

# **Type II application**

Investor conference

May 11, 2026



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Oncopeptides is a global biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary Peptide Drug Candidate platform, PDC, to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. Pepaxti® (melphalan flufenamide, also called melflufen) has been granted Marketing Authorization, in the European Union, the EEA-countries Iceland, Lichtenstein and Norway, as well as the UK. Pepaxti is indicated in combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapies, whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or after the last therapy. For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation. Melflufen was granted an accelerated approval in the US in February 2021, under the trade name Pepaxto®. The product is currently not marketed in the US.

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# Presenters



Sofia Heigis  
Chief Executive Officer



Henrik Bergentoft  
Chief Financial Officer

# Today's announcement

- **What are we announcing?**

- Oncopeptides intends to submit a Type II variation application to the European Medicines Agency (EMA).
- The submission follows an updated assessment of the evolving therapeutic and regulatory landscape in Europe.
- An approved application for a broader indication would significantly expand the potential addressable market for Pepaxti.
- 2x patients, 2x treatment cycles on average in the third line.

- **What are the next steps?**

- Application to be send during next few months with final EC decision in H1 2027.

- **What will be presented today?**

- Background on decision, potential financial implications, supporting data and next steps. A Q&A will follow.

# Key takeaways

## Market expansion

Submission seeks to get regulatory approval to at least **double the current addressable patient population** for Pepaxti in Europe by moving into 3rd line treatment and treating less refractory patients.

## Extended exposure

Average **treatment cycles** are according to clinical data expected to **double** in the 3rd line setting, compared to the current label.

## Clinical value

Built upon robust Phase 3 OCEAN study data previously deemed approvable by EMA.

## Pricing viability

Assessment shows evolved pricing landscape allows expansion **without compromising innovative price.**

# Background

# Looking back: 2023 - third line entry risk to Pepaxti value

SEPTEMBER 14, 2023 • PRESS RELEASE

## CHMP issues positive opinion on Type II variation to extend the therapeutic indication of Pepaxti based on OCEAN trial results

Regulatory

Stockholm — September 14, 2023 — Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today announces that the Committee for Medicinal Products for Human Use (CHMP), part of the European Medicines Agency (EMA), has, following their scientific assessment, adopted a positive opinion on Oncopeptides' application for earlier lines of treatment for patients with relapsed, refractory multiple myeloma (RRMM). The opinion from the CHMP will now be sent to the European Commission for a final decision.

SEPTEMBER 28, 2023 • PRESS RELEASE

## Oncopeptides opts to abandon Type II variation process for Pepaxti to optimize patient and shareholder value

Regulatory

Stockholm — September 28, 2023 — Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today announces its decision to opt to abandon the application process to allow Pepaxti access to earlier lines of treatment for patients with relapsed, refractory multiple myeloma (RRMM), a so-called type II variation. The decision follows an updated, comprehensive analysis of the current landscape for treatment of multiple myeloma and is made to optimize value for both patients and shareholders. The decision does not impact the company's financial projections or the estimated market potential of Pepaxti negatively.

“To move forward with an extension into earlier lines of treatment before fulfilling the higher unmet need in later lines could mean a new European price level for Pepaxti that does not reflect our innovation and ultimately risk the availability of Pepaxti for all patients and also erode shareholder value.”

- Sofia Heigis  
(from press release announcing Oncopeptides abandonment of Type II process on September 28, 2023)

# Today: 2026 - a more favorable pricing landscape



Strategic Factor	2023 Analysis	2026 Assessment
<b>Pricing anchor</b>	Cheapest comparator = generic	"Basket" including advanced therapies
<b>Payer precedence</b>	Limited / single comparator	Basket used in 2-3 line
<b>Commercial viability</b>	Unfavorable market access risk	Highly viable; preserves innovation value
<b>ACTION TAKEN</b>	Indication withdrawal	<b>TYPE II SUBMISSION INITIATED</b>



The transition to a "basket" approach in Germany ensures pricing reflects Pepaxti's innovation.

# Business impact

# Unlocking potential

**Oncopeptides' communicated SEK 1.5 Billion market potential today reflects the current indication.**

A third line expansion could add potential based on three core multipliers:

**2x**

Addressable Patients

**2x**

Average no of Treatment Cycles



Innovative Price

	Patients	Treatment cycles	Price
Current indication	≈20,000	~5	German list price 7,058/month*
Third line	Another ≈20,000	OCEAN study: Median = 8 Average = 11	<b>To be determined following market access and pricing negotiations</b>

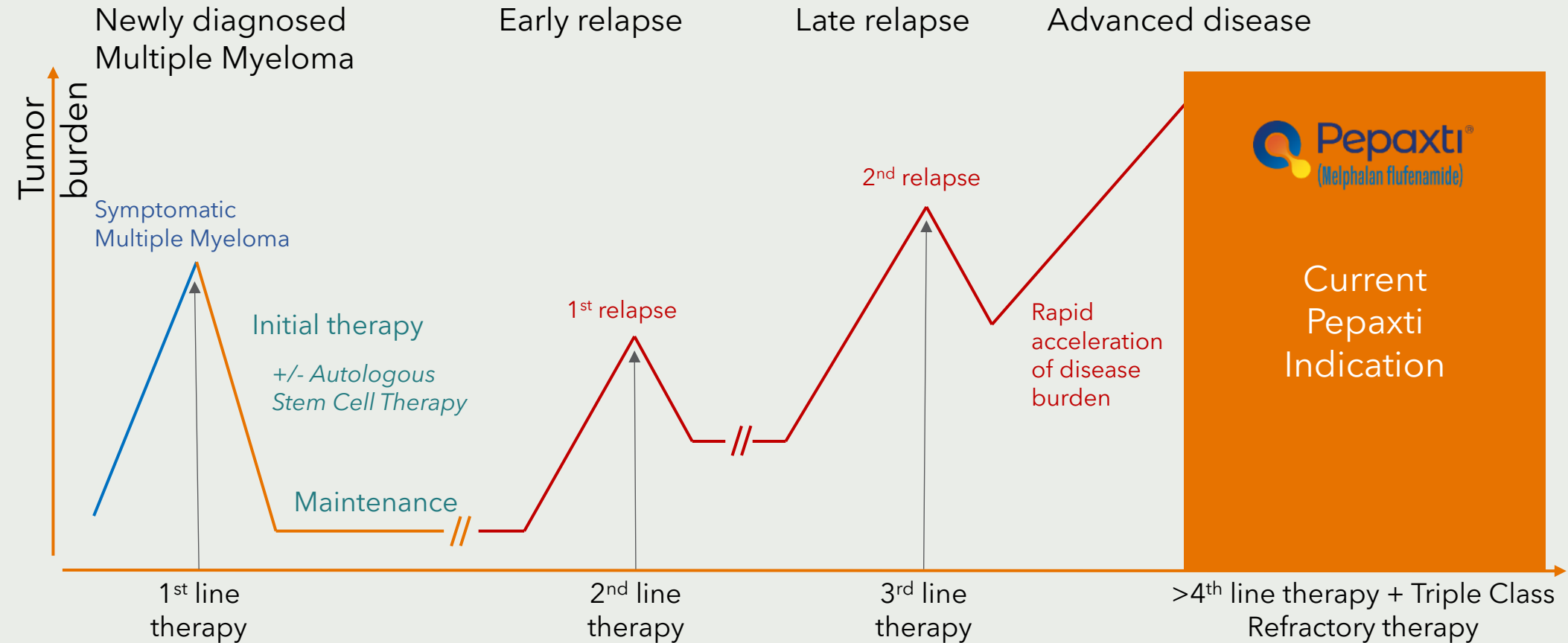
The price of a drug negotiated in Germany can influence its pricing in other European countries. Given Germany's status as a key reference country, a price there can set a benchmark for other nations. Individual countries also weigh other factors like health system priorities and economic conditions when setting drug prices.



# Scientific rationale

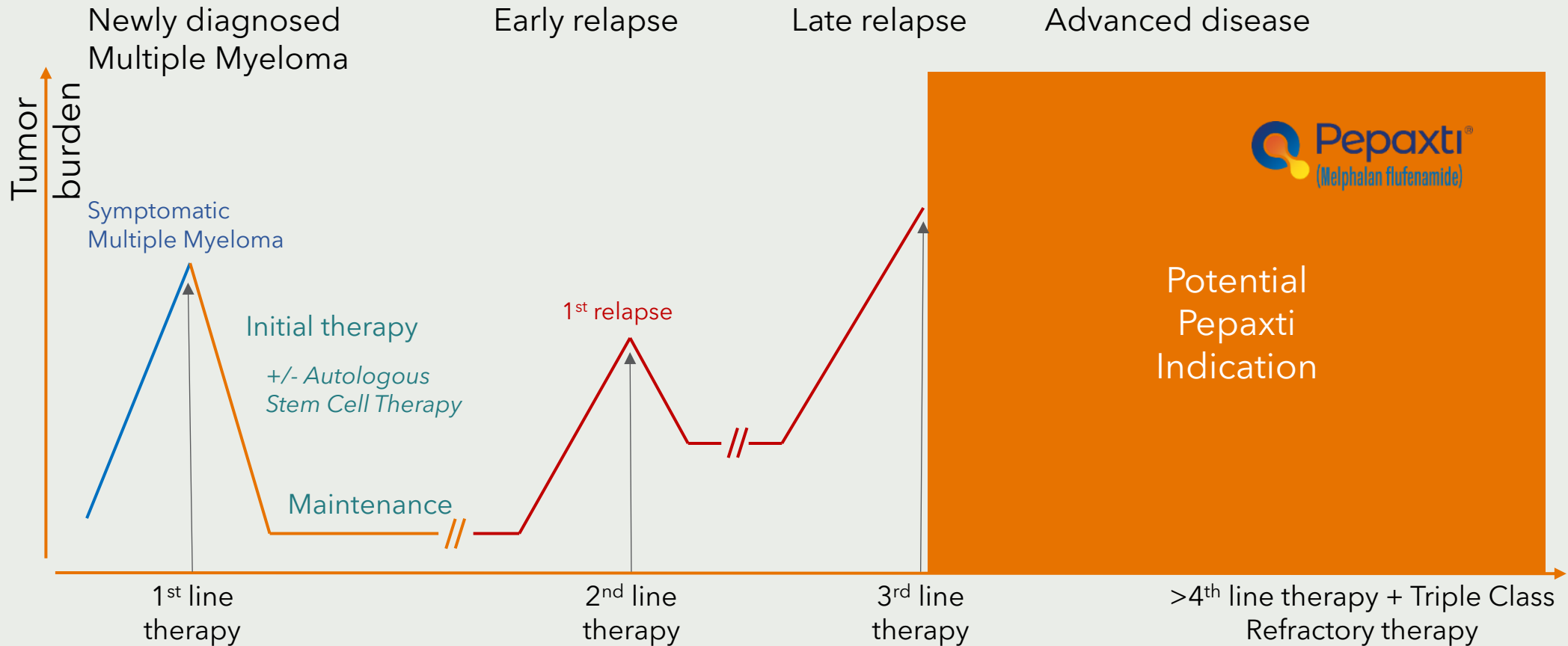
# Multiple Myeloma treatment course

## A marathon - not a sprint



# Multiple Myeloma treatment course

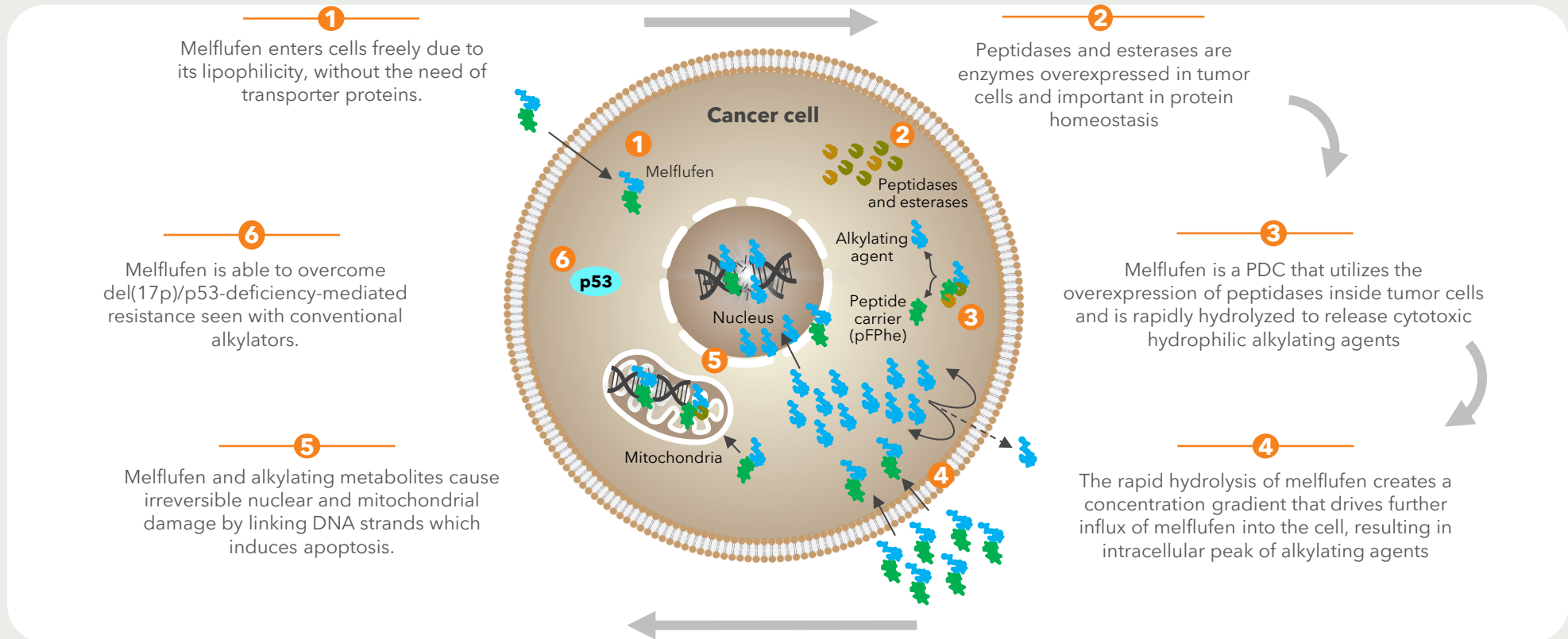
## A marathon - not a sprint



# Mode of Action



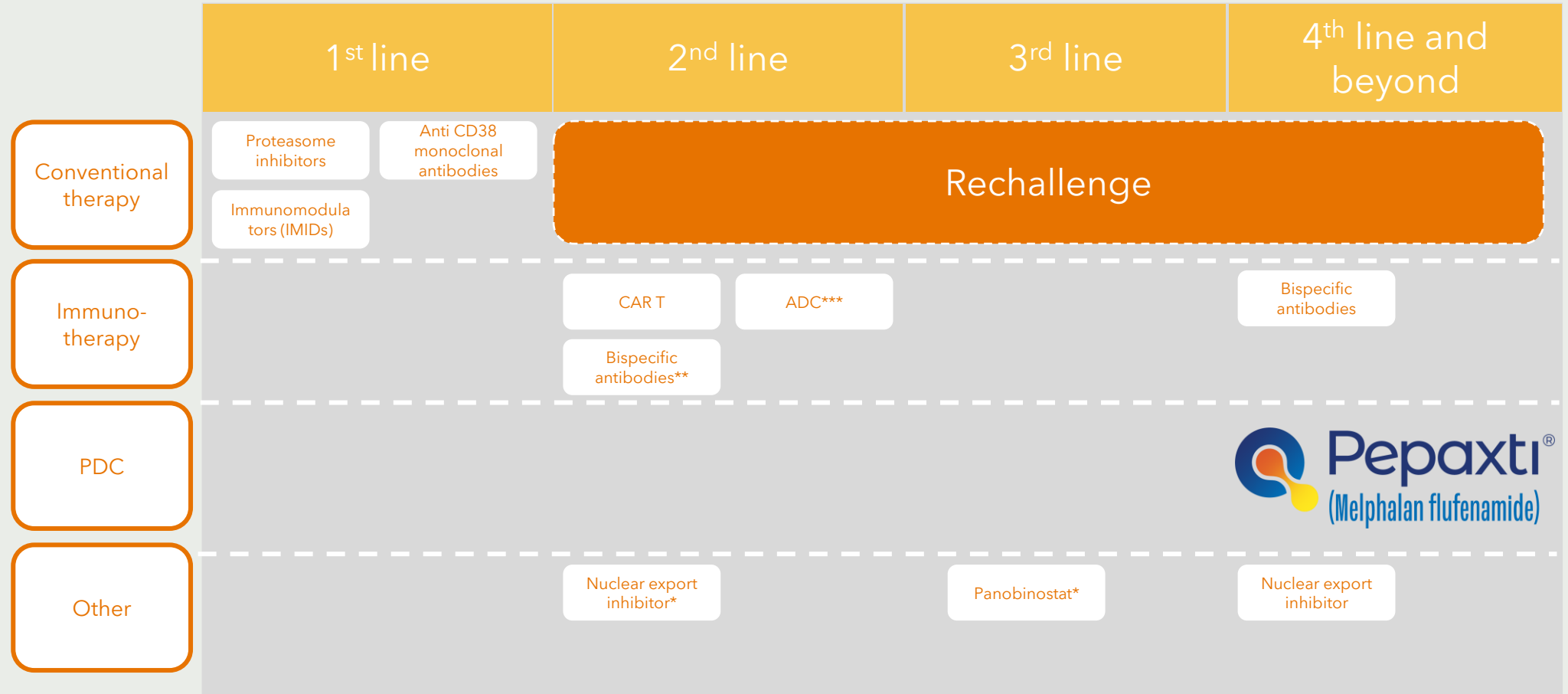
PDCs **enhance alkylation** through enzymatic enrichment and dual targeting of **both nuclear and mitochondrial DNA**



Del, deletion; PDC, peptide-drug conjugate; pFPhe, p-L fluoro-phenylalanine ethyl ester; melflufen, melphalan flufenamide; p53, tumor suppressor protein 53.

1. Chauhan D, et al. *Clin Cancer Res*. 2013;19(11):3019-31.
2. Wickström M, et al. *Oncotarget*. 2017;8(39):66641-66655.
3. Kumari R, et al. *Br J Cancer*. 2021;124(8):1428-1436.
4. Miettinen JJ, et al. *Cancers (Basel)*. 2021;13(7):1527.
5. Westermark U, et al. *Biochem Biophys Res Commun*. 2023;656:122-130.
6. Ray A, et al. *Br J Haematol*. 2016;174(3):397-409.
7. Mateos MV, et al. ASH 2020. Poster 3237.

# Multiple Myeloma treatment landscape



\*In combination with bortezomib

\*\*In combination, teclistamab+daratumumab (approved by FDA, filed with EMA; expected approval Q3 2026)

\*\*\*In combination with bortezomib or pomalidomide

# Clinical positioning: where Pepaxti fits



## Unable to receive Immunotherapy

Strategic option for patients unable to receive immunotherapy due to comorbidities, infections, frailty, suppressed immunesystem or QoL limitations.



## In-between immunotherapy

Ideal "bridge" between immune-based therapies to allow for T-cell recovery or antigen reset.



## Post-immunotherapy failure

RWD demonstrates Pepaxti can be an alternative for patients who have relapsed or become refractory after BCMA/CAR-T therapies.

# Broadening the therapeutic reach

- Current indication
  - 4th Line+ treatment
  - Adult patients with RRMM who have received at least 3 prior lines of therapies.
  - Refractory to at least 1 PI, 1 IMiD, and 1 anti-CD38 mAb.
- Future potential indication
  - 3rd line+ treatment
  - Adult patients with RRMM who have received at least 2 prior lines of therapies.
  - Refractory to Lenalidomide and the last line of therapy.



Removal of the "Triple Class Refractory" requirement facilitates earlier and more frequent patient identification.

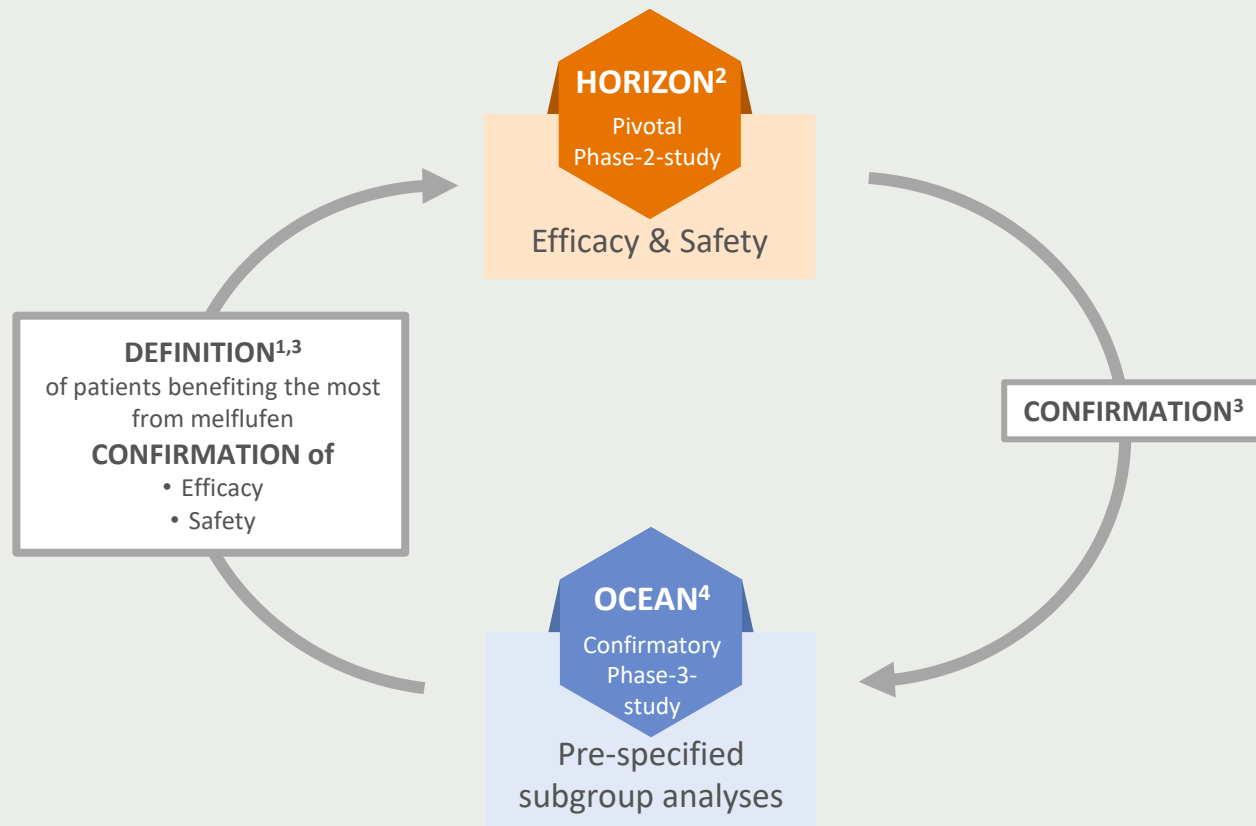


**OCEAN study data**

# The OCEAN study

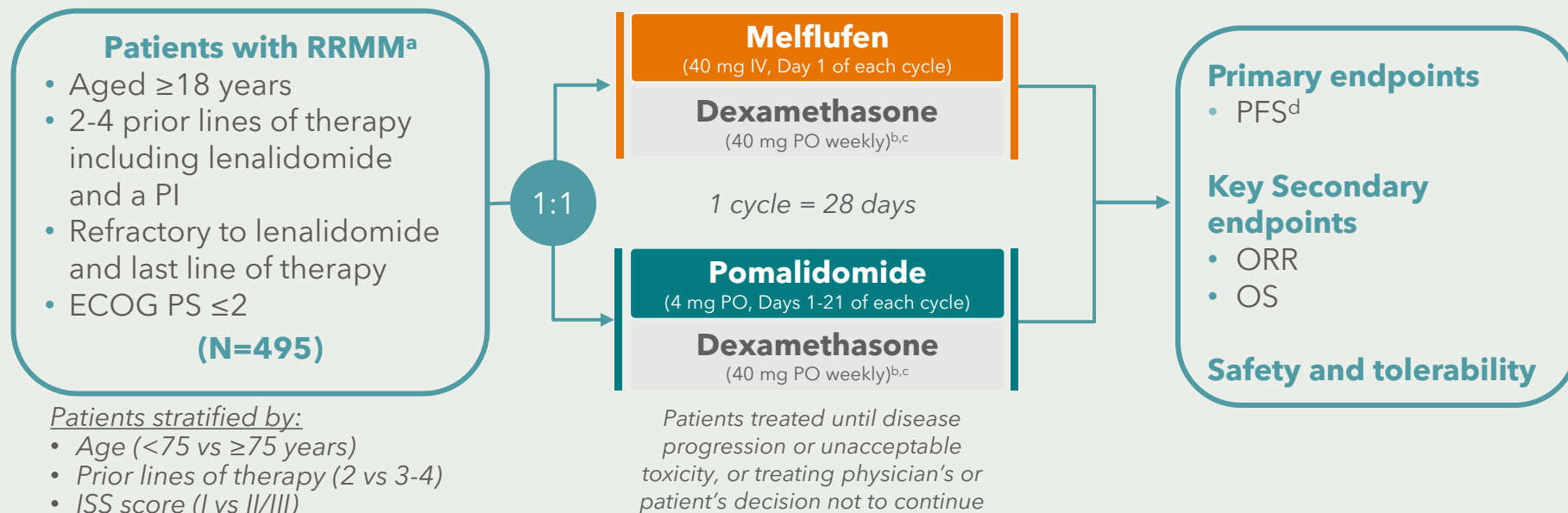


A **head-to-head study** vs. previous standard of care and confirmed efficacy + safety in current label **based on the HORIZON study**



# A head-to-head comparison study

A phase 3, randomized, open-label, global study<sup>1</sup>



• ECOG PS, Eastern Cooperative Oncology Group performance status; IMWG, International Myeloma Working Group; IRC, Independent Review Committee; ISS, International Staging System; IV, intravenously; melflufen, melphalan flufenamide; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; PO, orally; RRMM, relapsed/refractory multiple myeloma.

• <sup>a</sup>Select inclusion criteria. Other criteria apply. <sup>b</sup>Days 1, 8, 15, and 22 of each 28-day cycle. <sup>c</sup>The starting dexamethasone dose was reduced to 20 mg in patients aged  $\geq 75$  years. <sup>d</sup>Per IMWG uniform response criteria as assessed by the IRC.<sup>2</sup>

1. Schjesvold FH et al. *Lancet Haematol.* 2022;9:e98-110. 2. Rajkumar SV, et al. *Blood.* 2011;117:4691-4695.

# OCEAN: Patient characteristics

Target population vs current label population:

Characteristic	OCEAN (n=145)	Current label (n=52)
Age, median (IQR), years	71 (46-91)	70 (42-86)
Median time since diagnosis, years	3.5 (0.5-26.3)	7.4 (0.7-24.6)
Previous lines of therapy, median (IQR)	2 (2-4)	5 (3-10)
Previous ASCT, n (%)	24 (17%)	19 (37%)
Triple-class refractory disease, n (%)	17 (12%)	52 (100%)



Patients in OCEAN were **less refractory** and had **fewer previous lines of treatment** compared to later-line populations in current label

# OCEAN: Efficacy - PFS and OS results

## 9.3 months

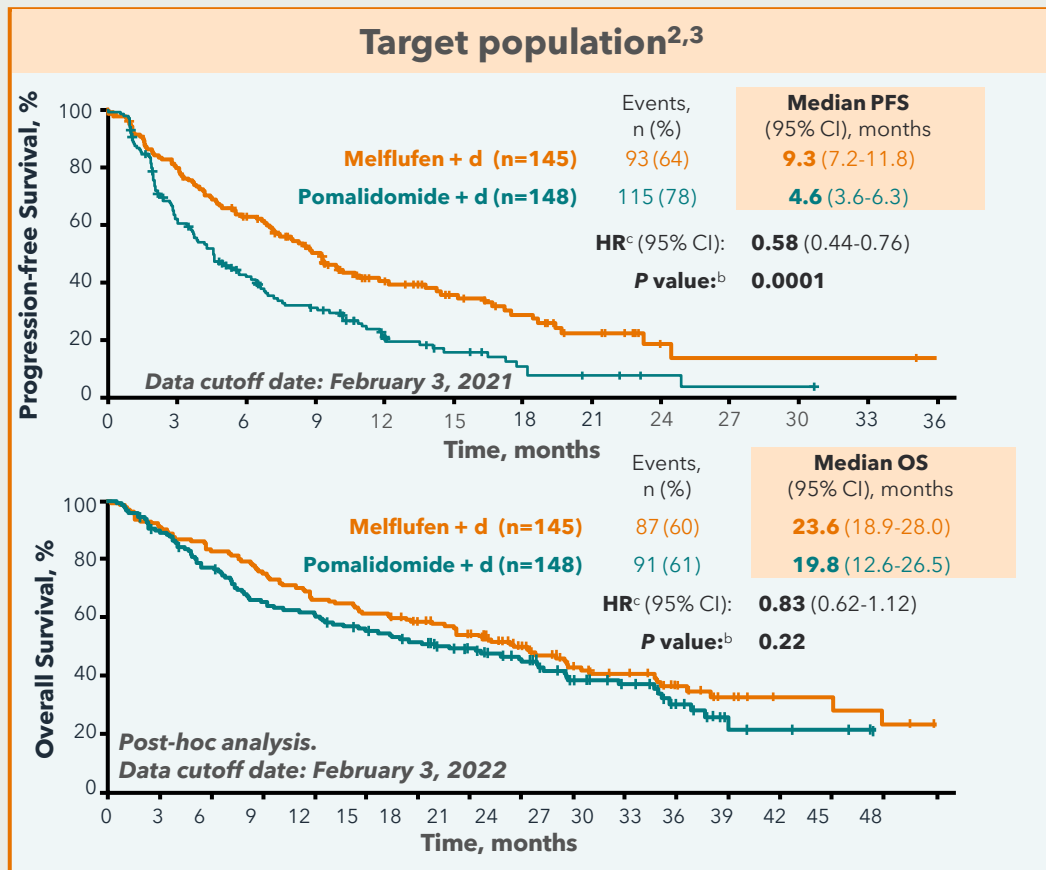
Median PFS (Target Population)

HR 0.58 | p=0.0001

## 23.6 months

Median OS (Target Population)

HR 0.83 | p=0.22



\*Target population: No ASCT or TTP ≥ 36 months post-ASCT.

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• ASCT, autologous stem cell transplant; CI, confidence interval; d, dexamethasone; HR, hazard ratio; IIT, intention-to-treat; PFS, progression-free survival; OS, overall survival.

• <sup>a</sup>Stratified hazard ratio. <sup>b</sup>Log-rank P value. <sup>c</sup>Unstratified hazard ratio.

• 1. Schjesvold FH et al. Lancet Haematol. 2022;9:e98-110. 2. Sonneveld P et al. Clin Lymphoma Myeloma Leuk. 2023;23(9):687-696. 3. In House Data. Oncopeptides AB (publ). DoF ALL-DOF-000055

# OCEAN: Efficacy - Overall response (ORR)



CR VGPR PR

**Statistical significance**  
**p = 0.0046**

**Next steps**

# Execution timeline and milestones



**May-July 2026**

Type II Variation  
Submission to EMA



**H2 2026**

Initial Regulatory Feedback  
expected



**H1 2027**

European Commission  
Final Decision



**2027**

Market Access & Price  
negotiations

**In conclusion**

# Bringing hope to patients

**Our commitment to innovation is driven by the desire to make a difference to patients.**

If approved and price negotiations are successful, this indication expansion represents a significant milestone for Oncopeptides, the patients we serve, and our shareholders.

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## Third line approval & market access

- ★ Increases total European sales potential
- ★ Efficient use of current commercial infrastructure
- ★ New complementary Mode of Action for third line patients

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## Potential added opportunities

- + Focus on key markets remain - for now
- + Approval and market access would change business case for Pepaxti and could open doors to new markets - in Europe and beyond - through own commercialization, partnerships or a combination.

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## Financial impact

- € 2x number of addressable patients  
and  
2x average number of treatment cycles
- € Market Access and price in third line  
remaining unknown factor
- € Our assessment of the current therapeutic  
and pricing landscape supports a move  
into third line with a maintained innovative  
price level



# Questions and answers

Bringing hope through science

