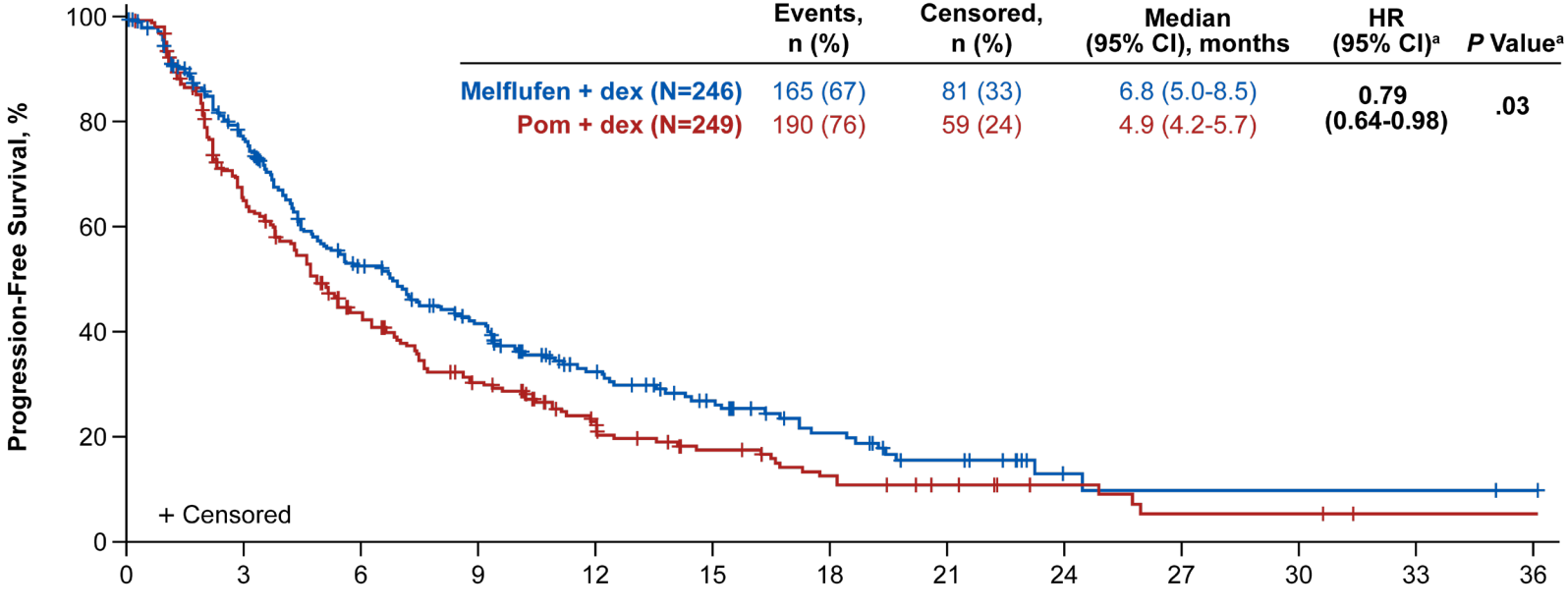
Key secondary endpoints
- ORR
- OS
- Safety and tolerability[d]

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.

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)	.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).

Data cut-off date: 3 Feb. 2021

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.

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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

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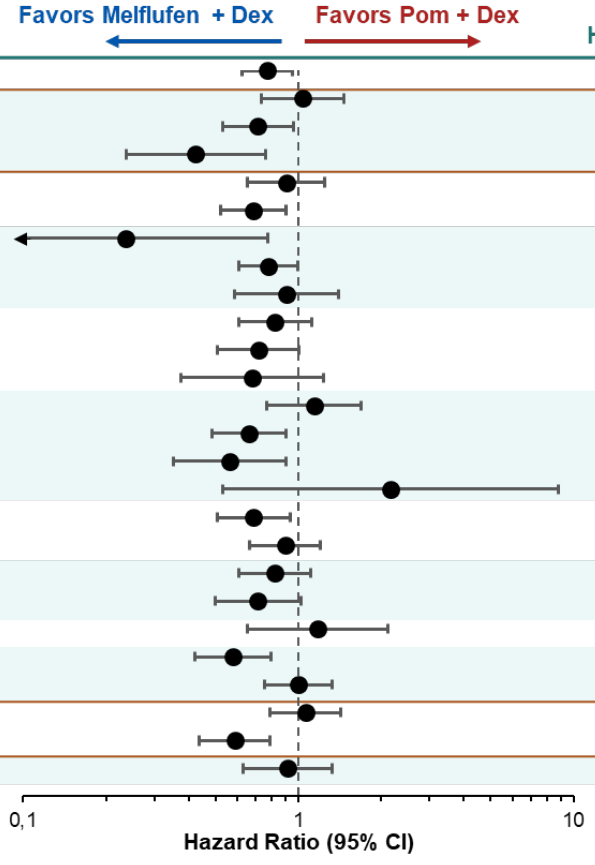
PFS was generally in favor of melflufen in subgroups

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 BSA	≤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

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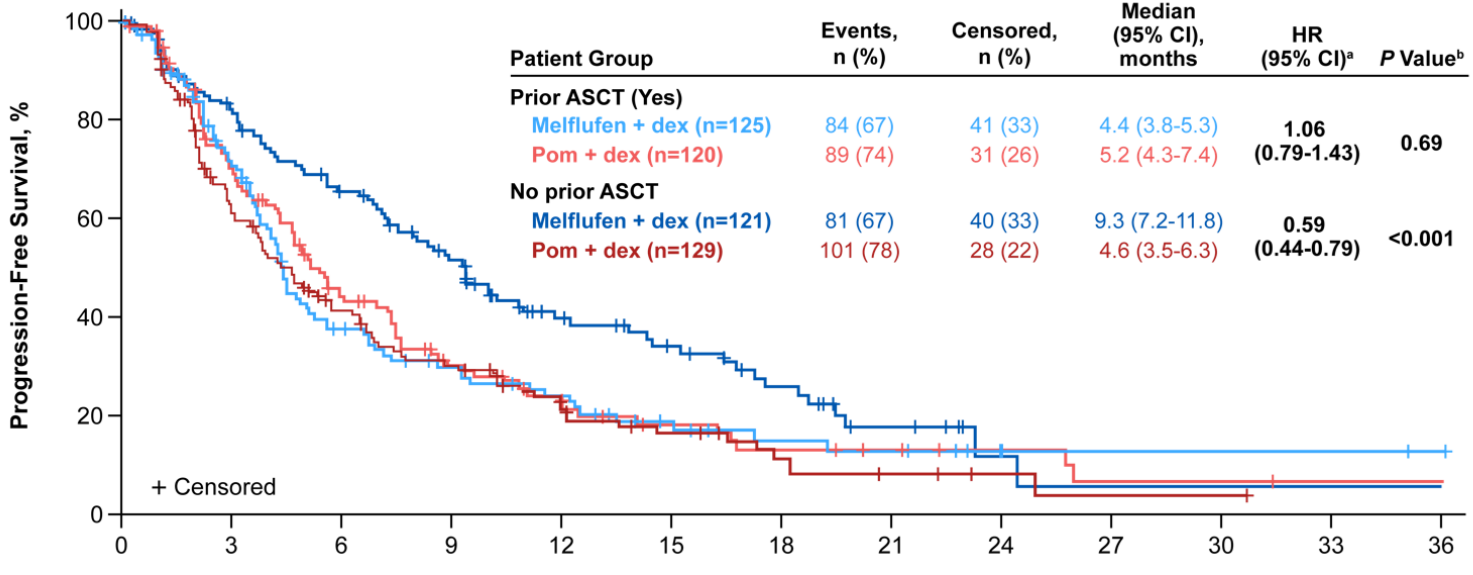
PFS benefit in the melflufen arm mainly driven by patients who had not received a prior ASCT

Prespecified subgroups



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

Data cut-off date: 3 Feb. 2021

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.

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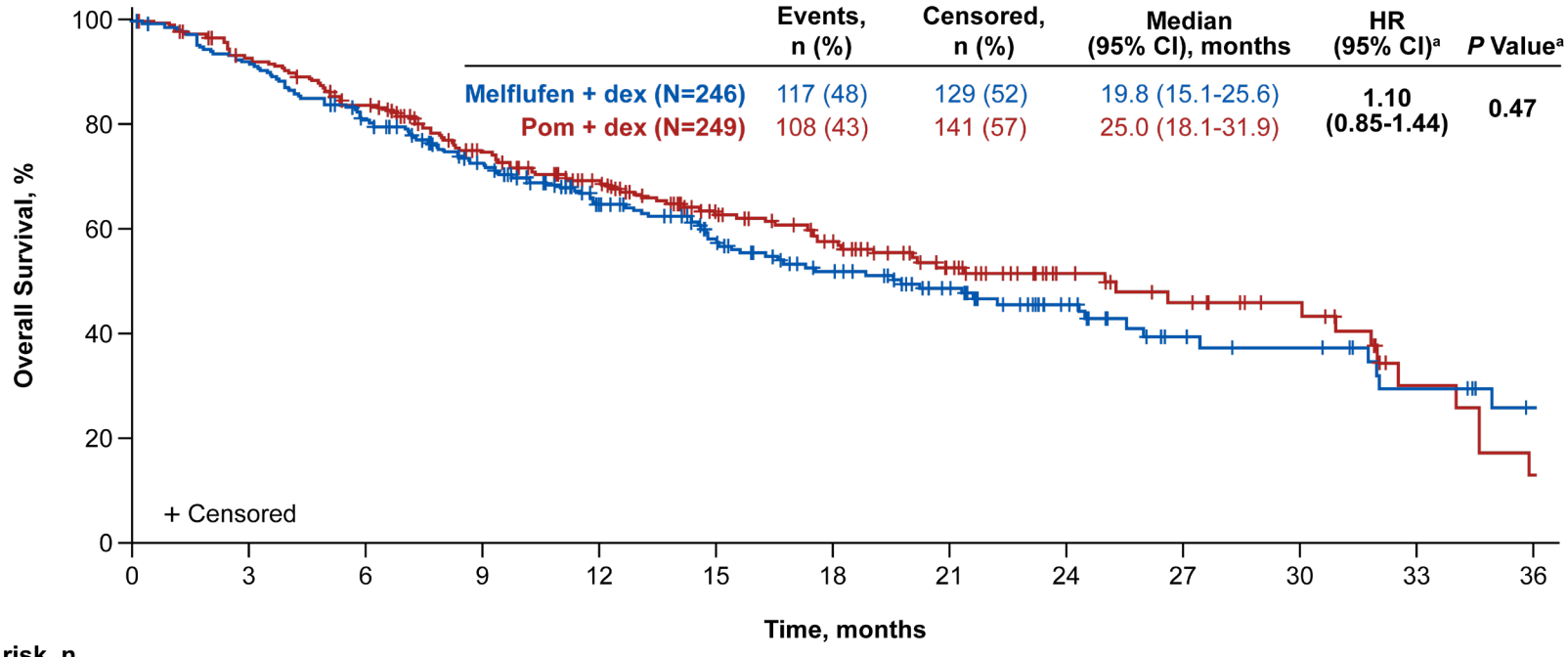
Overall survival by treatment group

Key secondary endpoint



Data cut-off date: 3 Feb. 2021

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

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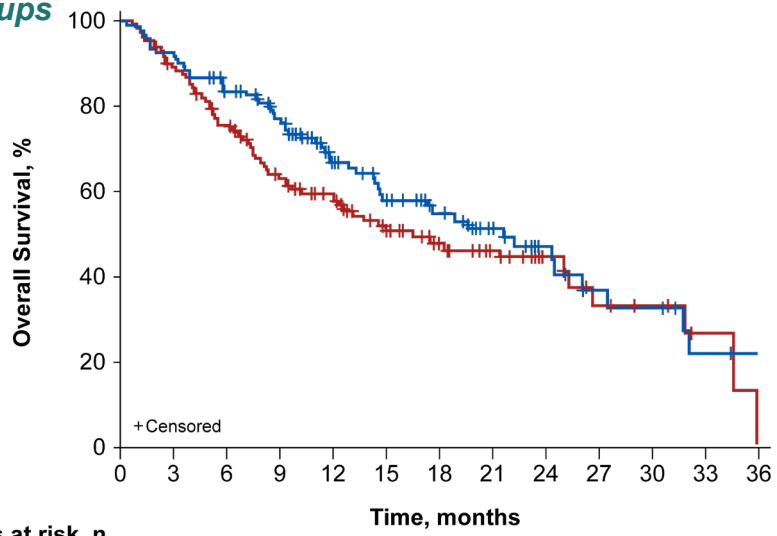
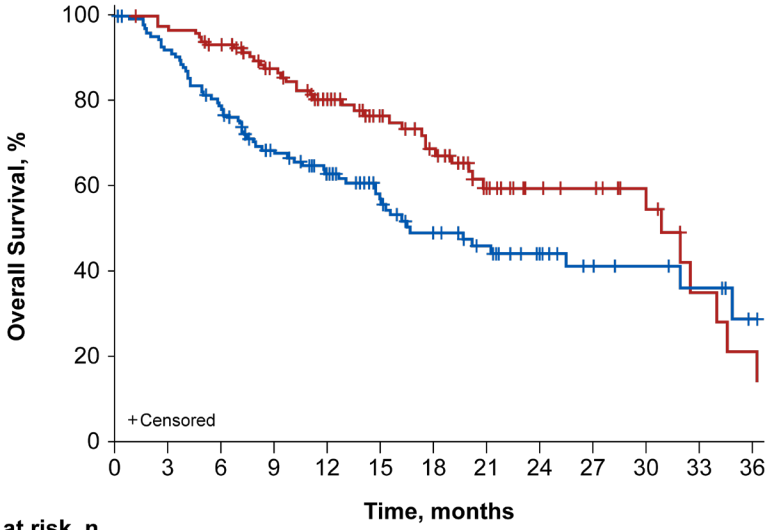
OS trended in favor of melflufen in patients without a prior ASCT, and favored pom in patients with a prior ASCT

Prespecified subgroups



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)	



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)	

Data cut-off date: 3 Feb. 2021

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

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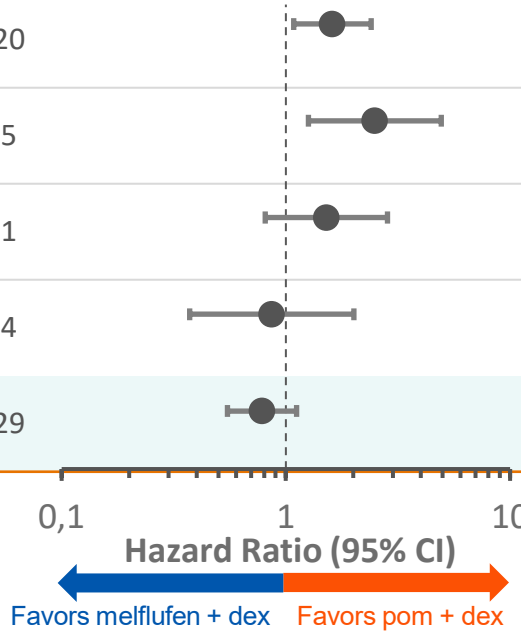
Time from prior ASCT impacts overall survival

Post-hoc analysis

	Events/Patients, n/N		HR (95% CI)[a]	*P* Value[b]
	Melflufen + Dex	Pom + Dex		
Prior ASCT (Overall)	61/125	41/120	1.61 (1.09-2.40)	0.017
ASCT <2.5 years ago	27/43	12/35	2.50 (1.26-4.94)	0.007
ASCT 2.5 to 5 years ago	22/48	18/51	1.52 (0.81-2.84)	0.190
ASCT >5 years ago	12/34	11/34	0.87 (0.37-2.01)	0.737
No prior ASCT	56/121	67/129	0.78 (0.55-1.12)	0.177



Data cut off date: 3 Feb, 2021

ASCT, autologous stem cell transplant; dex, dexamethasone; HR, hazard ratio; melflufen, melphalan flufenamide; NE, not estimable; OS, overall survival; pom, pomalidomide.
[a]Unstratified hazard ratio. [b]Log-rank *P* value.

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Efficacy in non- ASCT alkylator refractory patients

Efficacy differential versus Pom holds in Non-ASCT patients who are refractory to alkylators

	Non-ASCT Patients Full Subset		Non-ASCT Patients Alkylator Refractory Only	
	Melflufen+dex n=121	Pomalidomide+dex n=129	Melflufen +dex n=44	Pomalidomide+dex n=46
Median PFS, mo (95% CI)	9.33 (7.23-11.79)	4.63 (3.48-6.28)	8.30 (5.6-13.8)	3.80 (2.9-7.6)
Median OS, mo (95% CI)	21.62 (14.55-26.02)	16.53 (10.25-25.30)	24.30 (14.6-NA)	13.10 (9.3-NA)

Data cutoff 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)
Thrombocytopaenia	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 thrombocytopaenia	2 (1)	0
Neutropoenia	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 neutropoenia	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 neutropoenia	2 (1)	8 (3)
Febrile neutropoenia	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); neutropoenia includes neutropoenia, febrile neutropoenia, neutrophil count decreased, neutropenic sepsis, neutropenic infection, cyclic neutropoenia, band neutrophil count decreased, band neutrophil percentage decreased, neutrophil percentage decreased, agranulocytosis, granulocyte count decreased, and granulocytopenia; thrombocytopaenia includes haematopoietic thrombocytopaenia (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.

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.

Regulatory process and opportunity

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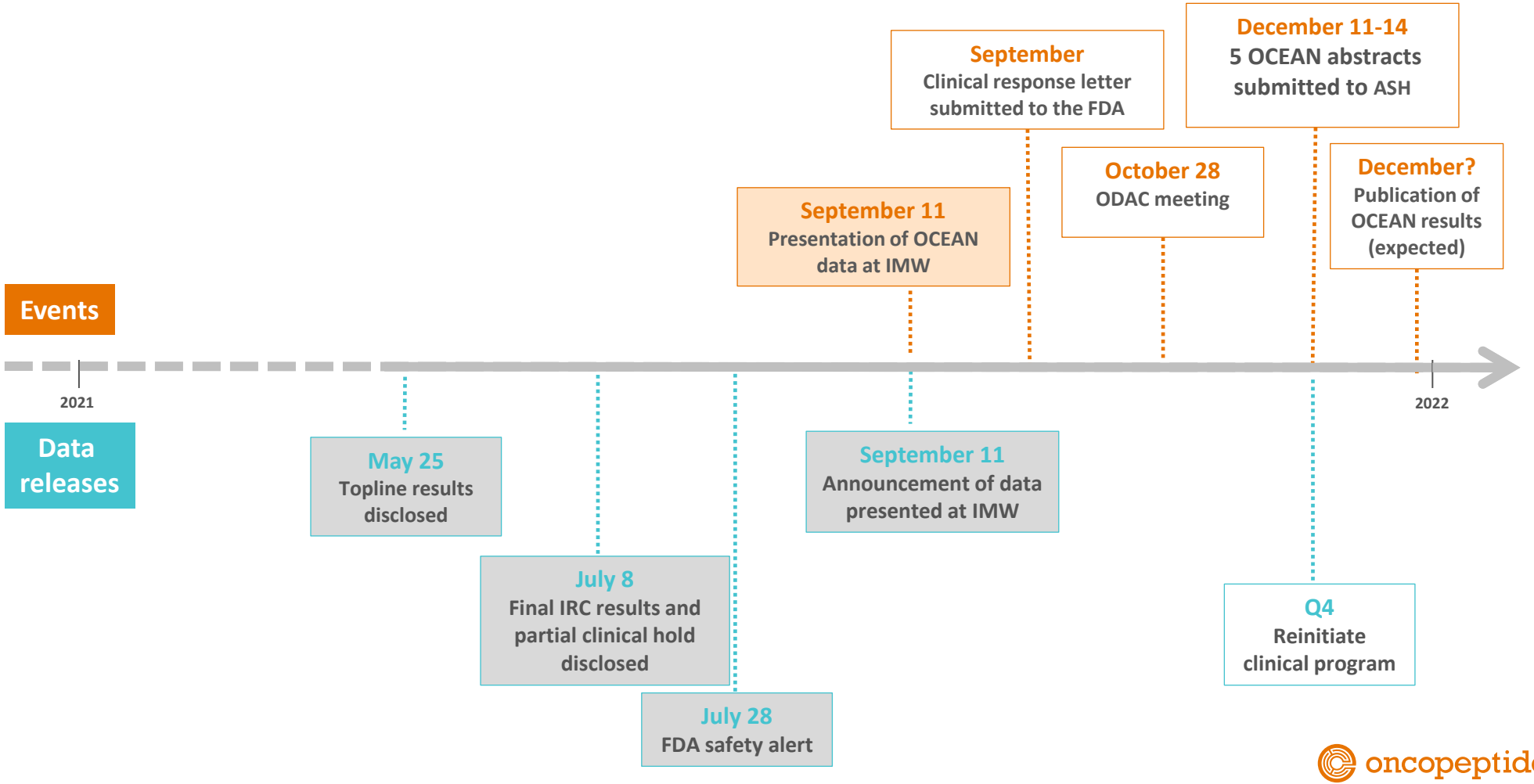
What is an ODAC meeting?

- Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs
- Consists of a core of 13 voting members including the Chair
- Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions
- The core of voting members may include one technically qualified member
- The vote is considered to be informative to the FDA but non-binding

Potential outcomes of the FDA review including ODAC

- OCEAN data results have generated a level of concern around OS that may challenge the continued accelerated approval of Pepaxto. Still various outcomes possible:
  - OCEAN data review at FDA results in a label that includes 3rd and 4th line
  - OCEAN data is viewed as “hypothesis generating” and that we need to confirm in our clinical development program
  - Withdrawal of Pepaxto from the US market
- Safety update on current HORIZON label possible

OCEAN study – regulatory timeline and upcoming events



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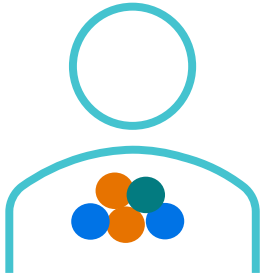
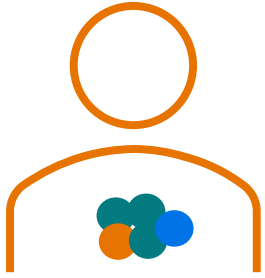
Profiles of non-transplanted and transplanted patients

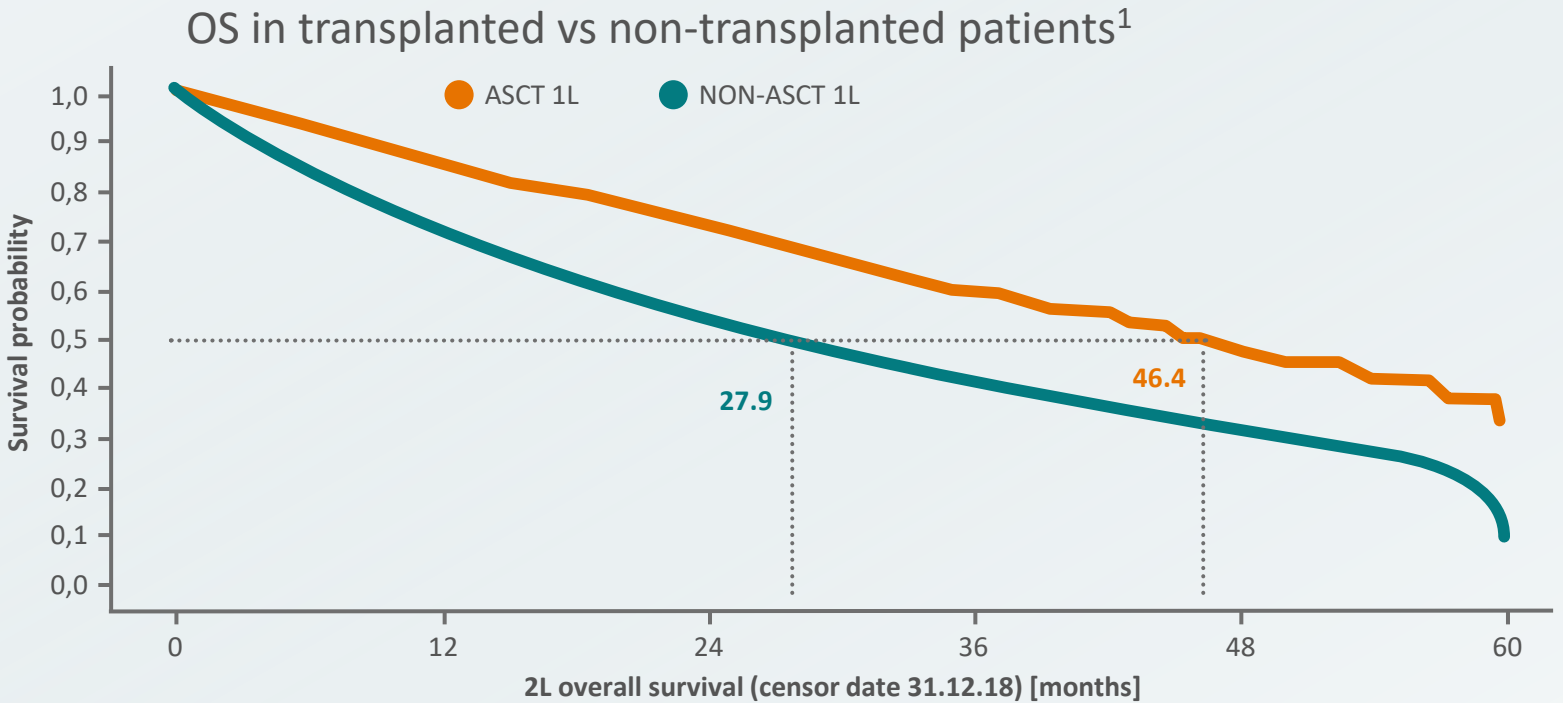


Non-Transplanted	
Age	Older
Performance Status	Lower
Co-morbidities	Higher
Previous exposure in OCEAN	• Regular dose alkylators • Len refractory • PI • CD38



Transplanted	
Age	Younger
Performance Status	Higher
Co-morbidities	Lower
Previous exposure in OCEAN	• High dose alkylators • Len refractory • PI • CD38

Higher unmet need for non-transplanted patients



Cyrille Touzeau & Nadia Quignot & Jie Meng & Heng Jiang & Artak Khachatryan & Moushmi Singh & Vanessa Taieb & Jean-Vannak Chauny & Gaëlle Désaméricq
Received: 8 February 2021 /Accepted: 12 April 2021
Survival and treatment patterns of patients with relapsed or refractory multiple myeloma in France — a cohort study using the French National Healthcare database (SNDS)

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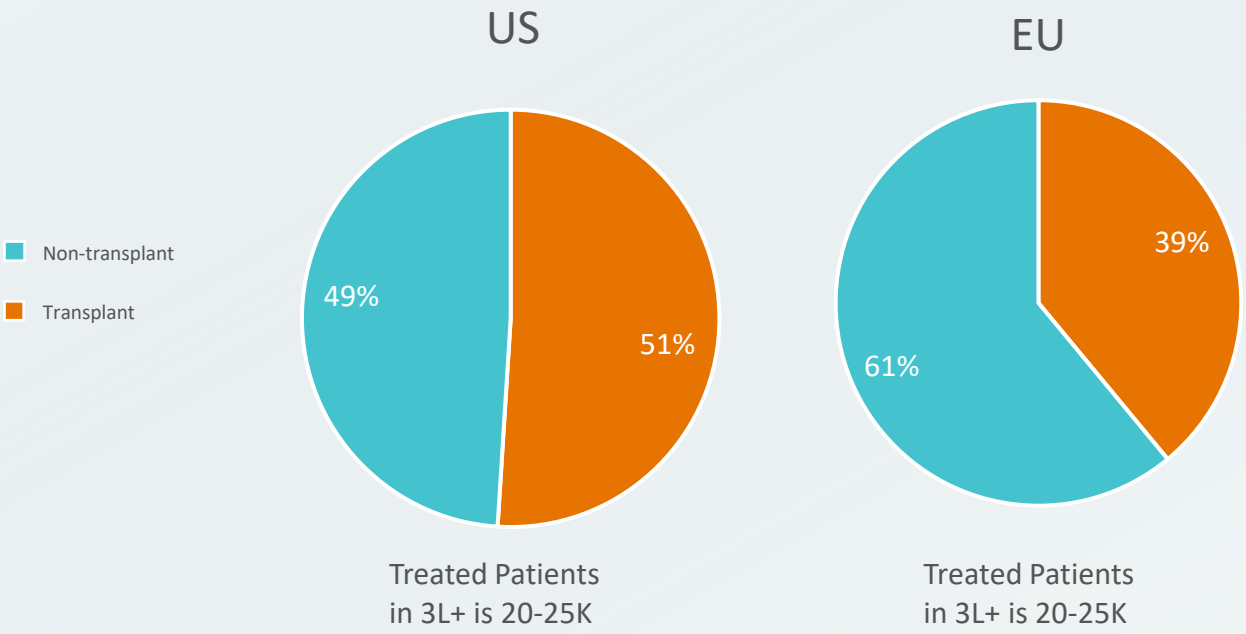
Addressable patient population

Large growing unmet need in a non-transplant setting

Transplant ineligible (non-transplant) patients make up 45%-60% in major markets across the US and EU



Melflufen offers benefits to address non-transplanted population

- Patients with high unmet need
- PDC mechanism offers novel approach against MM
- Striking efficacy in head-to-head trial versus pomalidomide
- Manageable safety profile (mostly hematologic toxicities)
- Convenient dosing for elderly population

SOURCE: CancerMPact, Kantar Nov 2020

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Data from PORT

Klaas Bakker

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Conclusions

- In this Phase 2 Study of patients with RRMM, melphalan C_{max}, AUC_{O-t} and AUC_{inf}, were bioequivalent after PVC and CVC administration of melflufen
  - Melphalan C_{max} was observed on average 7–9 minutes after the end of melflufen infusion for both routes of administration, which reflects the delay in distribution of melphalan from tissues to plasma
  - Differences observed between some PVC- and CVC-related PK parameters for melflufen and the metabolite desethyl-melflufen (values slightly higher for PVC vs. CVC) are considered to have no clinical consequences, because the duration of their plasma exposure is short
  - There were no local reactions after PVC administration of melflufen, and no new safety signals were reported after melflufen PVC and CVC administration

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Financials

Anders Martin-Löf

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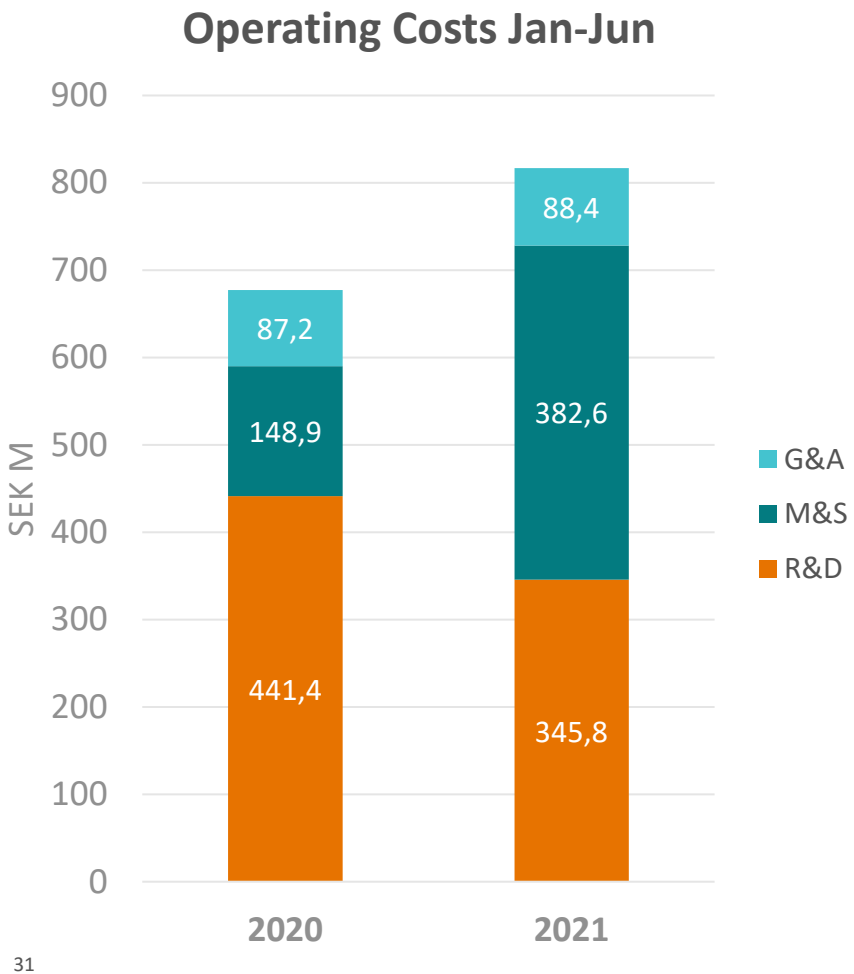
Financial results for January – June 2021



- Revenues amounted to SEK 85.7 M (-) for H1 66.4 M (-) for Q2
  - Gross margin of 96%
- Operating loss decreased to SEK 692.2 M (loss: 696.2) for H1 and 344.8 M (loss: 399.3) for Q2
  - R&D decreased primarily due to less cost in OCEAN and HORIZON projects
    - OCEAN SEK 78 M (177)
  - Number of co-workers increased to 313 (154) as of June 30
    - 142 (56) in US subsidiary
- Cash flow from operating activities neg. SEK 733.4 M (neg. 598.5) for H1 and neg. 346.7 M (neg. 285.7) for Q2
  - Neg. exchange rate effect of SEK 146.0 M
- Cash position was SEK 999.4 M (937.8) as of Jun 30, 2021
  - €40 M EIB loan facility unutilized
  - Measures to preserve cash implemented due to regulatory uncertainty

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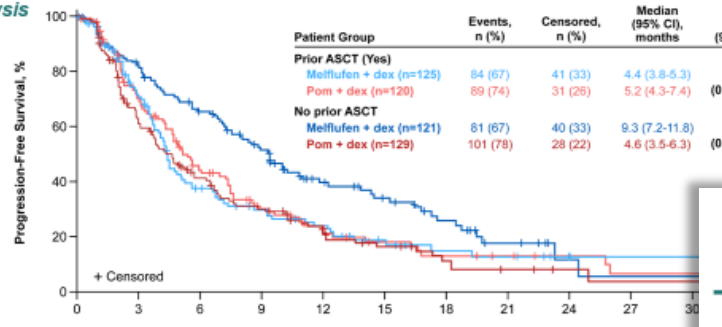
Concluding remarks

Marty J Duvall

OCEAN data summary – picture worth a thousand words

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
Pom + dex	77	45	26	18	11	8	6	4	2	2	1
No prior ASCT											
Melflufen + dex	94	73	54	31	23	15	7	2	1	1	1
Pom + dex	73	45	32	19	12	7	4	2	1	1	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.

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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 is 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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Summary

- Data presented at IMW encouraging
  - OCEAN Phase 3 study
  - PORT Phase 2 study
- Near-term focus is to reach an agreement with the FDA
  - ODAC meeting to be held on October 28
  - Various outcomes from FDA review possible
- Commercialization of Pepaxto in the US continues
- Regulatory process with the EMA proceeding according to plan
- ASH 2021 … more data to come

Q&A

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