

# Q3 Webcast – Science Leads the Way

November 9, 2022

# Speakers



**Jakob Lindberg**  
Chief Executive Officer



**Sofia Heigis**  
Chief Commercial Officer



**Annika Muskantor**  
Chief Financial Officer

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Oncopeptides is a biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary PDC platform to develop peptide-drug conjugated compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. The first drug coming from the PDC platform, Pepaxto® (INN melphalan flufenamide), also called melflufen was granted accelerated approval in the U.S., on February 26, 2021, in combination with dexamethasone, for treatment of adult patients with relapsed or refractory multiple myeloma. The Company voluntarily withdrew the drug on October 22, 2021, and rescinded the withdrawal on January 21, 2022. Due to regulatory hurdles the product is currently not marketed in the U.S. On August 18, 2022, the European Commission granted Pepaxti® (melphalan flufenamide) in combination with dexamethasone marketing authorization in EU and EEA countries, in adult patients with triple class refractory multiple myeloma. Oncopeptides is developing several new compounds based on its technology platforms.

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# Agenda Q3 Webcast

Time	Topic	Presenter
15	Company, clinical and regulatory update	Jakob Lindberg
20	Commercial update	Sofia Heigis
10	Financial update	Annika Muskantor
15	Closing remarks and Q&A	Jakob Lindberg



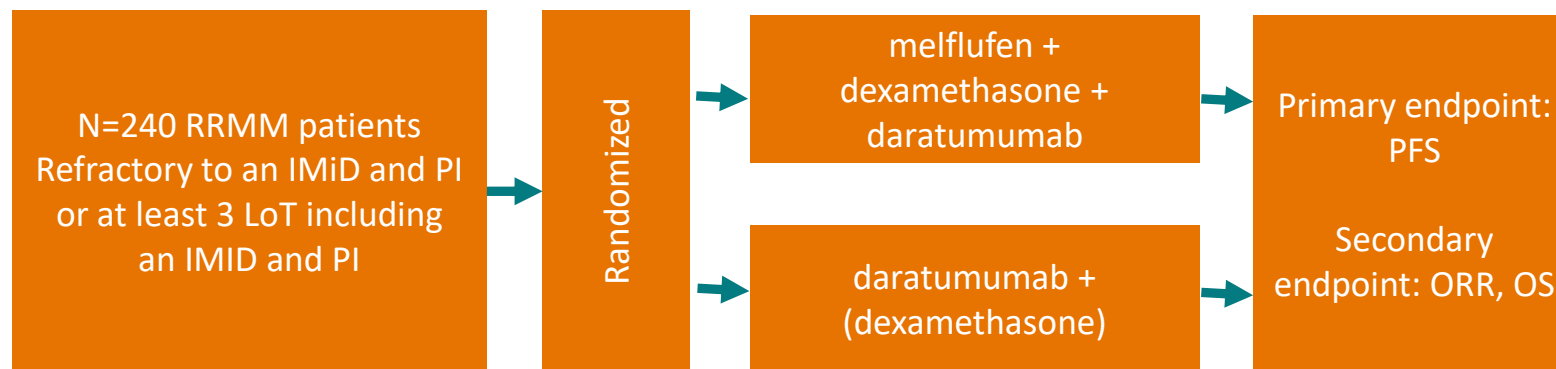
# **Company, Clinical and Regulatory update**

**Jakob Lindberg, Chief Executive Officer**

## Business highlights

- Pepaxti granted Marketing Authorization by European Commission
- Type II variation submission to EMA based on OCEAN-data
- LIGHTHOUSE data confirms EMA patient population and clinical benefit
- FDA dialogue continuing post ODAC
- Commercialization of Pepaxti - Germany first market to launch in Europe
- NK-Engager grant from Sweden's Innovation Agency
- Directed share issue of approximately SEK 435.6 million (USD 41.1 million)
- BoD authorized to decide on issuances of new shares to enhance flexibility

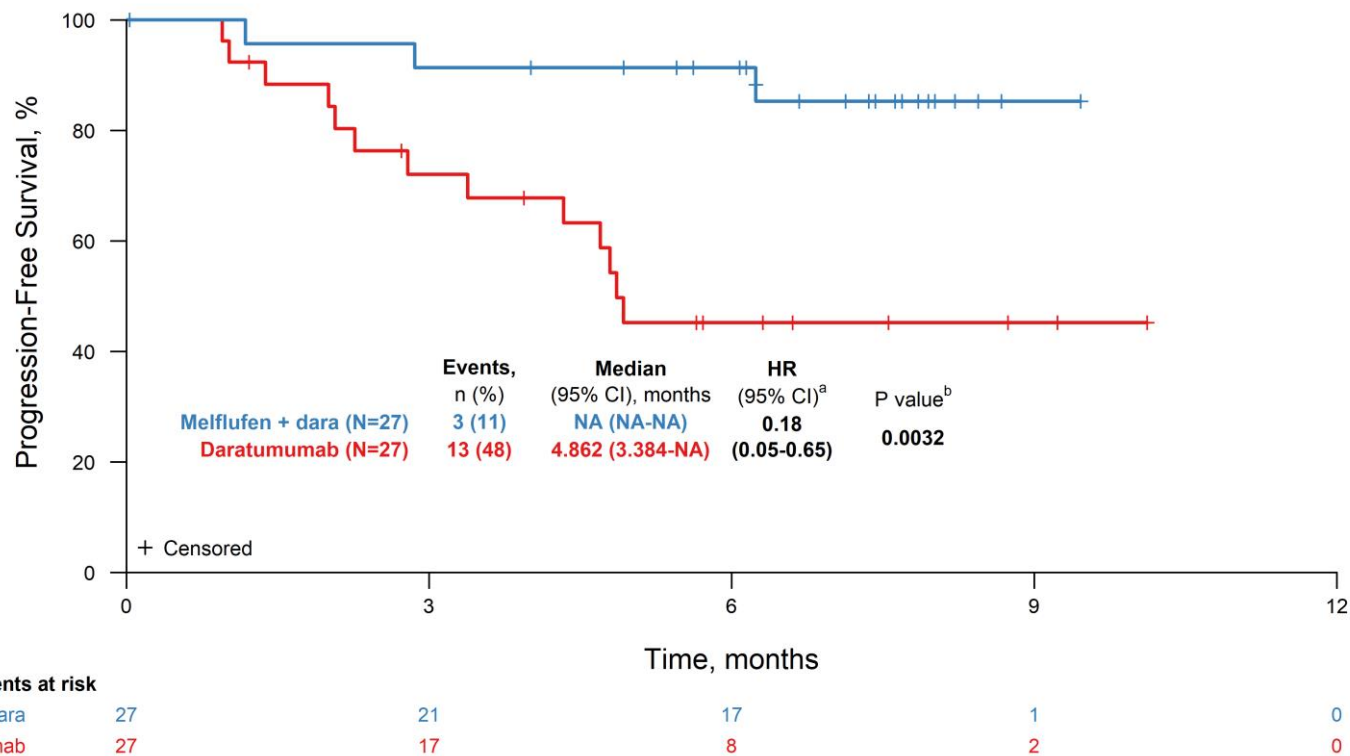
## Study design phase 3 LIGHTHOUSE study (n=54)



- A randomized, open label phase 3 trial, designed as a confirmatory study in addition to the phase 3 OCEAN study
- Patient recruitment prematurely halted with 54 randomized patients, due to a partial clinical hold requested by the US FDA

# OP-108 LIGHTHOUSE study

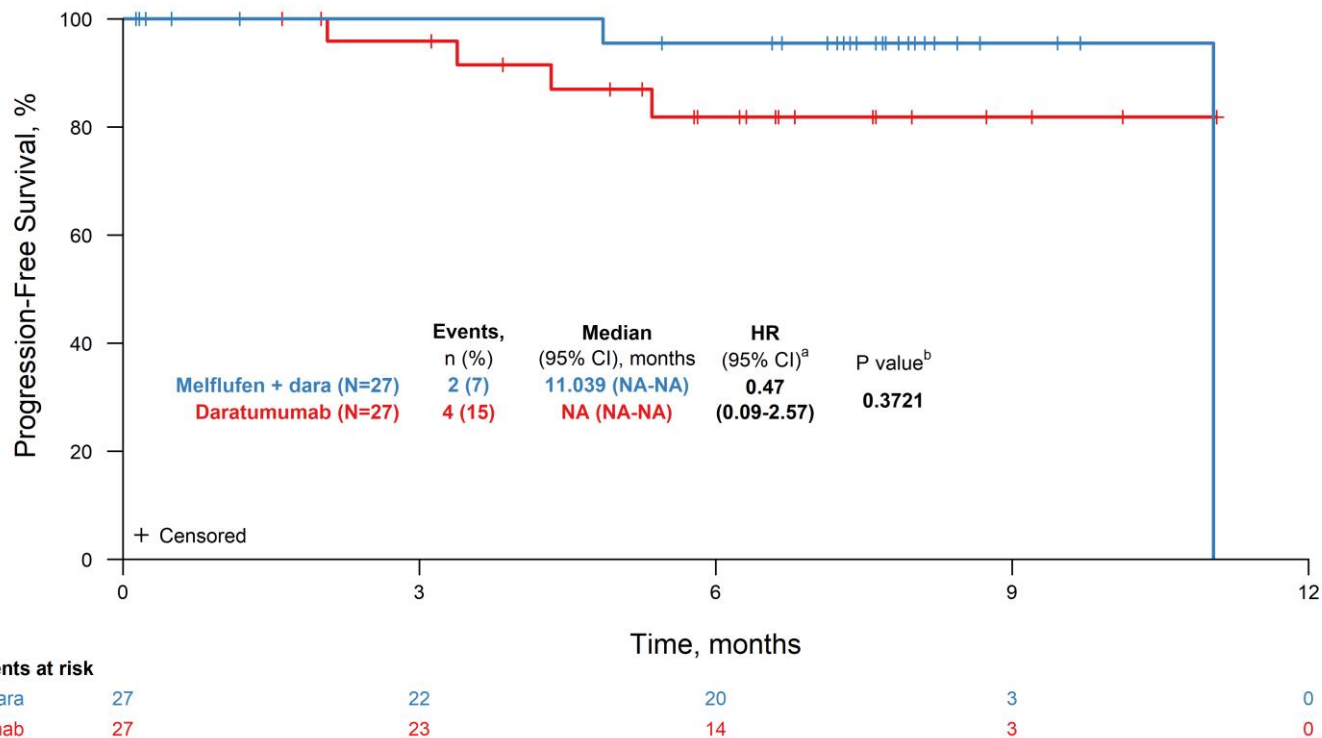
## PFS – Kaplan Meier – ITT Population





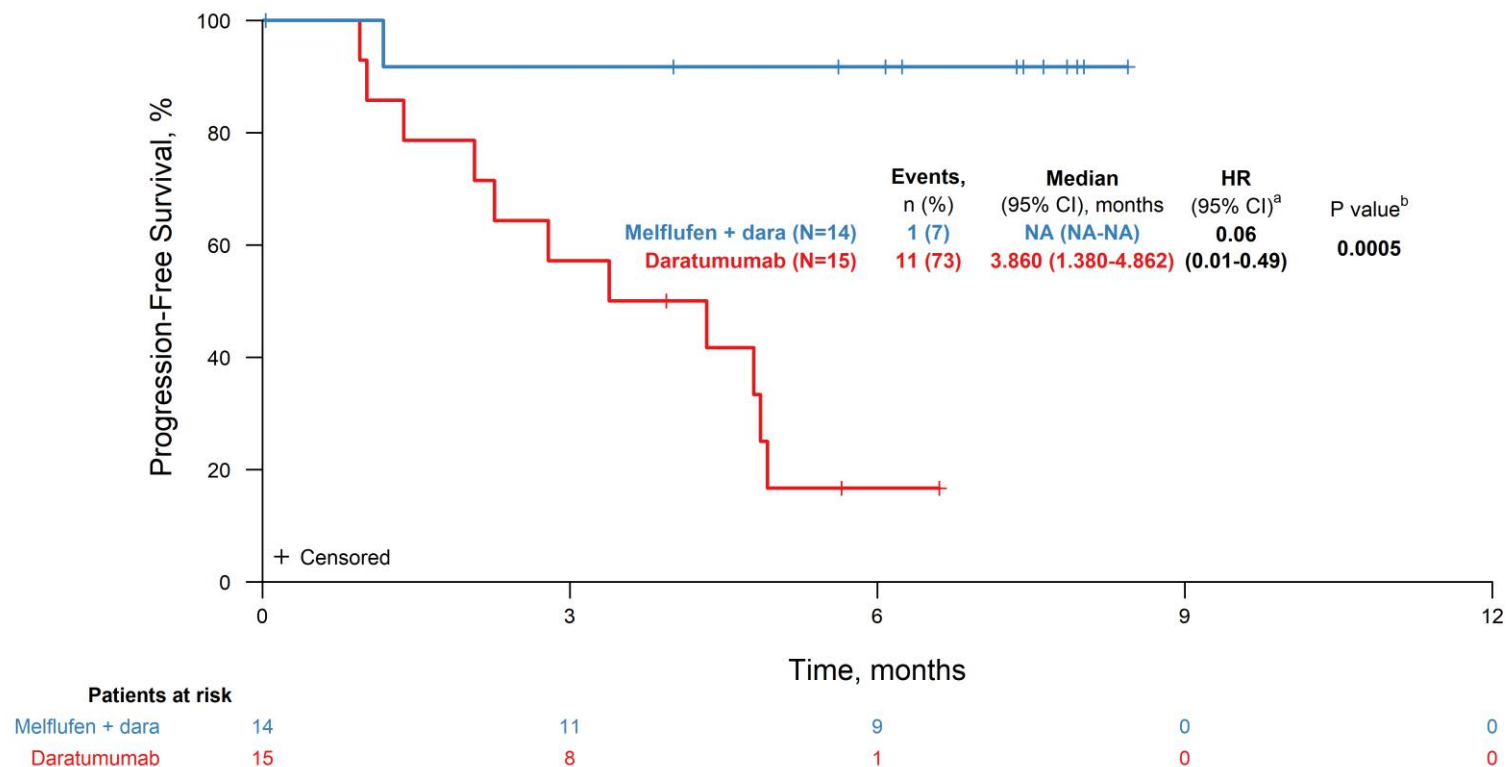
# OP-108 LIGHTHOUSE study

## OS – Kaplan-Maier – ITT Population



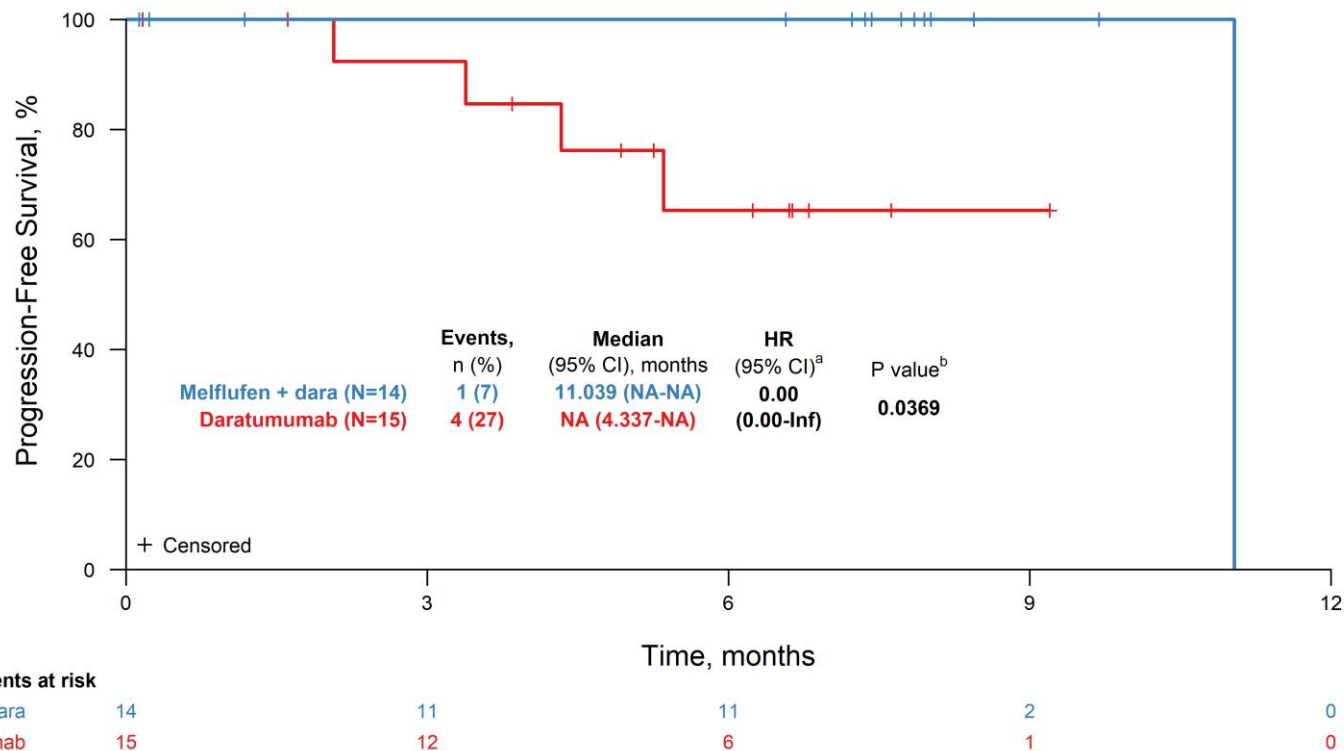
# OP-108 LIGHTHOUSE study

PFS – Patients progressing > 3y post-ASCT or no ASCT



# OP-108 LIGHTHOUSE study

OS – Patients progressing > 3y post-ASCT or no ASCT



# LIGHTHOUSE data confirms patient population and clinical benefit

- LIGHTHOUSE is the second phase 3 study to confirm the clinical benefit of melflufen
- In addition, it confirms the benefit in multiple myeloma patients with a treatment history with no or a successful stem-cell transplant in line with the recent full approval in Europe
- Furthermore, the data supports the EMA conclusion that there is no indication of absolute overall survival harm from treatment with melflufen



Jakob Lindberg CEO

## Pepaxti approved in Europe

- Marketing Authorization Approval granted by European Commission for triple class refractory multiple myeloma in EU and EEA countries; Iceland, Lichtenstein and Norway
- Approval based on phase 2 HORIZON and phase 3 OCEAN study
- No post marketing commitments
- Positive benefit risk profile in indicated patient population

## Pepaxti label in Europe

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 therapy, 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.**

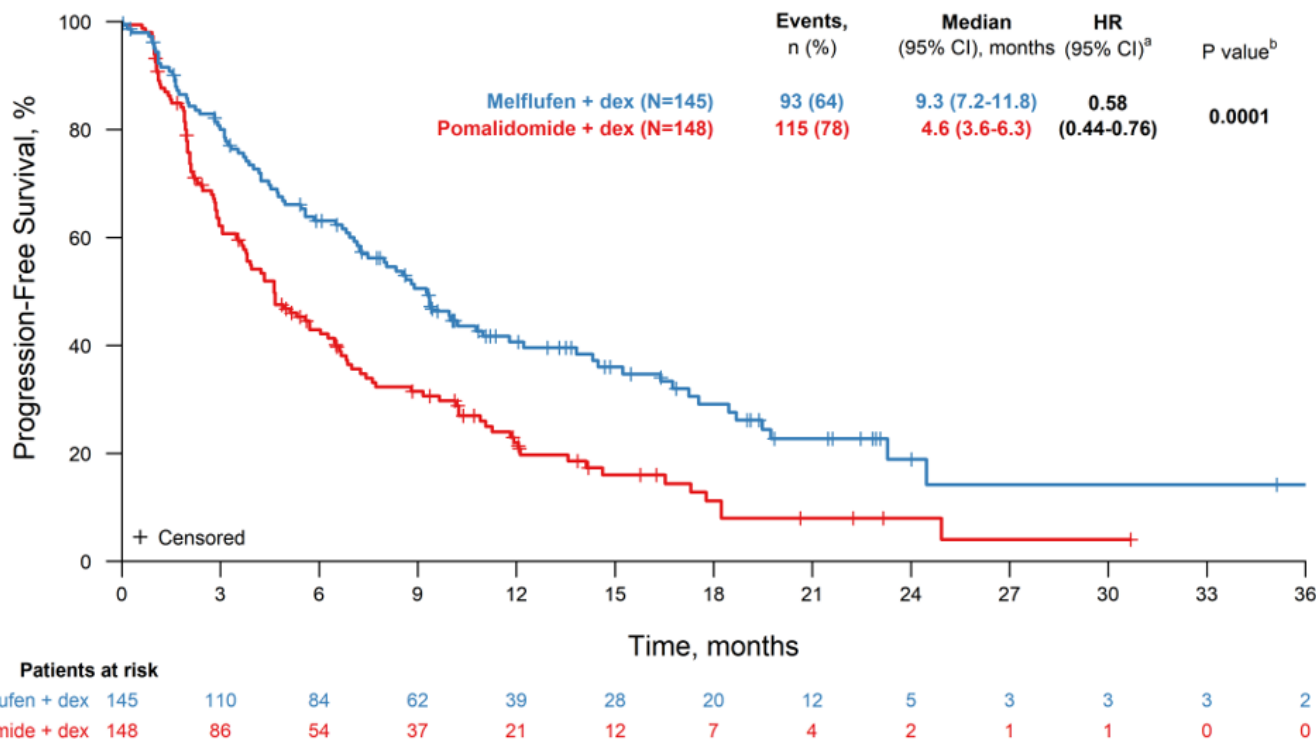
## Efficacy results in indicated EU-population

Response (n=52)	HORIZON study (assessed by investigator)
Overall response rate (ORR), 95% CI	28.8% (17.1%, 43.1%)
Duration of response (DOR), 95 % CI (months)	7.6 (3.0-12.3)
Time to response (TTR) (months)	2.3 (1.0-10.5)

Overall survival result in phase 3 OCEAN study constitutes a case of true survival heterogeneity as reflected in indication statement in accordance with EMA guidelines

# PFS in the OCEAN study – recommended population (verified by EMA)

## Post-hoc Analysis <sup>1,2</sup>



ASCT, autologous stem cell transplant; dex, dexamethasone; melflufen, melphalan flufenamide; PFS, progression-free survival; HR, Hazard Ratio; TTP, time to progression.

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

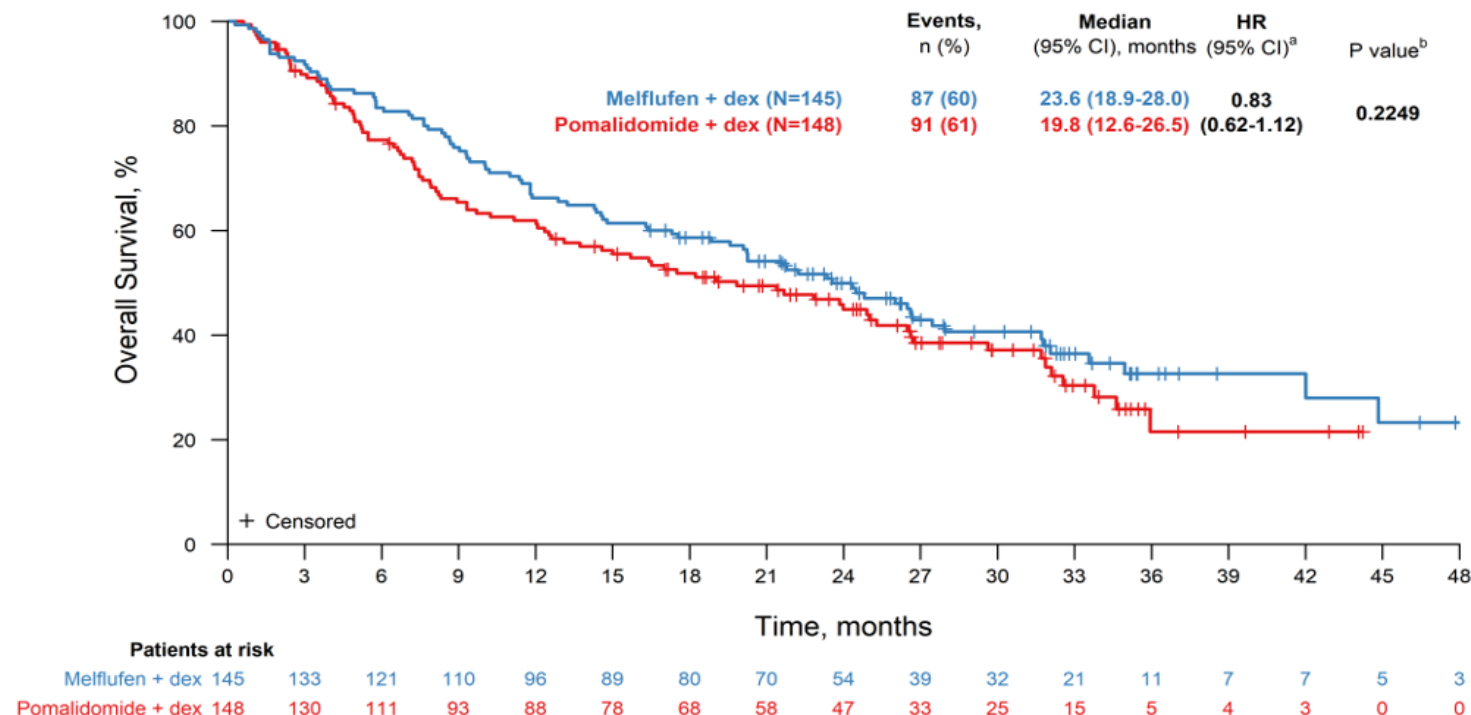
1. In House Data. Oncopeptides Pharmaceuticals. DoF ALL-DOF-000055; 2. European Medicines Agency. Assessment Report.

[https://www.ema.europa.eu/en/documents/assessment-report/pepaxti-epar-public-assessment-report\\_en.pdf](https://www.ema.europa.eu/en/documents/assessment-report/pepaxti-epar-public-assessment-report_en.pdf). Accessed August 26, 2022.



# OS in the OCEAN study – recommended population (verified by EMA)

## Post-hoc Analysis



Data cutoff date:  
3 Feb 2022

ASCT, autologous stem cell transplant; dex, dexamethasone; melflufen, melphalan flufenamide; OS, overall survival; HR, Hazard Ratio; TTP, time to progression.

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

In House Data. Oncopeptides Pharmaceuticals. DoF ALL-DOF-000055.

## No toxicological safety signals

- EMA confirms that no toxicological safety signal(s) have been identified
- However, EMA confirmed the true heterogeneity of the OCEAN study result:
  - For patients with a prior autologous stem cell transplantation, time between transplantation and disease progression should be at least 3 years
  - The non-transplanted, often older patient population, which represents the largest group of RRMM patients, particularly benefits from Pepaxti

## Early Access Program – an update

- Melflufen treatment can be provided to patients who cannot be adequately treated with approved, commercially available medications, or drugs accessible through clinical trials
- Eligible patients must have relapsed or refractory multiple myeloma, received at least two prior lines of therapy and be triple class refractory

**Patients approved: 74**

Patients discontinued: 2

 France = 36  Germany = 9  Spain = 12  UK = 6  Ireland = 1

 Austria = 1  Luxembourg = 1  Italy = 6  Switzerland = 2

## Continued FDA dialogue

- ODAC panel made a clear vote at the public hearing on September 22, and stated that the benefit-risk profile of Pepaxto is not perceived as favorable in the current US indication
- Oncopeptides has an ongoing dialogue with the FDA post ODAC, we don't know what the outcome will be or when a potential resolution can be reached

# DREAMM3 data potentially confirms IMiD OS interactions

## Head-to-head comparisons with pomalidomide+LDex

**OCEAN, Oncopeptides**  
PEPAXTO+LDex, n=495

- ITT PFS HR 0.79
- ITT OS HR 1.14
- <75 OS HR 1.26
- 75+ OS HR 0.62

**Takeda**  
Ixazomib+LDex, n=122

- ITT PFS HR 0.85
- ITT OS HR 1.43
- <75 OS HR 1.60
- 75+ OS HR 0.87

**DREAMM3, GSK**  
Belantamab, n=380

- ITT PFS HR 1.03
- ITT OS HR 1.14
- <75 OS HR ??
- 75+ OS HR ??

## R&D update – NK Engage project

- NK cell engaging immunotherapy with superior penetration and immune cell activation, built on proprietary SPiKEs platform
- Grant from Sweden's Innovation Agency demonstrates cutting edge research
- Eurostars program led by research consortium with scientist from;
  - Department of Cancer Immunology at Oslo University Hospital, Norway
  - Pharmatest Services Ltd in Turku, Finland
  - Oncopeptides with the Royal Institute of Technology, KTH, in Stockholm



# Commercial update

Sofia Heigis, Chief Commercial Officer

# Commercial launch of Pepaxti in Germany

- Largest multiple myeloma market in Europe
  - Prevalence of multiple myeloma: 59.000 patients\*
  - Annual incidence: 9.200 newly diagnosed patients\*
- Current indicated patient population 2.500 patients

\* Data from > 60 sick funds in Germany, year 2020



## Patient access, pricing and reimbursement of Pepaxti

- German market enables early patient access
- Launch ongoing since October 1
- Ex-manufacturer price 5.450 € per vial, average price 10.900 € per cycle/month
- Price is valid for one year and will be subject to negotiations with the National Association of Statutory Health Insurance Funds

# Lean organization and focused model

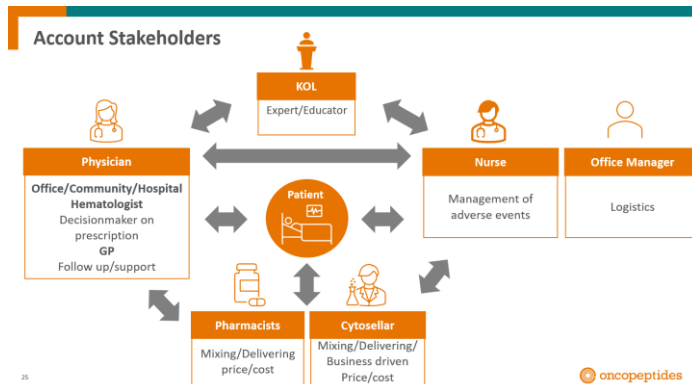
- Own organization with in-depth experience
- Focused account activation model
- Broad awareness plan
- Build team to broaden outreach across Germany
- Provide entry to Austria and Switzerland
- Pave the way for commercialization in Europe



# Account activation key to successful launch

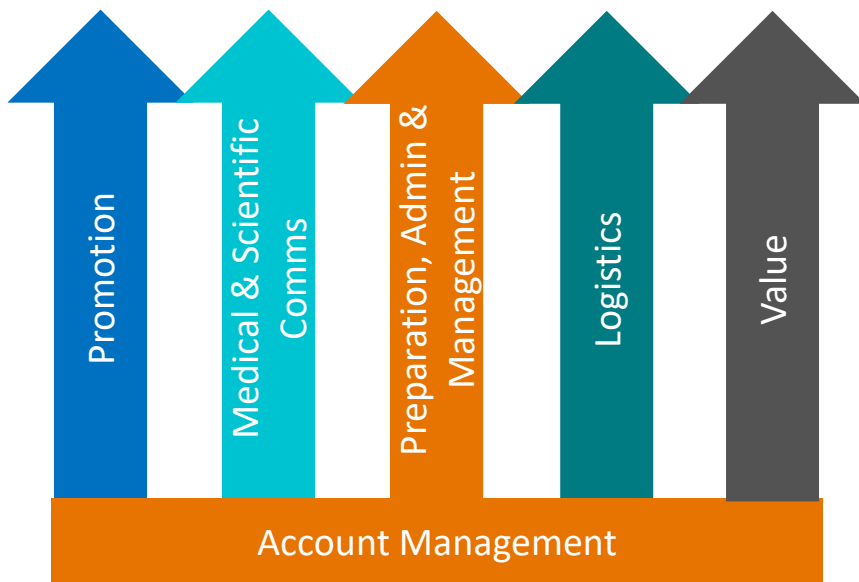
## Traditional Model

- Multiple roles to cover all competences
- Broad approach to support promotional sensitive indications
- Several persons share stakeholder contacts; sales & medical force
- Demands higher degree of F2F access to stakeholders
- Supported & complemented by marketing and Market Access



## Our Focused Model

- Limited number of roles with focus on key competences for Pepaxti
- Targeted and science driven approach to meet high unmet need
- One primary stakeholder contact allows effective execution
- Enables virtual interaction and facilitates customer access
- Complemented by marketing and Market Access



# Roadmap to commercialization in Europe

## Objective

Maximize value for patients and shareholders by ensuring patient access to melflufen



# Growing multiple myeloma market in Europe



## Market drivers

Incurable disease

Unmet medical need for convenient, efficacious and tolerable options

High adoption of new therapies

Increasing target population in later lines

## European MM market

**Annual incidence:** ~40.000 patients

**Target population** OCEAN indication:  
~17.000 patients

## Annual market potential

**1.5-2.0 billion SEK\***

\*Market potential assuming a successful type II variation, and that price negotiations will reflect the degree of innovation of the drug and the clinical benefit to the patients.

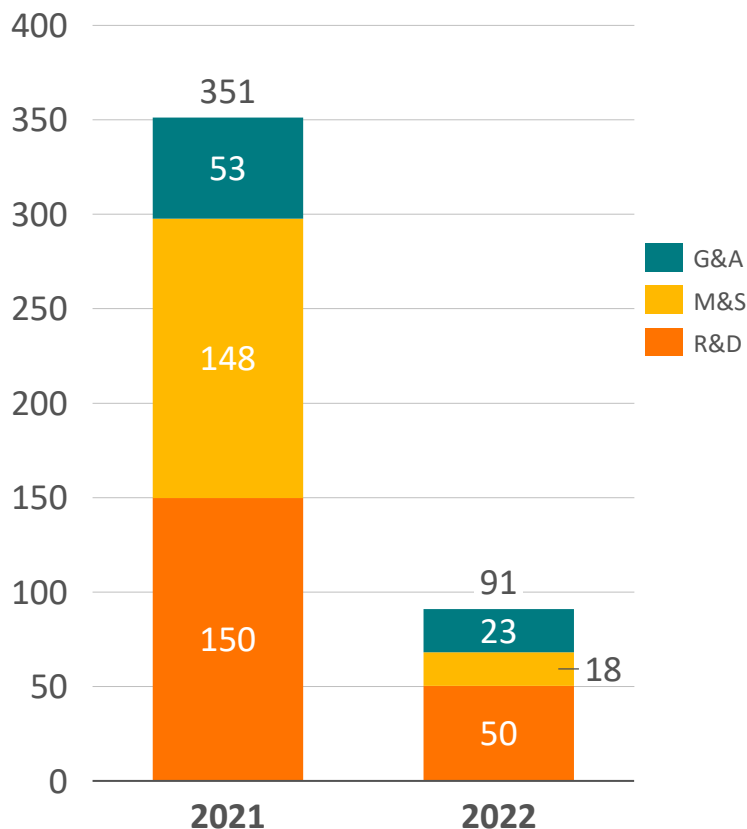


# Financial highlights

Annika Muskantor, Chief Financial Officer

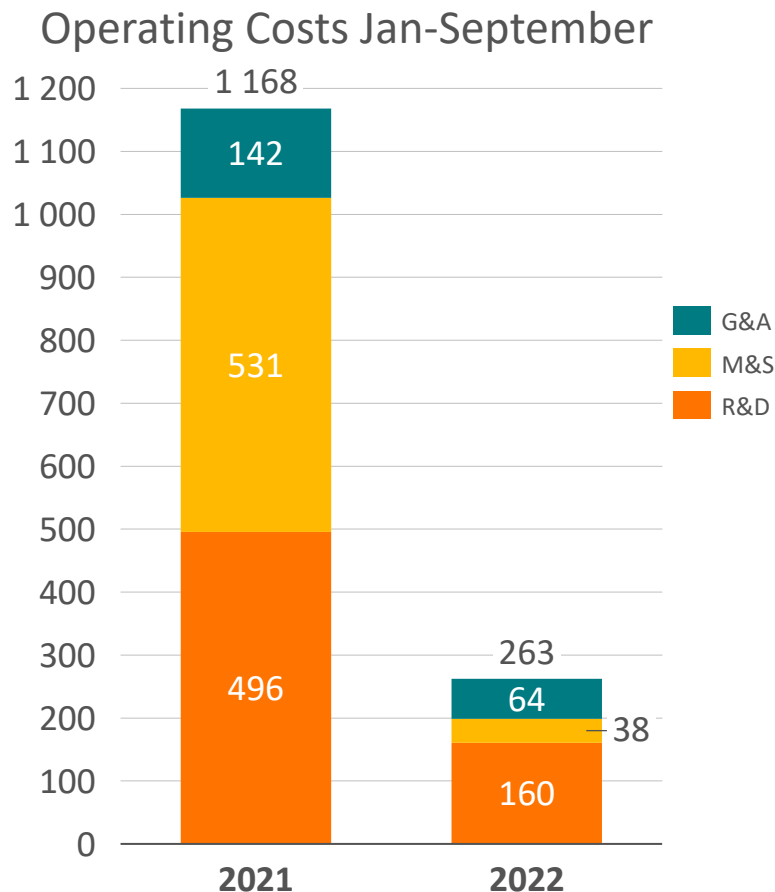
# Financial Highlights July – September 2022

## Operating Costs Jul-Sep



- Operating loss decreased to SEK 88.9 M (loss: 338.9)
- Lower overall cost driven by the downsizing in general and the close of US operations in particular
- R&D decreased primarily driven by close of studies - OCEAN SEK 19 M (31)
- Net sales of 0 M (54.3)
- Number of employees/co-workers decreased from 321 at end of Q3 2021 to 40 plus a few consultants, at the end of Q3 2022
- Cash flow from operating activities neg. SEK 70.8 M (neg. 336.5) EIB loan facility still ongoing discussions
- Cash end of September 427.4 M (671.3)
- Share issue closed in July; SEK 435.6 M before transaction related costs

# Financial Highlights January – September 2022



- Operating loss decreased to SEK 248.8 M (loss: 1 031.1)
  - Lower overall cost driven by the downsizing in general, and the close of US operations in particular
  - R&D decreased primarily driven by close of studies - OCEAN SEK 44 M (109)
- Cash flow from operating activities neg. SEK 342.9 M (neg. 1 069.9)
- Share issue finalized in July gross proceeds of 435.6 M



## Directed share issue – use of proceeds

- Capital raise of approx. SEK 435.6 million (USD 41.1 million) completed on July 14, 2022
- The capital will be used to strengthen the financial position and execute our strategy;
  - Initiate commercialization in Europe, launch Pepaxti in Germany in Q4 followed by Austria
  - Support EMA application for marketing authorization of Pepaxti in earlier treatment lines
  - Preclinical development of new drug candidates and expansion to new indications
  - Create foundation for marketing of Pepaxto in US ahead of a possible agreement with FDA

## Financing options to enhance company flexibility

- EGM authorized BoD to decide on issuances of new shares, as a complement to the authorization resolved by the AGM in June, to increase financial flexibility of the company
- Oncopeptides has an EIB loan facility. Oncopeptides and EIB are currently in negotiations, to update tranche definitions to reflect the current regulatory situation



# Conclusions and way forward

Jakob Lindberg, CEO

## Milestones ahead

- Commercial launch of Pepaxti in Germany
- Type II variations submission to EMA based on OCEAN data
- Preclinical data presented at American Society of Haematology



# Q&A



bringing hope through science