

# ONCOPEPTIDES OPERATIONAL UPDATE

Q2 2020, August 26, 2020



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## OPERATIONAL UPDATE

MARTY J DUVALL  
Chief Executive Officer

# MARTY J DUVALL

## PROFESSIONAL EXPERIENCE

- Executive Leadership experience from public and private companies; CEO, CCO, SVP, Global Commercial and Marketing roles
- Pharma and biotech experience across geographies; Aventis (Sanofi), MGI (Eisai), Abraxis (Celgene), Merck (MSD), ARIAD (Takeda) and Tocagen (Forte)
- Broad and deep oncology experience including; hematology (e.g. MDS, CTCL, CML, AML, MM, etc.), and solid tumors (e.g. breast, lung, prostate, H/N, gastric, GBM, etc.), biologics, small molecules, gene therapy and supportive care
- Launch experience; Taxotere (US, Europe and Asia), Abraxane (China), Dacogen (US and Europe), Sylatron (Global), Iclusig (US, Europe, and Asia) and Alunbrig



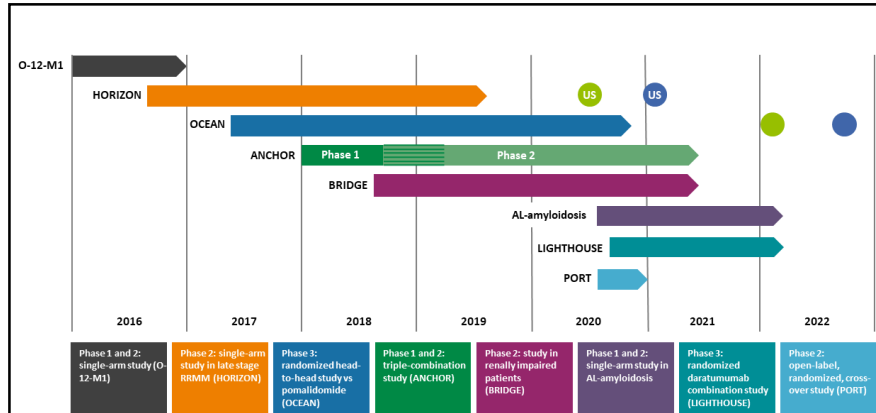


# TRANSFORMATION OF ONCOPEPTIDES

## OUR GROWTH STRATEGY



Discovery and IND  
generation



Portfolio Development and Life Cycle  
Management

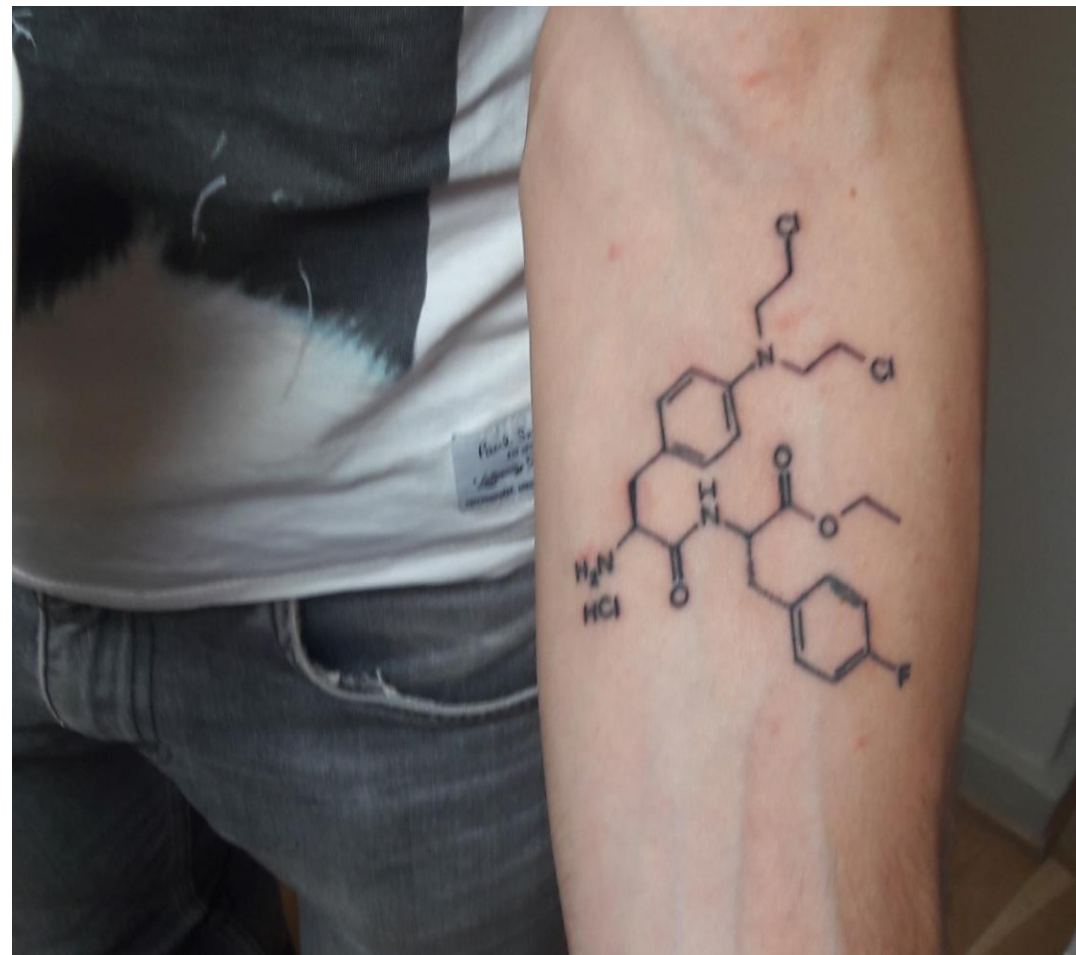


Launch investment and  
geographic expansion

# MELFLUFEN IS A FIRST IN CLASS PRODUCT

APPLICATION SUBMITTED FOR ACCELERATED APPROVAL IN THE US

Melflufen is a first in class peptide-drug conjugate (PDC) that targets aminopeptidases and rapidly releases alkylating agents into tumor cells



# SUMMARY OF Q2-2020

## VALUE GENERATION AND RISK REDUCTION

### IN THE NEWS: Oncopeptides Advances in Business Critical Areas

**BRIEF-Oncopeptides AB Says Board Of Directors Has Appointed Marty J Duvall As CEO**

HEALTHCARE MAY 6, 2020 / 8:54 AM / 4 MONTHS AGO

**BRIEF-Oncopeptides Raises SEK 1.41 Billion In Directed Issue**

**BRIEF - Oncopeptides takes over lab for pre-clinical drug development**

HEALTHCARE 15 JUN 2020 / 08:06 / IL Y A 2 MOIS

**BRIEF-Oncopeptides: Positive Results From Full Data Set Of Phase 2 HORIZON Trial In Triple-Class Refractory Multiple Myeloma Patients**

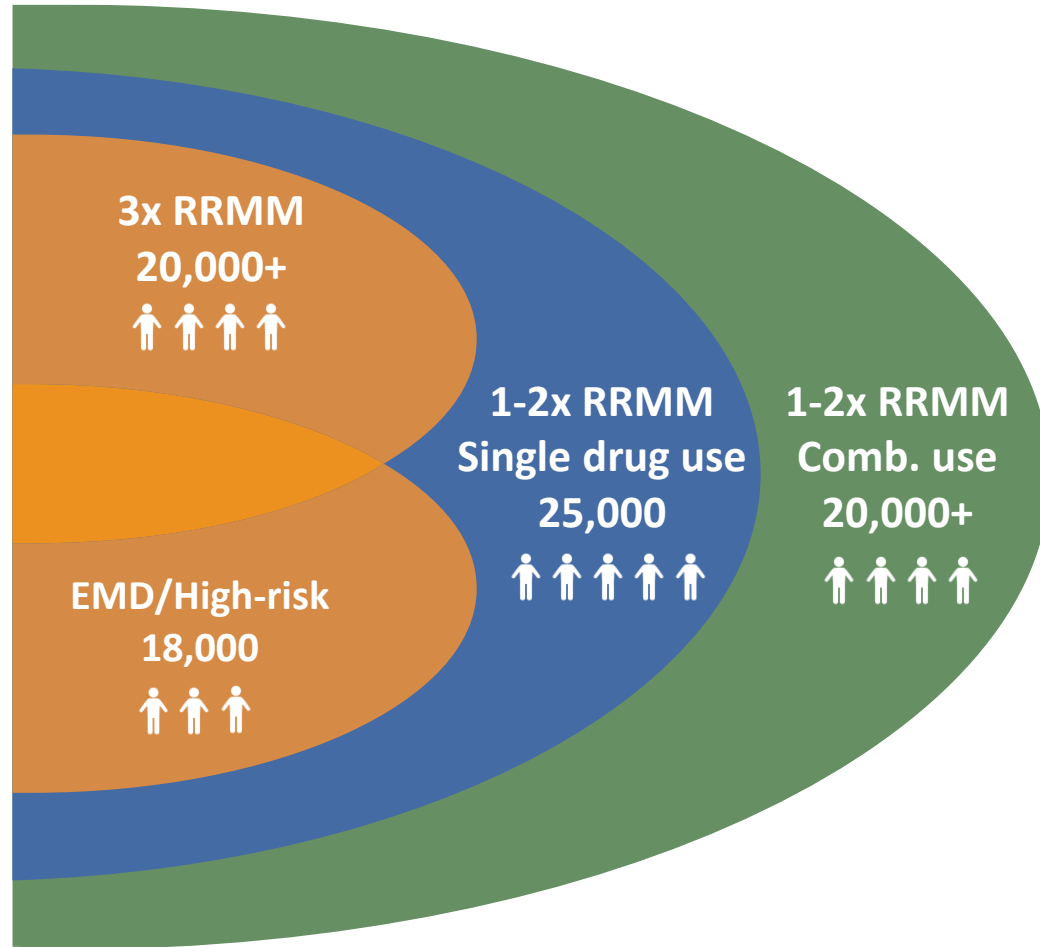
HEALTHCARE JUNE 30, 2020 / 8:11 AM / 2 MONTHS AGO

**BRIEF-Oncopeptides Submits New Drug Application To FDA**



# SIGNIFICANT MARKET OPPORTUNITIES

## US MARKET



### New data to drive label expansion



Anticipated label in triple-class refractory patients



Head-to-head superiority study with the most used regimen in RRMM



Combination with PI or anti-CD38 opens up 2L+ combination treatment



# DISEASE AWARENESS AND EDUCATION PAVES THE WAY FOR A NEW CLASS OF DRUG

This site is intended only for US healthcare professionals.

In multiple myeloma,

# GET TO THE ROOT OF RESISTANCE

Clonal evolution is a  
driver of resistance<sup>1,2</sup>

Triple-class refractory  
MM is an outcome of  
clonal evolution<sup>3</sup>

Explore the potential of  
PDCs and ADCs<sup>4</sup>

 oncopeptides

 oncopeptides

# REGULATORY TIMELINES

## NDA REVIEW PROCESS FOR MELFLUFEN

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- US FDA Submission\* – June 30
- Notification of File Acceptance – August 29
- 90-day Safety Update – September
- Review and label negotiations – Fall
- PDUFA (priority review)\*\* – February 2021
- PDUFA (standard review) – June 2021

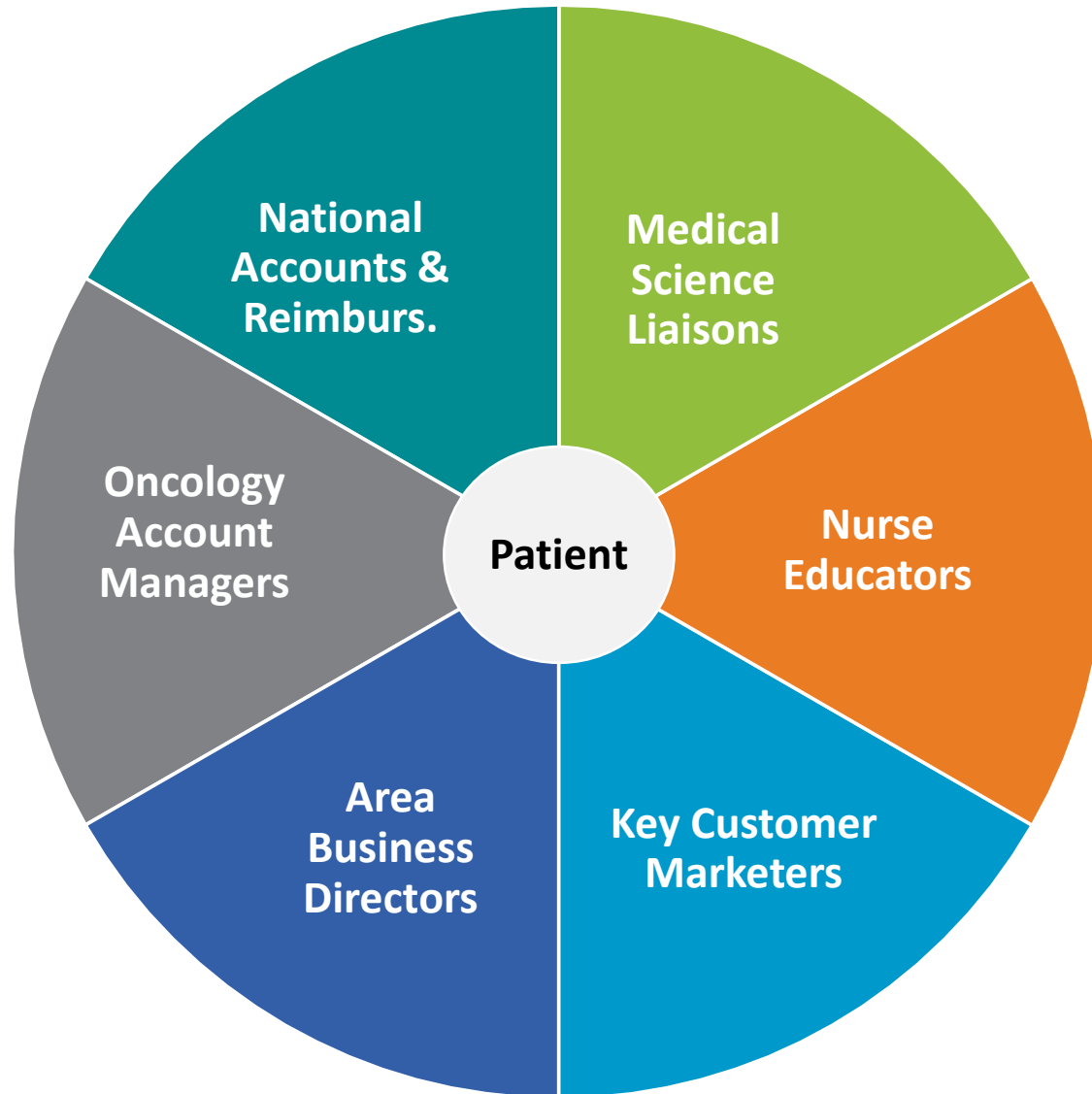
\* Evaluation underway for regulatory timelines in other key geographies

\*\*Mid-Cycle Review Meeting in November is driving our “launch readiness” timeline of mid-November



# PASSIONATE TO MAKE A DIFFERENCE FOR PATIENTS

## BUILDING A PATIENT FOCUSED ORGANIZATION



*“Ensuring that every patient who potentially could benefit from melflufen gains access”*

Marty J Duvall

# PAVING THE WAY FOR A SUCCESSFUL LAUNCH

## GLOBAL ORGANIZATION WITH SIGNIFICANT LAUNCH EXPERIENCE



**Joe Horvat**  
President, NA

- 24 Years Pharmaceutical/ Biotech Experience
- Merck KGaA, BMS
- US and Global Commercial Leadership (EMD Serono)
- 12 years of oncology experience



**Paula O'Connor, MD**  
Head of Med Affairs US

- Medical Oncologist
- 17 Years Pharmaceutical/ Biotech Experience
- Genentech, Medivation, Onyx, Clovis
- 30 years of oncology experience



**Mohamed Ladha**  
Head of Commercial US

- 17 Years Pharmaceutical/ Biotech Experience
- Schering Plough, Merck, Pfizer, ARIAD/Takeda
- US and Global Commercial Leadership
- 17 years of oncology experience

An accomplished US Medical Affairs and Commercial Team with nearly 100 oncology product launches







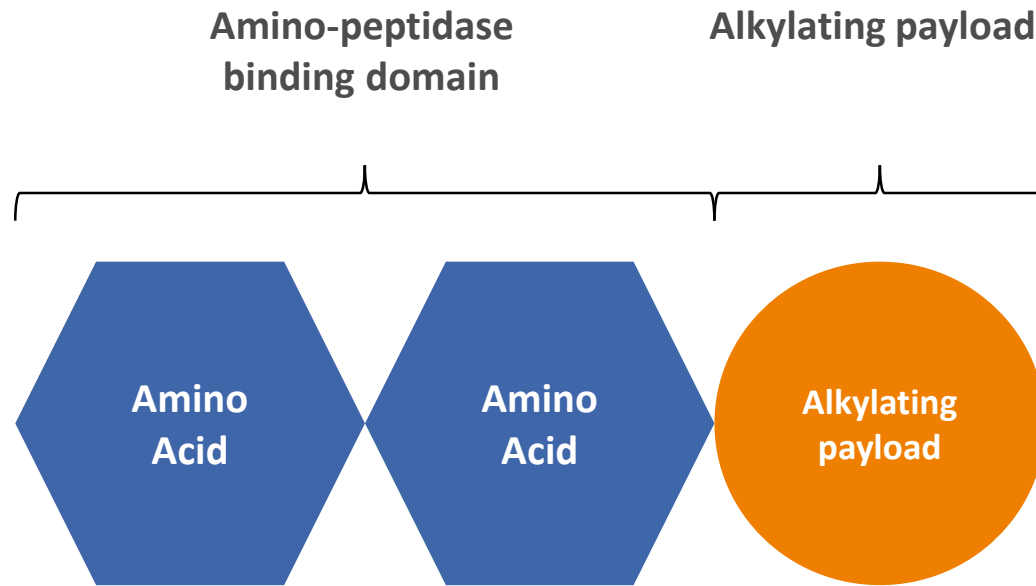
# MELFLUFEN AND THE PDC PLATFORM

JAKOB LINDBERG  
Chief Scientific Officer



# MELFLUFEN - A FIRST IN CLASS DRUG CANDIDATE

## A PEPTIDE-DRUG CONJUGATE TARGETING AMINOPEPTIDASES



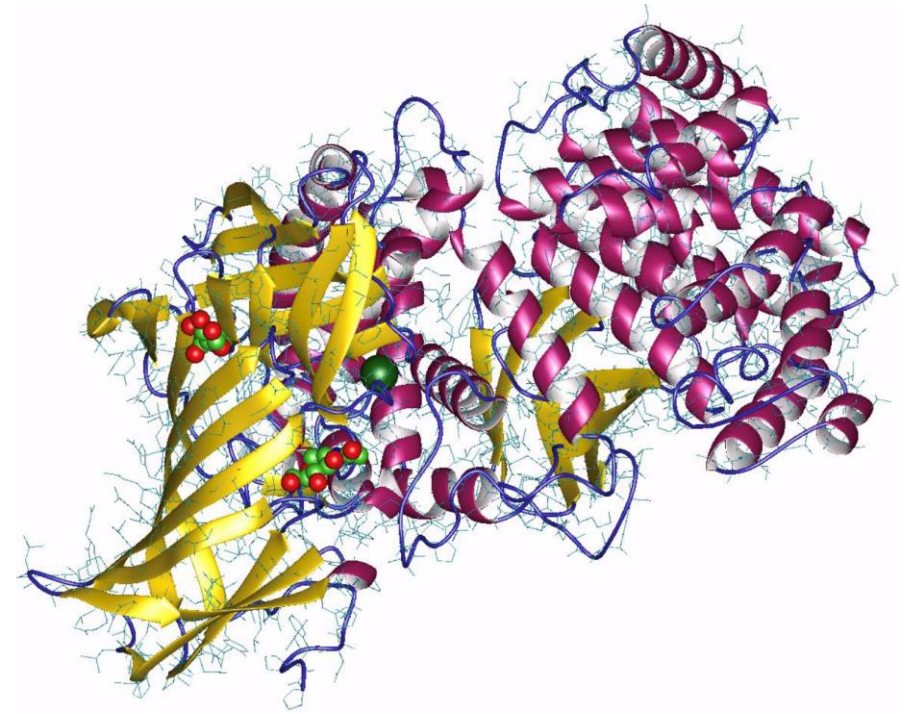
- **Increased potency** of linked toxin due to aminopeptidase targeting with subsequent hydrolysis
- **Potency increase** over the course of disease, i.e. with **degree of malignancy**
- **Circumvent** significant amount of **transport associated resistance development**
- **Circumvent** significant amount of **programmed cell-death related resistance developed**, e.g. p53 deletion or mutation
- **Aminopeptidase targeting** enables **additional beneficial activity** to direct cytotoxic effect, e.g. anti-angiogenesis and metastatic process

# AMINOPEPTIDASES ARE EXCELLENT CANCER TARGETS

## KEY ROLE IN CANCER CELL SURVIVAL, PROLIFERATION AND MIGRATION

Amino-peptidases play a key role in protein homeostasis, and in other critical functions such as cell-cycle progression, programmed cell death and cell migration

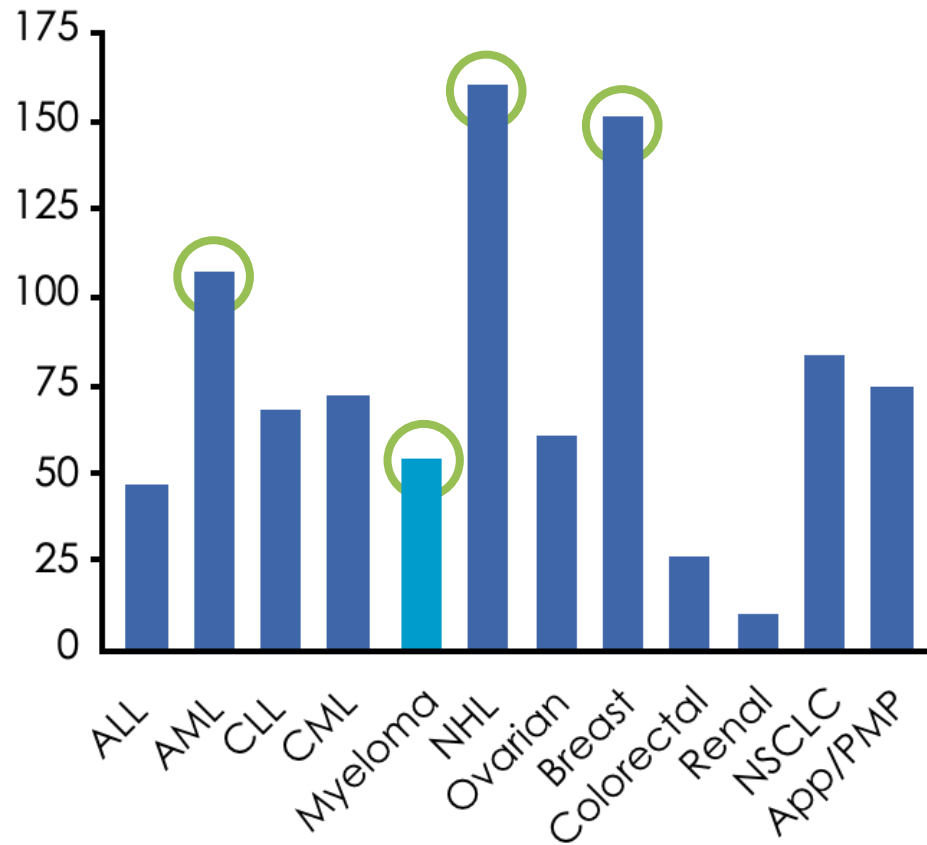
- I Amino-peptidases are over-expressed in cancer cells
- II Amino-peptidase expression is increased between diagnosis and relapse in patient cancer samples
- III Amino-peptidase expression correlates with mutational burden and poor clinical outcome



# PDC PLATFORM

## THERAPEUTIC ACTIVITY IN MOST CANCERS

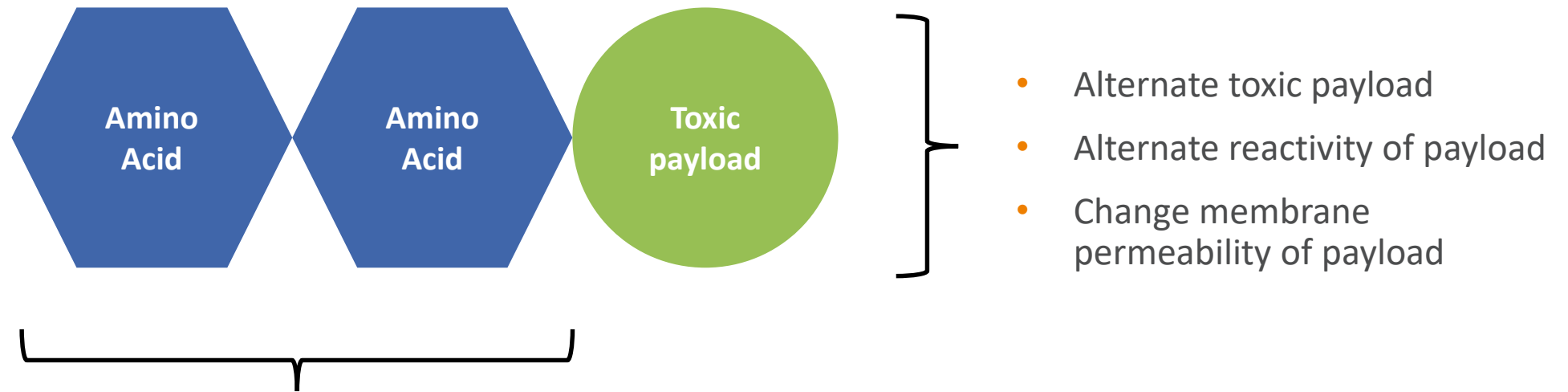
PDC Potentiation



- Melflufen is focused on multiple myeloma and AL-amyloidosis
- New molecules are based on PDC platform
- Potential broadening of indications in AML, Non-Hodgkin Lymphoma and breast cancer

# PEPTIDE DRUG CONJUGATE TECHNOLOGY

VERSATILE PLATFORM WITH MULTIPLE VENUES FOR FUTURE DEVELOPMENT



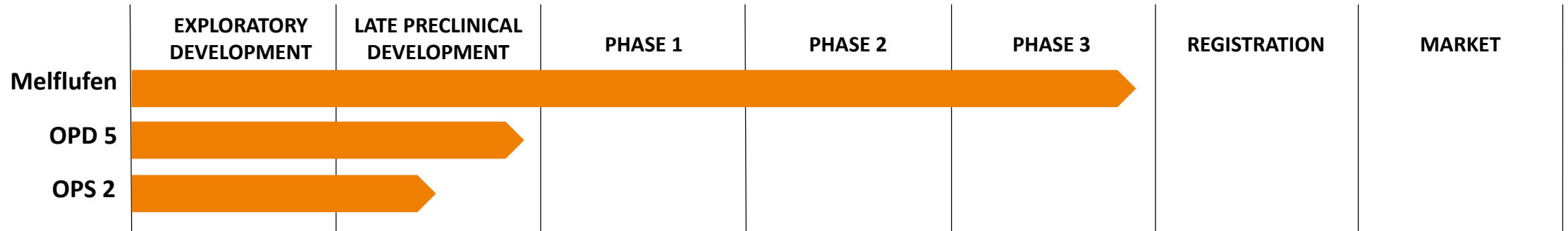
- Modify amino-peptidase binding domain to alter specificity for different amino-peptidases

- Alternate toxic payload
- Alternate reactivity of payload
- Change membrane permeability of payload



# PDC PIPELINE

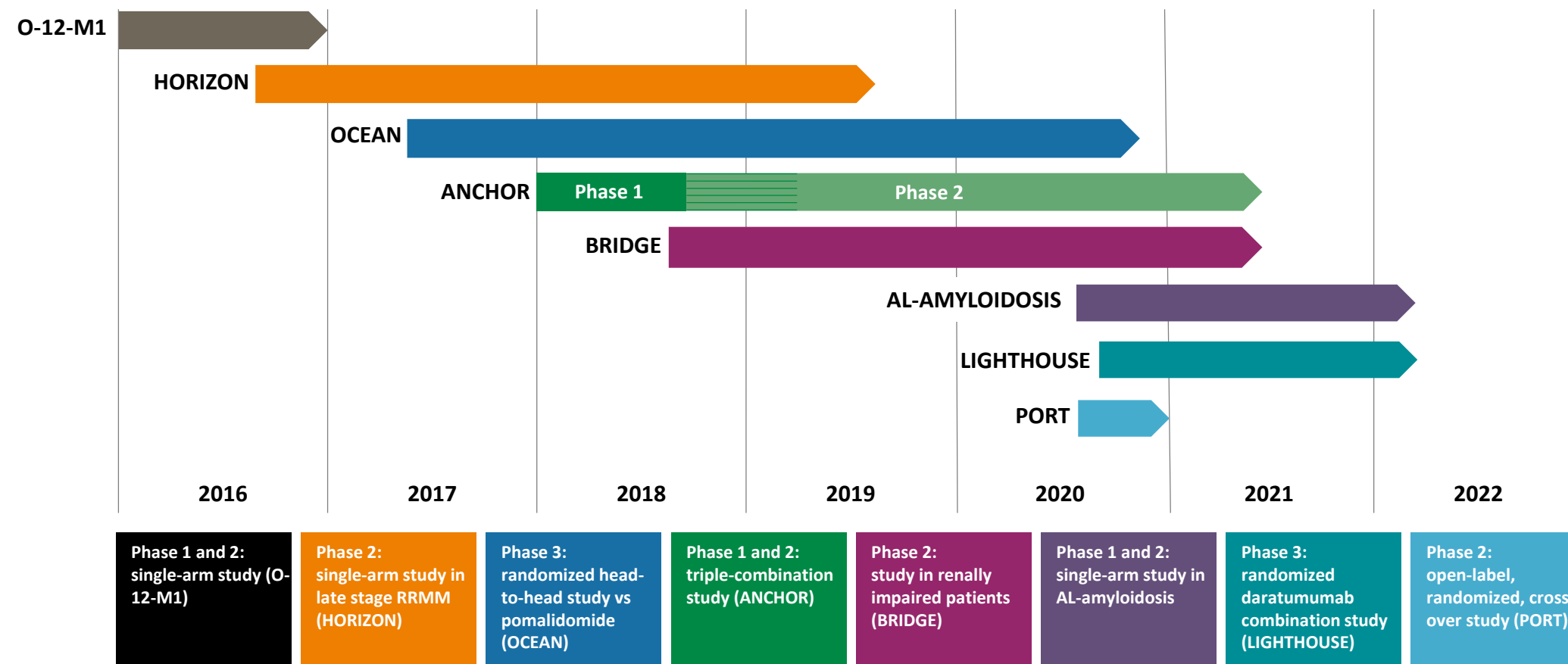
## FROM PRE-CLINICAL TO CLINICAL DEVELOPMENT 2020/21



- OPD5 – High-dose treatment in i.e. bone-marrow transplantation ready for clinical development late 2020
- OPS2 – Second generation PDC candidate with alkylating payload potentially ready for clinical development in 2021

# MELFLUFEN CLINICAL DEVELOPMENT PROGRAM

## FULL CLINICAL DEVELOPMENT PROGRAM IN RRMM



The arrows show estimated Last Patient In, in the studies

# FINAL DATA IN TRIPLE CLASS REFRACTORY MULTIPLE MYELOMA

## INDEPENDENT REVIEW COMMITTEE DATA



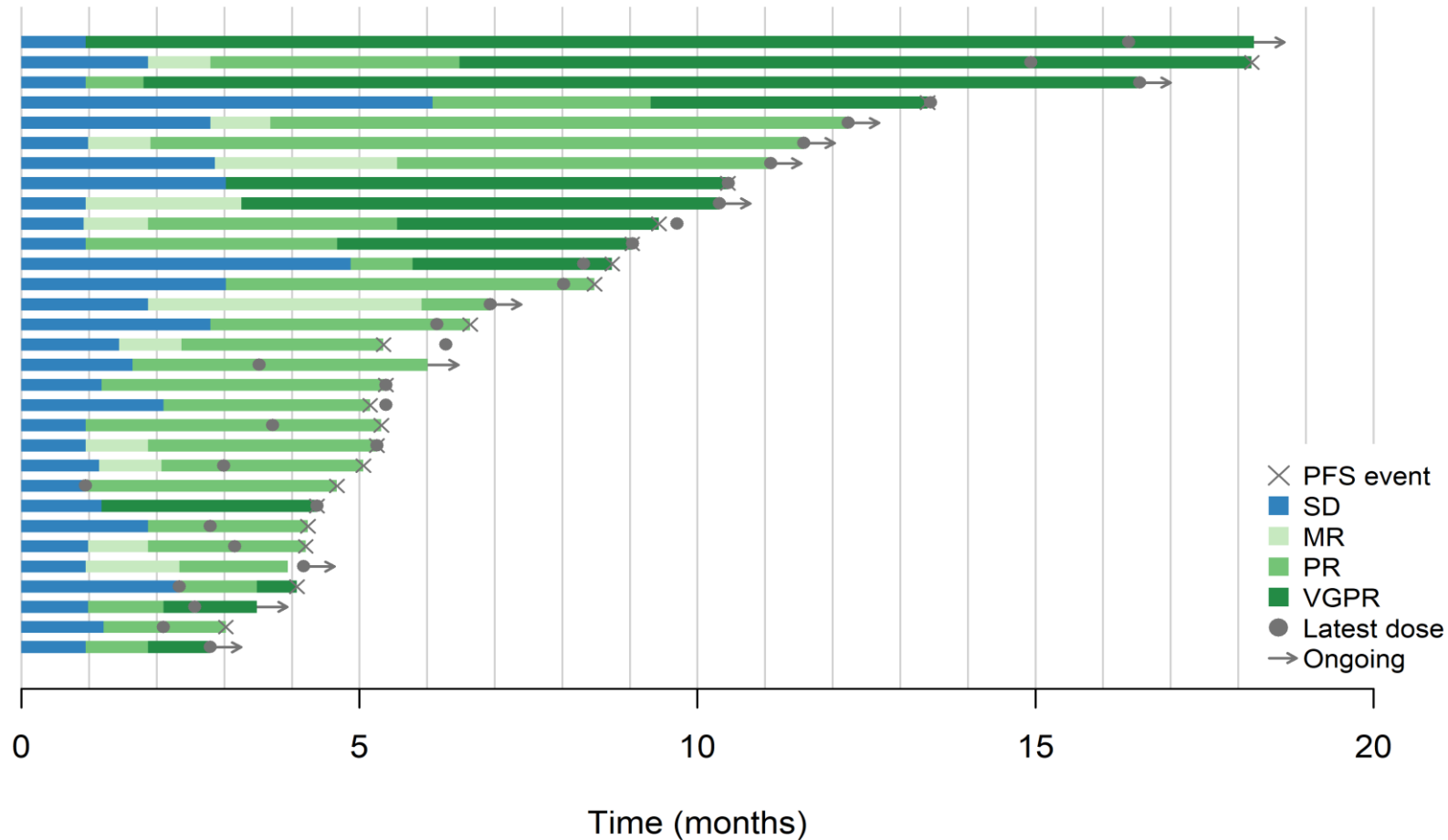
Primary End-Point	Investigator Assisted Data Jan 14 <sup>th</sup>	IRC Data Jan14 <sup>th</sup>	Incl. unconfirmed responses Jan 14 <sup>th</sup>
Overall Response Rate (ORR) – ITT n=157	29%	30%	31% (inv. and IRC)
ORR – 3x RRMM n=119	26%	26%	27% (inv. and IRC)
ORR – EMD n=55	24%	27%	NA

Note: Two unconfirmed responses on January 14<sup>th</sup> have later been confirmed.

Safety profile demonstrates that hematological toxicities were common but manageable, and non-hematological toxicities were infrequent

# STRONG ACTIVITY IN HIGHLY REFRACTORY MM PATIENTS

## RESPONDING PATIENTS PROGRESSION FREE FOR 8.5 MONTHS



# COMPETITIVE MELFLUFEN DATA

## TRIPLE CLASS REFRACTORY MULTIPLE MYELOMA PATIENTS

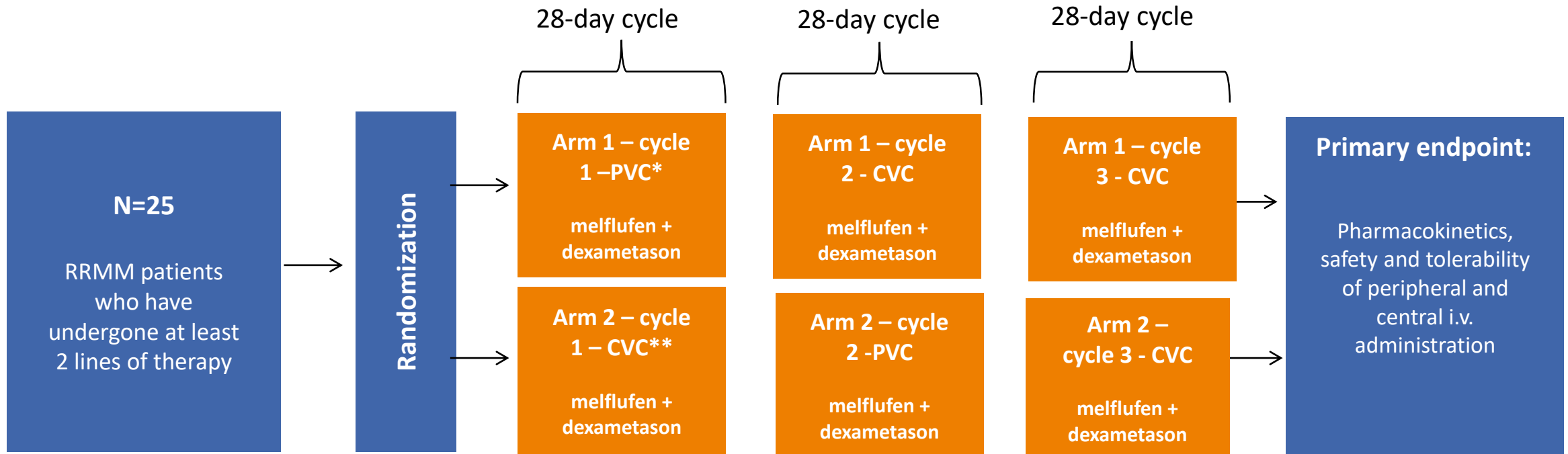


	Melflufen Oncopeptides US NDA, June 30, 2020		Xpovio Karyopharm US approval, July 2019		Blenrep GSK US Approval, Aug 6, 2020	
Number of patients studied	119		122		95	
Overall Response/Clinical Benefit Rate	26%/39%		25%/39%		31%/36%*	
mDOR / mPFS responders	5.5m / 8.5m		3.8m / 4.0m		NR/NR	
Progression-free survival	3.9 months		3.7 months		2.8 months*	
Overall survival	11.2 months		8.0 months		14.9m*	
Share of patients with EMD	42%		22%		20%*	
Serious Adverse Event Rate	51%		58%		40%	
Non-hematologic toxicity (grade 3/4) reported in >5% of patients	Pneumonia	9%	Fatigue Hyponatremia Nausea Pneumonia Diarrhea Sepsis Hypokalemia Mental status General det.	25% 20% 10% 9% 7% 6% 6% 6% 6%	Keratopathy Decreased Visual Acuity Pneumonia Pyrexia	44% 28% 7% 6%



# RECENTLY INITIATED PHASE 2 PORT STUDY

## COMPARING PERIPHERAL AND CENTRAL ADMINISTRATION



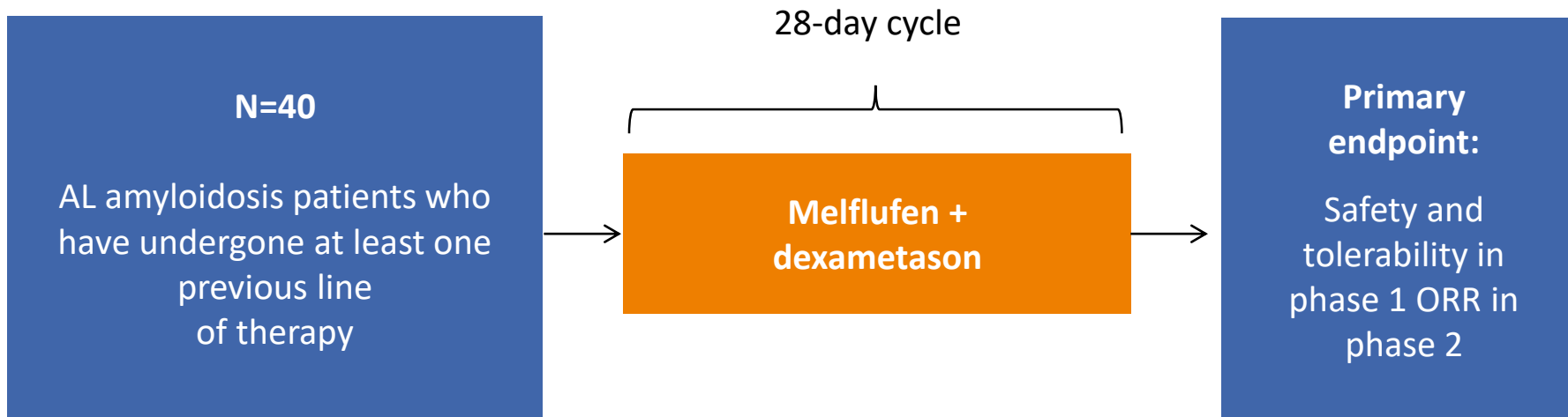
\* PVC = Peripheral i.v. administration of melflufen

\*\* CVC = Central i.v. administration of melflufen

# AL AMYLOIDOSIS – A RARE DISEASE WITH AN UNMET MEDICAL NEED

## THE FIRST STUDY WITH MELFLUFEN OUTSIDE MULTIPLE MYELOMA

- A rare disease that occurs in 30,000 to 45,000 patients in the U.S. and Europe
- Median overall survival 3.5 years
- Patients suffer from a plasma-cell disease
- A heterogenous collection of diseases involving protein deposition in one or several organs



# FINANCIAL UPDATE

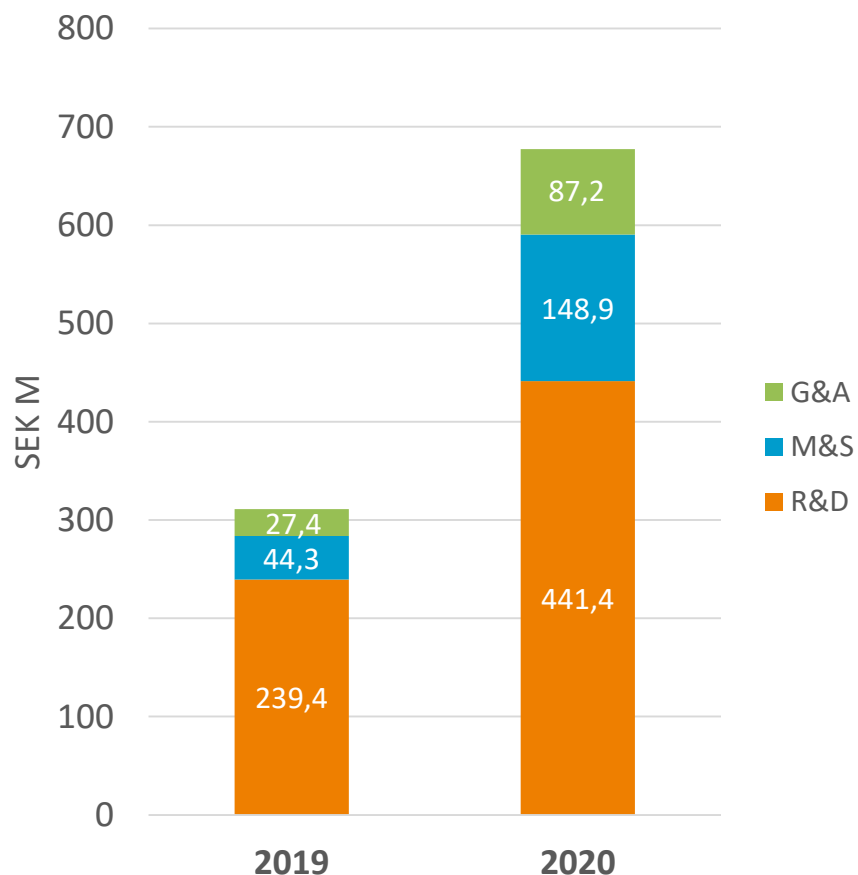
ANDERS MARTIN-LÖF  
Chief Financial Officer



# FINANCIAL RESULTS

## FOR THE PERIOD JAN-JUN 2020

### Operating Costs Jan-Jun



- Operating loss increased to SEK 696.2 M (loss:305.6)
  - R&D increase primarily due to increase in clinical & drug supply: SEK 332.5 M (193.9)
    - OCEAN SEK 177.2 M (110.7)
    - HORIZON SEK 35.7 M (29.5)
    - LIGHTHOUSE SEK 34.6 M (2.7)
    - ANCHOR SEK 20.8 M (19.4)
  - Build-up of commercial and medical affairs explains increase in M&S
    - US subsidiary incl. admin SEK 112.5 M (16.8)
  - Limited effect of non-cash costs for incentive programs SEK 25.9 M (17.8)
- Cash flow from operating activities neg. SEK 598.5 M (neg. 265.8)
- Cash position was SEK 937.8 M (626.8) as of Jun 30, 2020
  - Directed share issue raising SEK 1,413.9 M before issue costs of SEK 85.2 M in May 2020 closed in two steps in May and July
  - Second step of SEK 673.5 M after issue costs not included in cash as of Jun. 30

# CONTINUOUS NEWSFLOW

## MAJOR EVENTS OVER THE NEXT 12 MONTHS

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



**Q&A**

THANKS FOR YOUR ATTENTION

