

Post-ASH Webcast December 10th 2019

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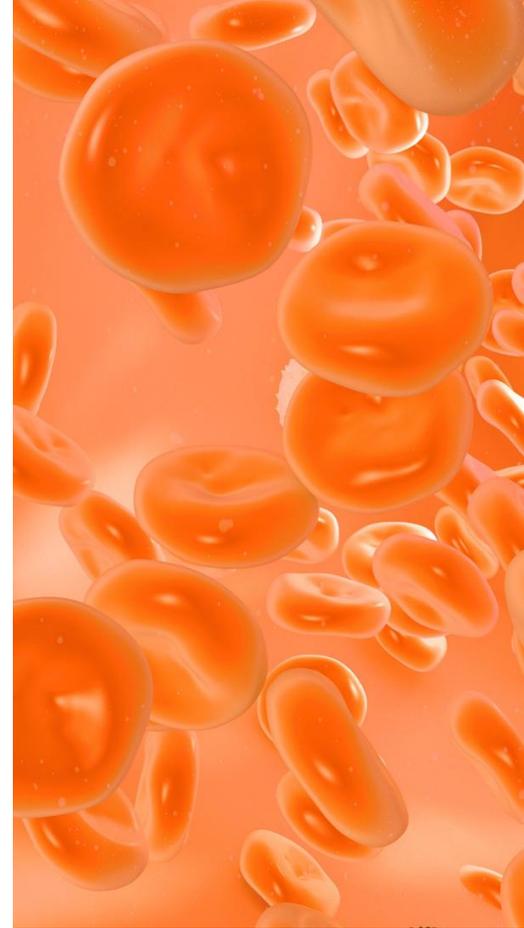
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Pre-NDA meeting held with the FDA on December 3rd

Submission progressing according to plan

Minor change to submission timeline due to
technical addition to submission package





- Most significant US conference event for Oncopeptides so far
- Six poster presentations
- Updated efficacy and safety data from HORIZON and ANCHOR
- Strong pre-clinical data with melflufen in AL amyloidosis sets the path for the new clinical studies
- Data presented was well received. This reinforces that melflufen has the clear potential to play a key role in the treatment of multiple myeloma

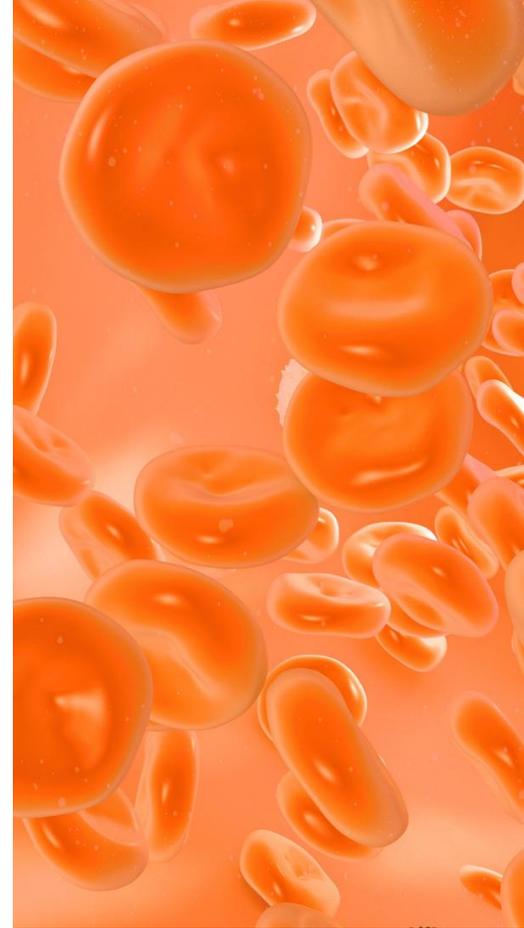
Key take aways from ASH

Promising clinical data presented at ASH with melflufen

- ORR of 29% in HORIZON overall. 24% in triple-class refractory patients with a median duration of response of 7.5 months
- Progression-free survival of 14.3 months for the combination of melflufen with daratumumab (ANCHOR)

BCMA targeted therapies still struggling in terms of usability despite utilizing a good target in myeloma

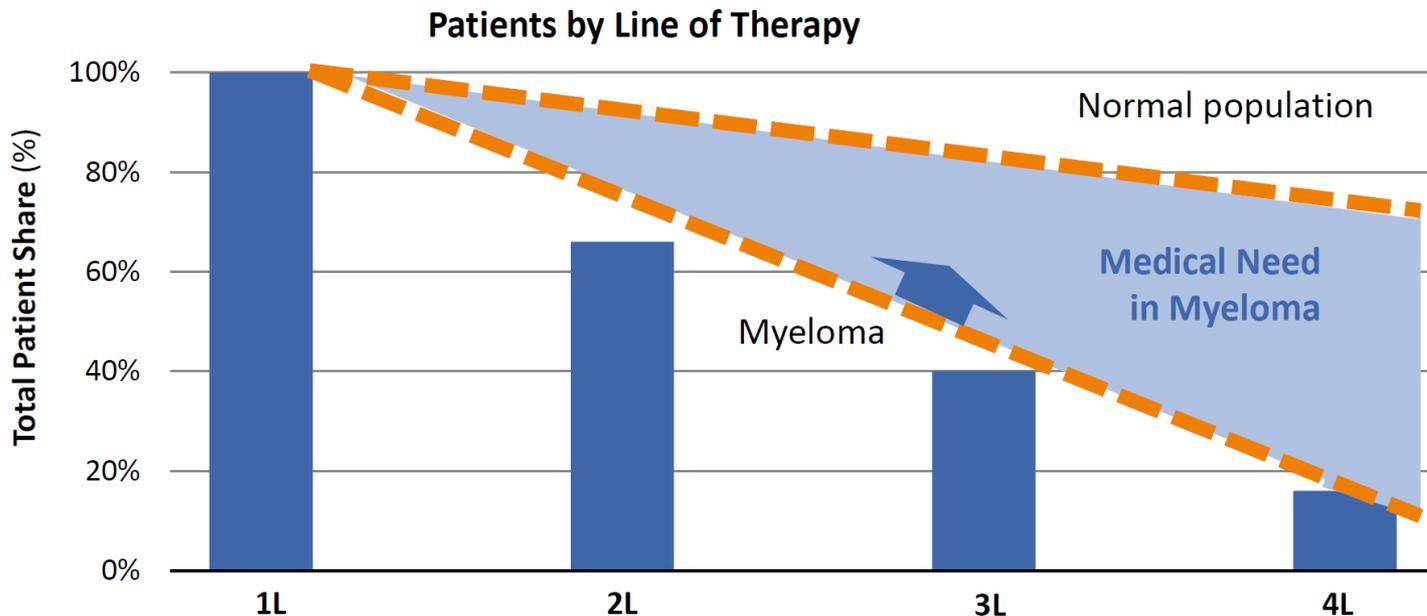
- GSK916 suffers from ocular toxicity
- Bi-specific antibodies with BCMA-CD3 suffers from cytokine release syndrome with associated ICU requirements
- CAR-Ts directed against BCMA suffers from complexity and cost in comparison with durability of responses



BCMA is a good target in myeloma but seemingly still no usable approach

- AMG420 abandoned due to poor usability
 - CC-93269 from BMY/ Celgene showed good efficacy parameters in line with other BCMA therapies but requires ICU or ICU-like monitoring with treatment for cytokine release syndrome in conjunction with administration
 - GSK916 suffers from ocular toxicity (69% of patients in DREAMM-1)
 - CAR-Ts suffer from toxicity, cost and complexity that does not align with the clinical benefit
- Conclusion: There is currently no anti-BCMA construct with clinical data that have a reasonable chance to generate broad market appeal based on available data

Triple-class refractory patients is a significant and growing unmet medical need in myeloma



Estimated
>20,000
Triple-Class
refractory
patients in the
US and
growing

RRMM Data – Single agent comparison

1x RMM

2x RMM

3x RMM

Pomalidomide

ORR: 23.5-31%
mPFS: 3.6-4.1m
mDOR: 7.0-7.4m
mOS: 12.7-14.4m

Carfilzomib

ORR: 22.9%
mPFS: 3.7m
mDOR: 7.8m
mOS: 15.6m

Daratumumab (iv)

ORR: 29%
mPFS: 3.7m
mDOR: 7.4m
mOS: 17.5m

Selinexor

ORR: 25%
SD+: 75%
mPFS: 3.7m
mDOR: 4.4m
mOS: 8.6m
EMD%: 22%

Daratumumab (sc)

ORR: 44%
mPFS: 6.1m
mDOR: 5.5m
mOS: NR

Melflufen (O-12-M1)

ORR: 31%
mPFS: 5.7m
mDOR: 8.4m
mOS: 20.7m

Melflufen (HORIZON)

ORR: 55%
mPFS: 4.6m
mDOR: NR
mOS: 17.6m

Melflufen (HORIZON)

ORR: 24%
SD+: 71%
mPFS: 4.0m
mDOR: 7.5m
mOS: 11.3m
EMD%: 32%



Data from HORIZON presented at ASH

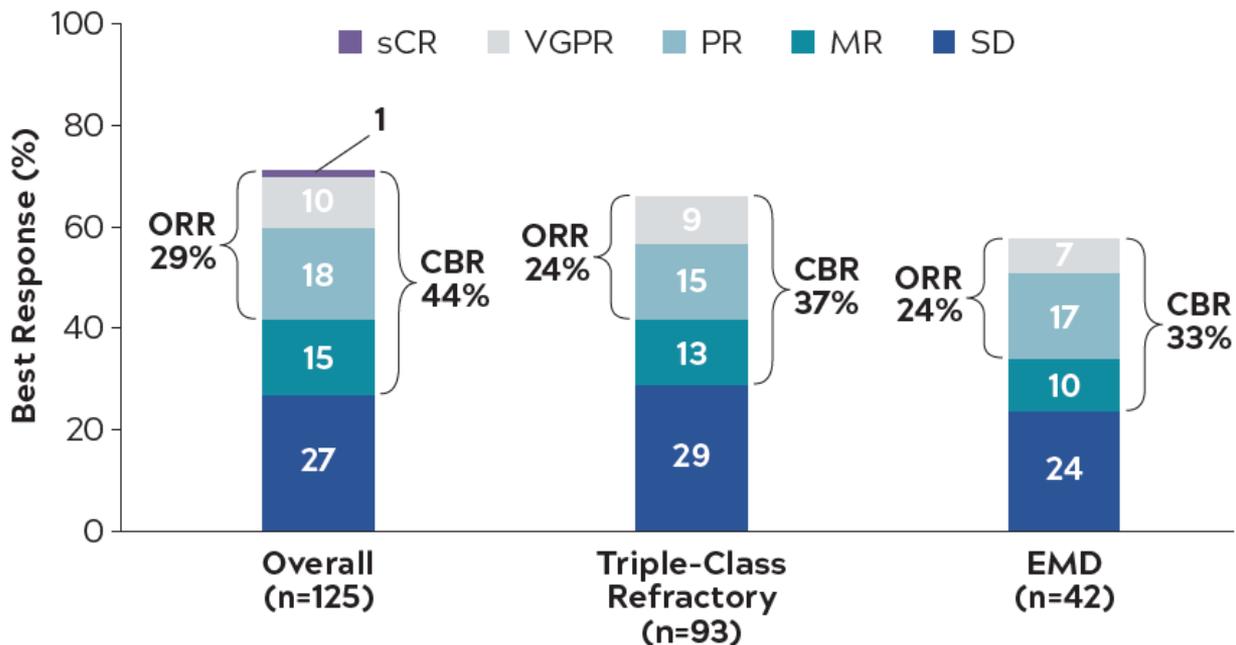


Baseline Characteristics ^a	N-154
Age, median (range), y	64.5 (35-86)
Gender (male / female), %	56 / 44
Time since diagnosis, median (range), y	6.5 (0.7-24.6)
No. of prior lines of therapy, median (range)	5 (2-12)
ISS stage I / II / III / unknown, %	37 / 27 / 32 / 4
ECOG PS 0 / 1 / 2, %	25 / 60 / 15
High-risk cytogenetics, ^b %	38
≥2 High-risk abnormalities, %	13
Del(17p), %	12
Extramedullary disease, %	32

- Efficacy population (n=125): patients dosed on or before 15 May 2019 with additional follow-up of at least 20 weeks until 01 October 2019 data cutoff
- Safety population (N=154): all patients dosed on or before 01 October 2019 data cutoff

^aBaseline is defined as the most recent assessment before administration of the first dose of study drug. ^bHigh-risk cytogenetics at study entry was based on fluorescence in situ hybridization defined as t(4;14), del(17/17p), t(14;16), t(14;20), gain(1q) per Sonneveld P, et al.¹⁴ 77 patients (50%) had unknown cytogenetics. ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System.

Promising overall response rates in both triple-class refractory patients and patients with EMD at relapse

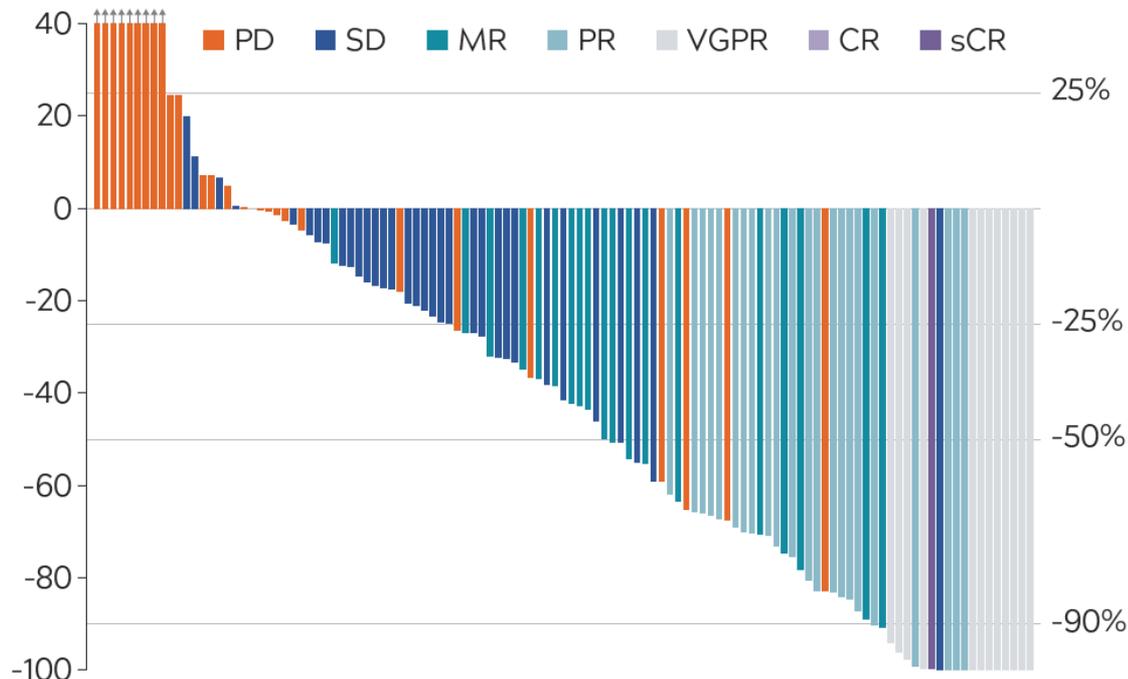


^aResponse was investigator assessed.

CBR, clinical benefit rate; EMD, extramedullary disease; IMWG, International Myeloma Working Group; MR, minimal response; ORR, overall response rate; PR, partial response; sCR, stringent complete response; SD, stable disease; VGPR, very good partial response.

Source: Mateos MV, et al. ASH 2019. #1883

Disease was stabilized in 83% of patients^a



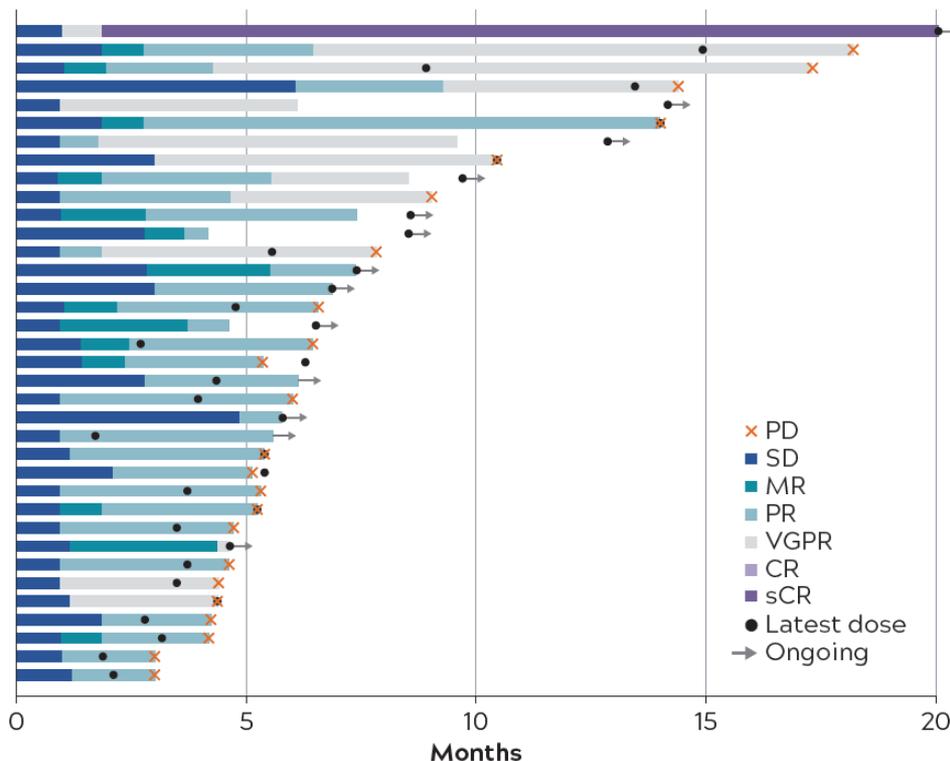
- Overall, 83% of the patients had a reduction of M-protein despite all patients having progressing disease at study entry

^aIn total, 10 patients had missing M-protein data.

M-protein, monoclonal protein; MR, minimal response; PD, progressive disease; PR, partial response; sCR, stringent complete response; SD, stable disease; VGPR, very good partial response.

Source: Mateos MV, et al. ASH 2019. #1883

Melflufen showed durable responses (n=36)^a



- Median Duration of Response in triple-class refractory patients was 7.5 months

^aThe swim-lane plot is based on response assessments reported by the investigators. Gaps between the bar and latest dose indicate no response data are currently available for that time.

CR, complete response; MR, minimal response; PD, progressive disease; PR, partial response; sCR, stringent complete response; SD, stable disease; VGPR, very good partial response.

Strong patient centric safety profile

TEAE ^a	Grade 3, n (%)	Grade 4, n (%)
Anemia	56 (36)	1 (1)
Neutropenia	47 (31)	54 (35)
Thrombocytopenia	32 (21)	74 (48)
White blood cell count decreased	13 (8)	15 (10)
Pneumonia	11 (7)	2 (1)
Febrile Neutropenia	6 (4)	2 (1)
Lymphopenia	6 (4)	2 (1)
Leukopenia	4 (3)	6 (4)

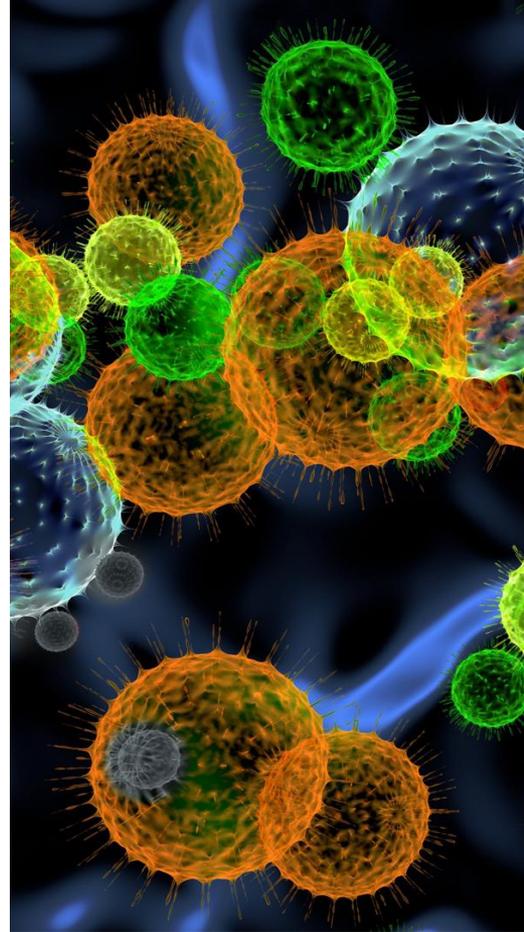
^aGrade 3 and 4 TEAEs occurring in $\geq 5\%$ of patients.
TEAE, treatment-emergent adverse event.

- Absence of grade 3 and 4 TEAEs outside of the hematological system and infections and infestations
- Hematological toxicity clinically manageable
 - Only 3 patients (2%) with melflufen-related bleeding events reported as serious TEAEs
 - 71% of patients maintained the dose
- 18% of patients experienced a grade 3 or 4 infection
- 5 patients (3%) died, none was considered related to melflufen treatment

Encouraging data for melflufen in combination with daratumumab

Summary of combination with daratumumab – n=33

- Median of 2 prior lines of therapy
- True RRMM population (not maintenance refractory) – 39% had disease progression while on last line of therapy and 60% high-risk cytogenetics
- **ORR of 76%** with good tolerability and deepening responses - 22 patients ongoing
- Median **PFS of 14.3 months**



Melflufen in combination with daratumumab: Response assessment

- Of the 33 patients, 25 responded to treatment, with an ORR of 76% and a CBR of 79%

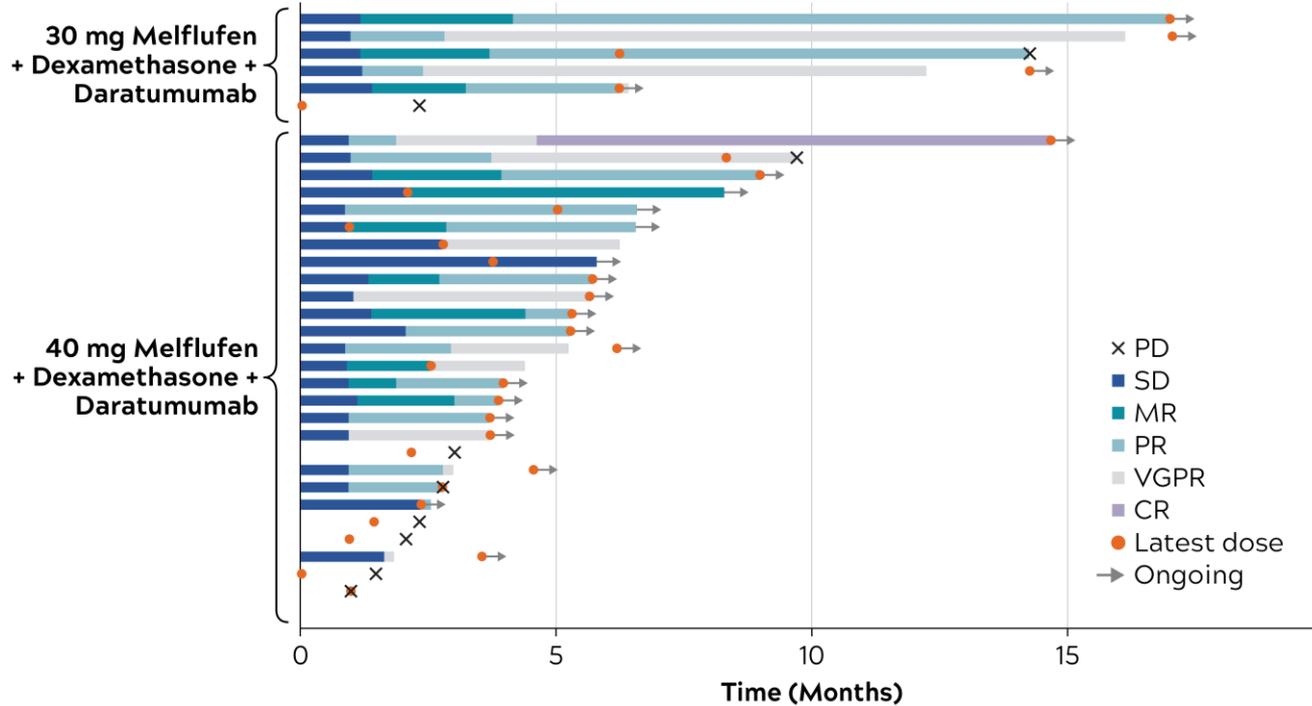
Subgroup	Patients, n							Patients, %	
	sCR	CR	VGPR	PR	MR	SD	PD	ORR	CBR
Total (n=33)	1	0	11	13	1	2	5	76	79
Melflufen 30 mg (n=6)	0	0	3 ^a	2	0	0	1	83	83
Melflufen 40 mg (n=27)	1	0	8 ^b	11	1	2	4	74	78

^aIncludes 1 unconfirmed VGPR.

^bIncludes 2 unconfirmed VGPRs.

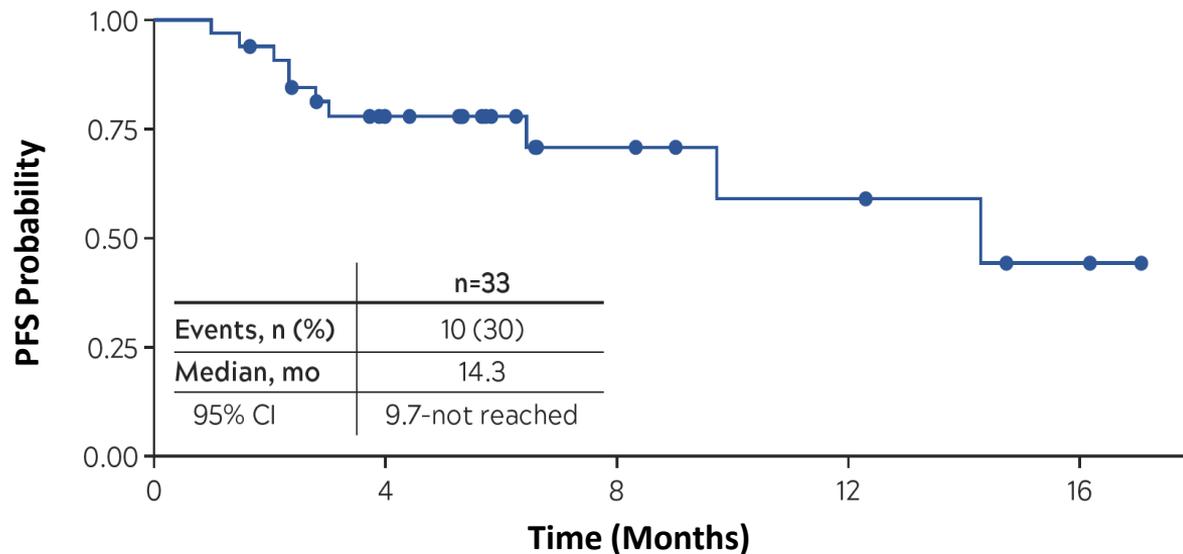
CBR, clinical benefit rate; CR, complete response; MR, minor response; ORR, overall response rate; PD, progressive disease; PR, partial response; sCR, stringent CR; SD, stable disease; VGPR, very good PR.

Responses became deeper over time – 22 patients were still on treatment at the time of the data-cut



^aThe swim-lane plot is based on response assessments reported by the investigators. Gaps between the bar and latest dose indicate there were no response data available for that time. CR, complete response; EoT, end of treatment; MR, minor response; PD, progressive disease; PR, partial response; SD, stable disease; VGPR, very good PR.

Emerging Progression-Free Survival of 14.3^a months



- Most patients were progression-free at data cutoff, with 10 events in 33 patients
- Median PFS was 14.3 months (95% CI, 9.7-not reached)
- Patients were censored on their latest progression-free observation

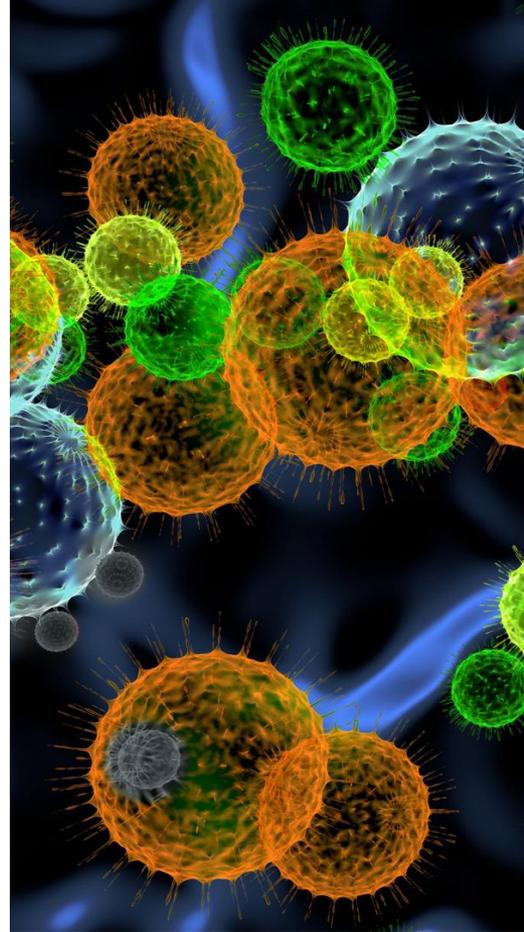
^aThese data are immature since 23 patients are still in PFS follow-up.
PFS, progression-free survival.

Source: Ocio EM, et al. ASH 2019. #3124

Emerging data for melflufen in combination with bortezomib

Summary of combination with bortezomib – n=6

- Elderly population – Median of 2.5 prior lines of therapy
- True RRMM population (not maintenance refractory) – 50% had disease progression while on last line of therapy
- 4/6 responded on therapy (**ORR 67%**) with good tolerability and deepening responses – 3 pts ongoing
- Median PFS not reached with the longest patient on treatment for 16 months



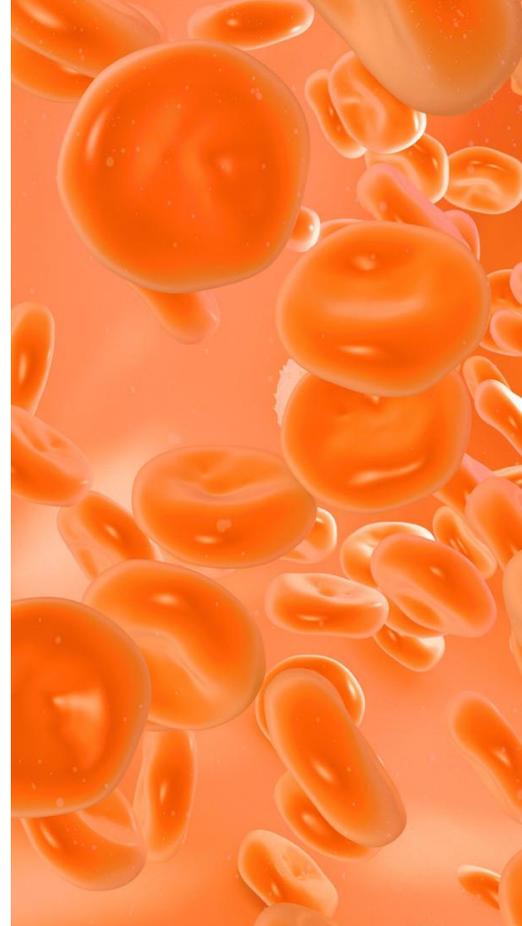
Summary

Strong efficacy data in HORIZON with good tolerability – 24% ORR and 7.5 months duration of response in triple-class refractory myeloma patients

Strong activity data in ANCHOR – both in combination with daratumumab and bortezomib. Very positive signal with regard to durability of responses in combination with daratumumab (and hence PFS) in comparison with most recent and novel combination data in RRMM

BCMA targeted therapies struggling with usability despite representing a good target

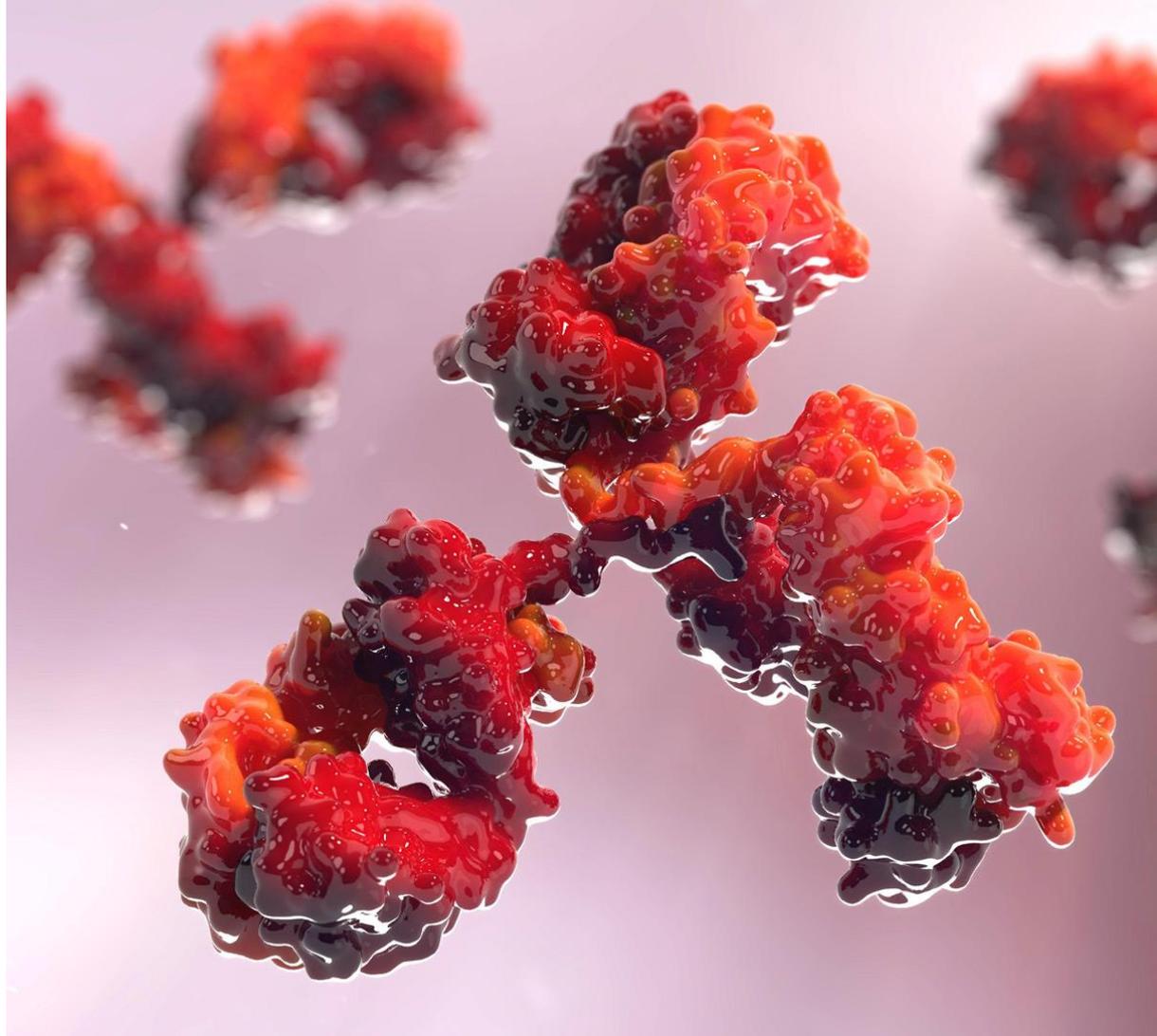
NDA submission process on track after a good pre-NDA meeting with the FDA. Submission planned during first half of 2020



The coming quarters will be very information rich

	Dec 2019	Q1 2020	Q2 2020	Q3 2020	Q4 2020
✓	Data from HORIZON, ANCHOR at ASH	FPI LIGHTHOUSE	LPI BRIDGE	Top-line results OCEAN	Potential accelerated approval in US
	FPI Amyloidosis Trial	LPI OCEAN	New data and updates at EHA NDA submission	LPI ANCHOR	Potential Launch in US

Q&A



***Thank you for
your attention!***

