# Post-EHA Webcast
# June 16th 2020

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oncopeptides

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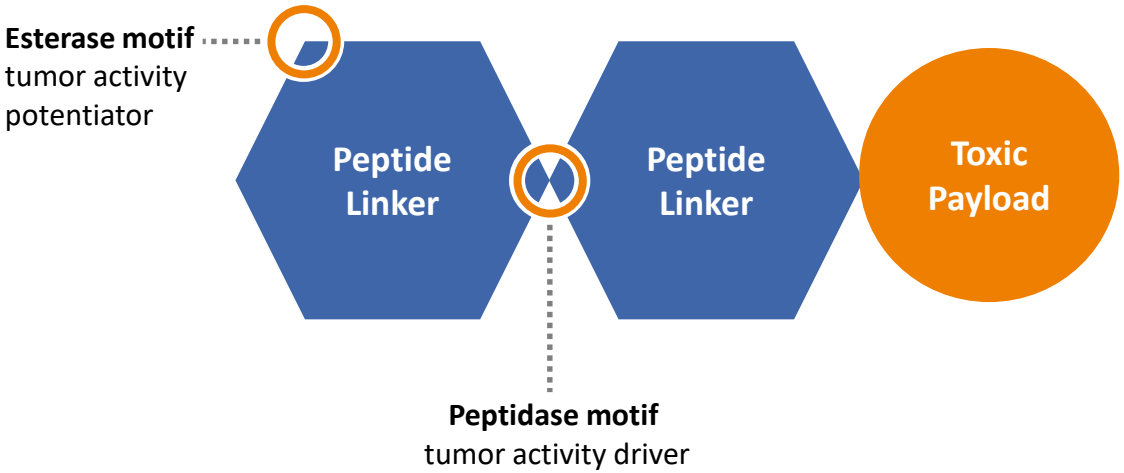
# Unique Peptide Drug Conjugate Platform

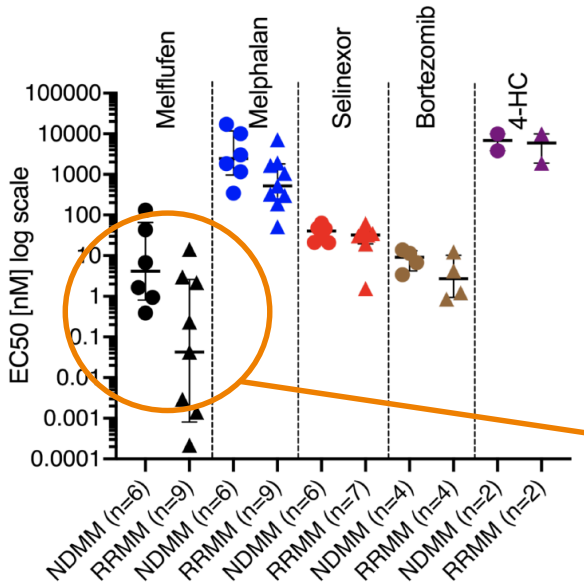



- Targeted delivery of toxins
- Utilizing enzymatic motifs

## EHA pre-clinical highlights:

# Potency Increases with Malignancy

**Figure 4. Comparison CD138+CD38+ cell EC50 values between NDMM and RRMM patient samples in the five tested drugs.**



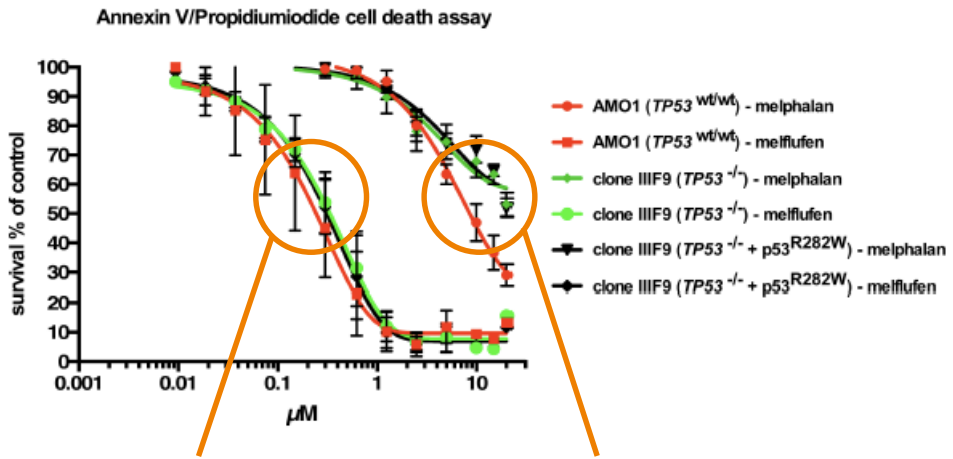

- Potency of melflufen increases in vitro against myeloma patient samples as disease progresses
  - NDMM = newly diagnosed MM
  - RRMM = relapsed refractory MM

**Melflufen**: **Increased potency as disease progresses**

EHA pre-clinical highlights:

# Cytotoxic Activity of Melflufen Differs from Alkylators

**Figure 3.** Melflufen vs. melphalan effects in the AMO-1 *TP53* model system assessed 72h after treatment with increasing doses of the drugs.




**Melflufen**:
No difference

**Melphalan**:
Almost inactivated

Cytotoxic activity of melflufen differs from alkylators in myeloma tumor cells

- Red = tumor cell
- Green = tumor cell with p53 deletion
- Black = tumor cell with mutated p53

# HORIZON Rationale

- Despite advances in therapy, outcomes remain poor for patients with RRMM[1,2]
- Treatment choice after relapse depends on patient characteristics, prior therapy and response to therapy[3,4]
- Switching is harder to achieve as new combinations in earlier lines, result in resistance to multiple drugs[3-5]
- Melflufen is a first-in-class peptide drug conjugate that delivers an alkylating payload into tumor cells[6-10]
- Efficacy and safety was demonstrated in O-12-M1, a phase 1/2, dose-finding study in patients with RRMM[11]
  - Among 45 patients who received melflufen plus dex, overall response rate was 31%, median duration of response was 8.4 months, and median progression-free survival was 5.7 months
  - The safety profile of melflufen plus dex was primarily characterized by clinically manageable hematologic AEs and a low frequency of nonhematologic AEs

AE, adverse event; dex, dexamethasone; RRMM, relapsed/refractory multiple myeloma.

1. Kumar SK, et al. *Leukemia.* 2017;31:2443. 2. Gandhi UH, et al. *Leukemia.* 2019;33:2266. 3. Pawlyn C, et al. EHA 2019. Abstract S873. 4. Moreau P, et al. *Blood Cancer J.* 2019;9:38. 5. Cejalvo MJ, et al. *Expert Rev Hematol.* 2017;10:383-392.
6. Chauhan D, et al. *Clin Cancer Res.* 2013;19(11):3019-3031. 7. Wickström M, et al. *Invest New Drugs.* 2008;26(3):195-204. 8. Ray A, et al. *Br J Haematol.* 2016;174(3):397-409. 9. Strese S, et al. *Biochem Pharmacol.* 2013;86(7):888-895.
10. Wickström M, et al. *Oncotarget*. 2017;8(39):66641-66655. 11. Richardson PG, et al. *Lancet Haematol.* 2020;7:e395-e407.

**Richardson PG, et al. EHA 2020. #EP945.**

# HORIZON Study Design

HORIZON

***Phase 2, Pivotal, Single-Arm, Multicenter Study (NCT02963493)***

**Adult patients with**

- RRMM refractory to pom or anti-CD38 mAb or both
- ≥2 prior lines of therapy, including an IMiD and a PI
- ECOG PS ≤2

**(N=157)**

*Data cutoff date: January 14, 2020*

**Melflufen 40 mg + dex 40 mg[a]**
*(until disease progression or unacceptable toxicity)*

| | 28-Day Cycle | | | |
|---|---|---|---|---|
| | D1 | D8 | D15 | D22 |
| Melflufen (IV) | ✓ | | | |
| Dex (oral) | ✓ | ✓ | ✓ | ✓ |

[a] *Patients aged ≥75 years received dex 20 mg.*

EoT — PFS and OS follow-up for ≤24 months

**Primary endpoint**

- ORR

**Secondary endpoints**

- DOR
- PFS
- OS
- CBR
- TTR
- TTP
- TTNT
- Safety
- HRQOL

**Objective to evaluate the efficacy and safety of melflufen plus dex in patients with RRMM**

- Intention-to-treat (ITT) population used for all analysis
- Subgroups included patients with triple-class refractory disease and patients with EMD

CBR, clinical benefit rate; dex, dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; EMD, extramedullary disease; EoT, end of treatment; HRQoL, health-related quality of life; IMiD, immunomodulatory agent; IV, intravenous; mAb, monoclonal antibody; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; RRMM, relapsed/refractory multiple myeloma; TTNT, time to next treatment; TTP, time to progression; TTR, time to response.

**Richardson PG, et al. EHA 2020. #EP945.**

# Patient Disposition and Follow Up

HORIZON

- 157 patients were enrolled and received ≥1 dose of study medication; 131 patients (83%) had discontinued therapy and 26 patients (17%) remained on therapy
  - Most common reasons for treatment discontinuation were disease progression (56%) and AEs (17%)

- The study is fully recruited with median follow-up time of 14 months
  - The last patient enrolled into the study began treatment ≥3 months prior to the data cutoff date

AE, adverse event.

**Richardson PG, et al. EHA 2020. #EP945.**

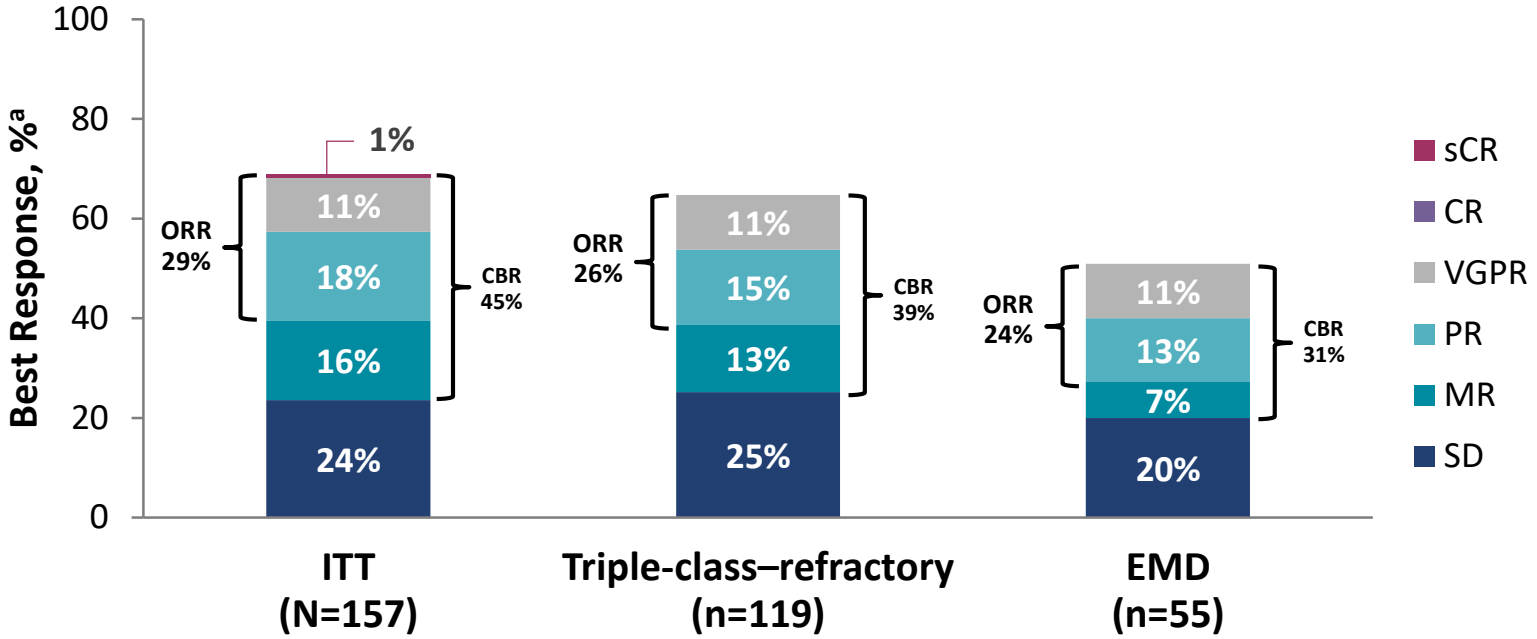
# Baseline Patient Characteristics

HORIZON

| Patient characteristics | ITT (N=157) | Triple Class Refractory (n=119) | EMD (n=55) |
|---|---|---|---|
| Median age (range), years | 65 (35-86) | 65 (35-86) | 64 (43-82) |
| Male sex, n (%) | 89 (57) | 70 (59) | 31 (56) |
| High-risk cytogenetics, n (%)[a] | 59 (38) | 41 (34) | 19 (35) |
| ISS stage (I/II/III) at study entry, %[b] | 40/31/25 | 34/30/30 | 36/25/33 |
| EMD at study entry, n (%)[c] | 55 (35) | 50 (42) | 55 (100) |
| Median no. of prior lines of therapy (range) | 5 (2-12) | 5 (2-12) | 5 (2-12) |
| Triple-class–refractory, n (%)[d] | 119 (76) | 119 (100) | 50 (91) |
| Refractory to ≥1 anti-CD38 mAb | 125 (80) | 119 (100) | 50 (91) |
| Refractory to prior alkylator therapy [e] | 92 (59) | 76 (64) | 33 (60) |

Data cutoff date: January 14, 2020. [a] High-risk cytogenetics at study entry was based on fluorescence in situ hybridization defined as t(4;14), del(17/17p), and t(14;16)[1]; 31 patients (20%) had unknown cytogenetics. Cytogenetic assessments were not centralized. [b] At study entry, 6 patients in the ITT population had unknown or missing ISS stage. [c] EMD was defined as a multiple myeloma disease originating either in, but extending beyond, the cortical bone or as a separate soft tissue mass. [d] Defined as refractory to or intolerant of ≥1 PI, ≥1 IMiD, and ≥1 anti-CD38 mAb. [e] Including 21 patients (13%) refractory to prior melphalan in the ITT population.
EMD, extramedullary disease; ISS, International Staging System; ITT, intention-to-treat; mAb, monoclonal antibody; PI, proteasome inhibitor.
1. Sonneveld P, et al. *Blood.* 2016;127:2955-2962.
**Richardson PG, et al. EHA 2020. #EP945.**

# Best Overall Response Rate



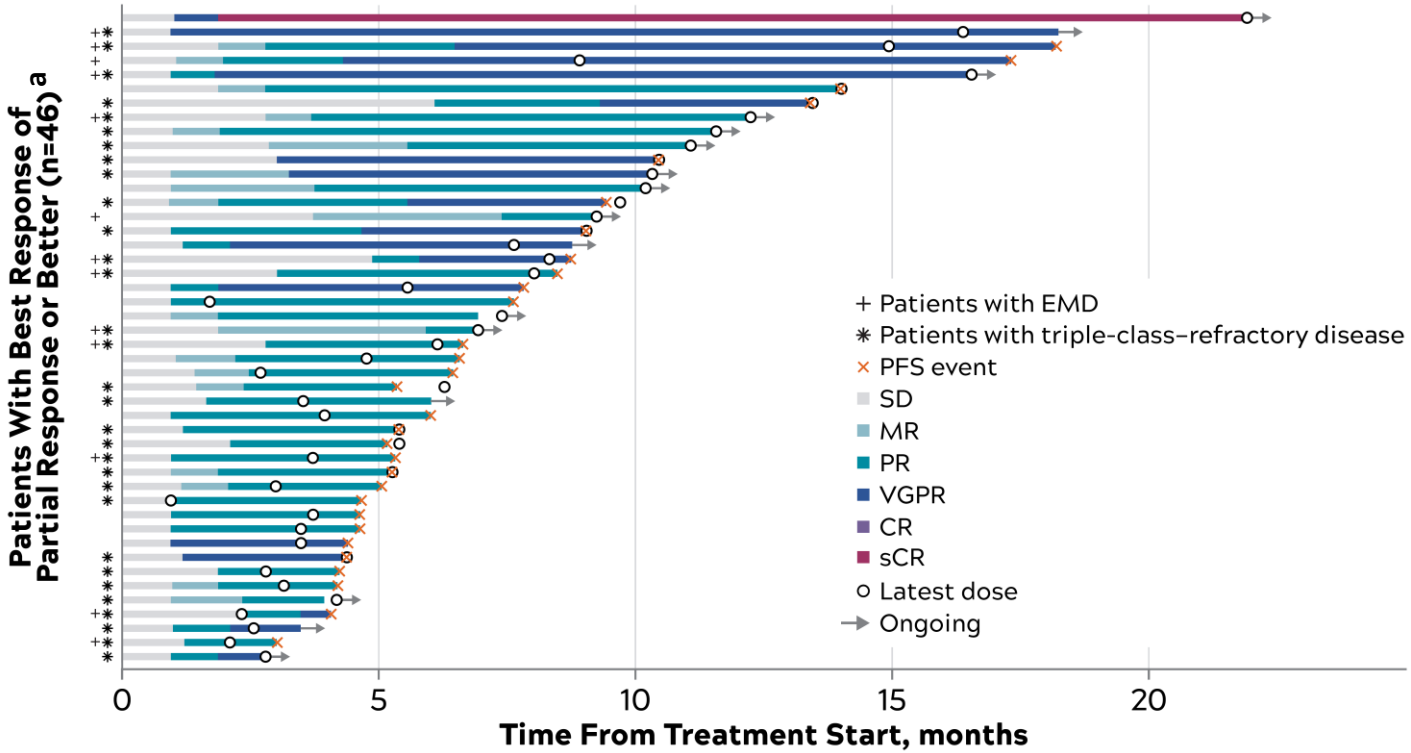

- The ORR was 29% (95% CI, 22-37) in the ITT population, 26% (95% CI, 18-35) in the triple-class refractory population, and 24% (95% CI, 13-37) in the EMD subgroup, and were consistent with the findings of the IRC

Data cutoff date: January 14, 2020. [a] Investigator-assessed best overall response per International Myeloma Working Group uniform criteria.[1]
CBR, clinical benefit rate; CR, complete response; EMD, extramedullary disease; IRC, Independent Review Committee; ITT, intention-to-treat; MR, minor response; NE, not evaluable; ORR, overall response rate; PR, partial response; sCR, stringent complete response; SD, stable disease; VGPR, very good partial response.

1. Rajkumar SV, et al. *Blood.* 2011;117:4691-4695.

**Richardson PG, et al. EHA 2020. #EP945.**

# Swim Lane of Patients with ≥ Partial Response




Data cutoff date: January 14, 2020. [a] Investigator-assessed best overall response per International Myeloma Working Group uniform criteria.[1]
CR, complete response; EMD, extramedullary disease; ITT, intention-to-treat; MR, minimal response; PFS, progression-free survival; PR, partial response; sCR, stringent complete response; SD, stable disease; VGPR, very good partial response.

1. Rajkumar SV, et al. *Blood.* 2011;117:4691-4695.

**Richardson PG, et al. EHA 2020. #EP945.**

# Patients Should Remain on Treatment as Long as Possible

HORIZON

## Time to response

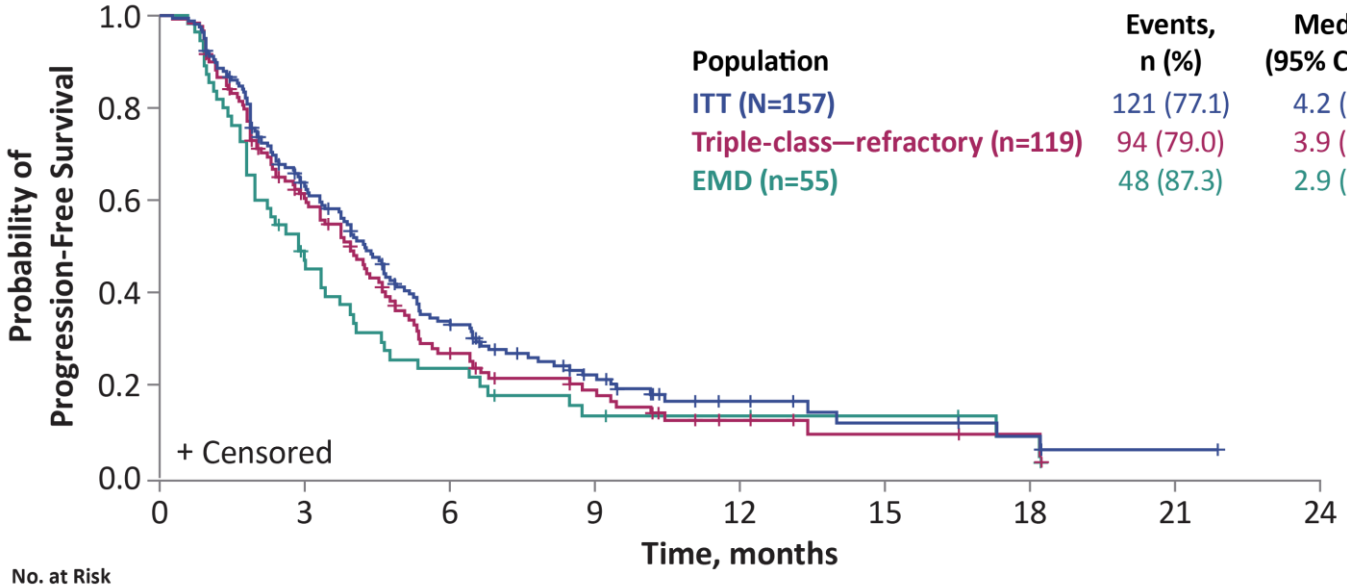
- Median time to best response was 1.9 months in the ITT population
- Responses deepened with longer treatment duration
- In some patients, response was extended beyond last dose of melflufen

## Duration of response

- Median DOR was 5.5 months (95% CI, 3.9-7.6) in the ITT population, 4.4 months (95% CI, 3.4-7.6) in the triple-class refractory population, and 5.5 months (95% CI, 1.8-not evaluable) in the EMD subgroup
- Among responders (≥PR), median PFS (95% CI) was 8.5 months (5.4-13.4) in the ITT population, 8.5 months (5.3-13.4) in the triple-class refractory population, and 17.3 months (5.3-NE) in patients with EMD

Data cutoff date: January 14, 2020.
DOR, duration of response; EMD, extramedullary disease; ITT, intention-to-treat.
**Richardson PG, et al. EHA 2020. #EP945.**

# Progression Free Survival




| Population | Events, n (%) | Median PFS (95% CI), months |
|---|---|---|
| ITT (N=157) | 121 (77.1) | 4.2 (3.4-4.9) |
| Triple-class—refractory (n=119) | 94 (79.0) | 3.9 (3.0-4.6) |
| EMD (n=55) | 48 (87.3) | 2.9 (2.0-3.8) |

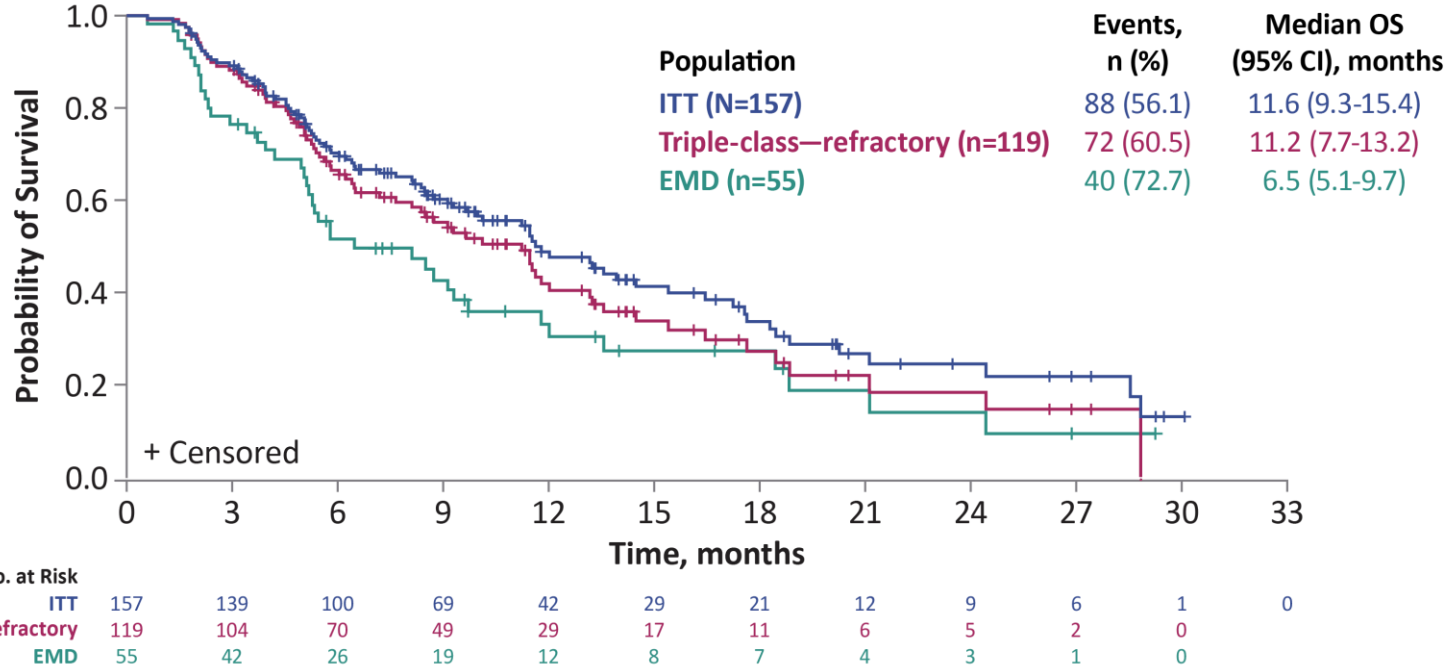
| No. at Risk | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| ITT | 157 | 91 | 46 | 22 | 9 | 5 | 3 | 1 | 0 |
| Triple-class—refractory | 119 | 64 | 26 | 15 | 6 | 3 | 2 | 0 | |
| EMD | 55 | 24 | 12 | 6 | 5 | 4 | 2 | 0 | |

- Among responders (≥PR), median PFS (95% CI) was 8.5 months (5.4-13.4) in the ITT population, 8.5 months (5.3-13.4) in the triple-class refractory population, and 17.3 months (5.3-NE) in patients with EMD

Data cutoff date: January 14, 2020.
EMD, extramedullary disease; ITT, intention-to-treat; NE, not evaluable; PFS, progression-free survival; PR, partial response.
**Richardson PG, et al. EHA 2020. #EP945.**

# Overall Survival

HORIZON




- Among responders (≥PR), median OS (95% CI) was 17.6 months (15.4-NA) in the ITT population, 16.5 months (12.0-NA) in the triple-class refractory population, and 18.5 months (12.0-NE) in patients with EMD

Data cutoff date: January 14, 2020.
EMD, extramedullary disease; ITT, intention-to-treat; OS, overall survival.
**Richardson PG, et al. EHA 2020. #EP945.**

# Consistent Safety Profile

| | AEs (occurring in ≥15% of patients) (N=157), n (%) | | | | |
|---|---|---|---|---|---|
| | Any-Grade | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| **Any AE[a]** | **157 (100)** | **0** | **7 (4)** | **40 (25)** | **100 (64)** |
| Hematologic[b] | | | | | |
| Neutropenia | 129 (82) | 1 (<1) | 4 (3) | 50 (32) | 74 (47) |
| Thrombocytopenia | 128 (82) | 5 (3) | 3 (2) | 40 (25) | 80 (51) |
| Anemia | 111 (71) | 3 (2) | 41 (26) | 66 (42) | 1 (<1) |
| Nonhematologic | | | | | |
| Nausea | 50 (32) | 31 (20) | 18 (11) | 1 (<1) | 0 |
| Fatigue | 46 (29) | 17 (11) | 25 (16) | 4 (3) | 0 |
| Asthenia | 42 (27) | 13 (8) | 23 (15) | 5 (3) | 1 (<1) |
| Diarrhea | 42 (27) | 24 (15) | 18 (11) | 0 | 0 |
| Pyrexia | 38 (24) | 24 (15) | 11 (7) | 3 (2) | 0 |
| Cough | 26 (17) | 16 (10) | 10 (6) | 0 | 0 |
| URTI | 25 (16) | 3 (2) | 19 (12) | 3 (2) | 0 |
| Constipation | 23 (15) | 18 (11) | 4 (3) | 1 (<1) | 0 |

- Hematological AEs were common
- Non-hematological AEs infrequent
- 70% of patients maintain 40mg dose
- 58% of patients had either a dose reduction or dose delay
- 51% of patients had SAE (any grade)

Data cutoff date: January 14, 2020. [a] Treatment-emergent AEs by maximum severity. AEs are coded to preferred term using MedDRA, version 19.1. [b] Hematologic AEs of special interest (neutropenia, thrombocytopenia, and anemia) were categorized by standardized MedDRA query.
AE, adverse event; URTI, upper respiratory tract infection.
**Richardson PG, et al. EHA 2020. #EP945.**

# Summary and Conclusions

| | Melflufen<br>Final Data<br>EHA 2020 | Xpovio<br>Karyopharm<br>US approval July 2019 | Belantamab<br>GSK<br>In filing |
|---|---|---|---|
| **Number of patients studied** | 119 | 122 | 97 |
| **Overall Response/Clinical Benefit Rate** | 26%/39% | 25%/39% | 31%/34% |
| **mDOR / mPFS responders** | 5.5m / 8.5m | 3.8m / 4.0m | NR (≈7-8m) /NR (≈8-9m) |
| **Progression-free survival** | 3.9 months | 3.7 months | 2.9 months |
| **Overall survival** | 11.2 months | 8.0 months | NR (≈10months) |
| **Share of patients with EMD** | 42% | 22% | 23% |
| **Serious Adverse Event Rate** | 51% | 58% | 36% (excl. ocular tox.) |
| **Non-hematologic toxicity (grade 3/4) reported in >5% of patients** | Pneumonia 9.2% | Fatigue 25.2%<br>Hyponatremia 20.3%<br>Nausea 9.8%<br>Pneumonia 8.9%<br>Diarrhea 7.3%<br>Sepsis 5.7%<br>Hypokalemia 5.7%<br>Mental status 5.7%<br>General det. 5.7% | Keratopathy/ Blurred vision 27.4%<br>Hypercalcemia 7.4%<br>Pneumonia/ Lung infections 6.3% |

# Consistent News Flow

| Q2 2020 | Q3 2020 | Q4 2020 | H1 2021 |
|---|---|---|---|
| ✓ Last patient in OCEAN | First patient in Amyloidosis study | Potential accelerated approval in US | Top-line results OCEAN |
| ✓ EHA data update | First patient in Expanded Access Program (US) | Potential launch in the US | Last patient in ANCHOR |
| NDA submission | | First patient in LIGHTHOUSE | Last patient in BRIDGE |

# *Q&A*

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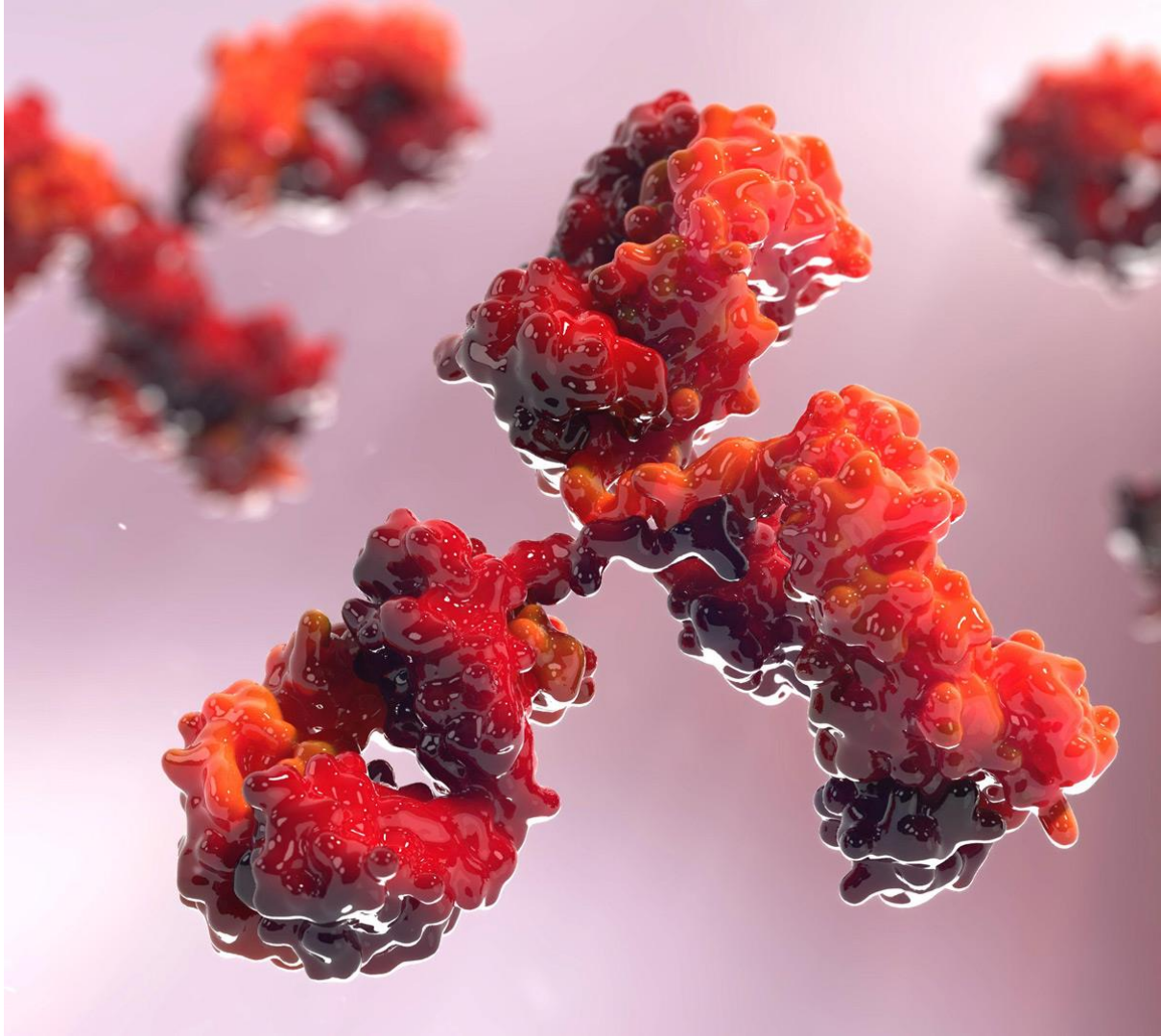

***Thank you for your attention!***

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