# THE TRANSFORMATION OF ONCOPEPTIDES

# Capital Markets Day

November 30, 2020



## **DISCLAIMER**

**IMPORTANT:** You must read the following before continuing. The following applies to this document, the oral presentation of the information in this document by Oncopeptides AB (the "Company") or any person on behalf of the Company, and any question-and-answer session that follows the oral presentation (collectively, the "Information").

The Company has filed a New Drug Application with the US FDA seeking approval for melphalan flufenamide in combination with dexamethasone for the treatment of adult patients with multiple myeloma whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD-38 monoclonal antibody. The safety and efficacy have not been established. It has not been approved for use by any regulatory agency.

Melflufen is an abbreviated form of the international non-proprietary name (INN) melphalan flufenamide

The Information contains forward-looking statements. All statements other than statements of historical fact included in the Information are forward-looking statements. Forward-looking statements give the Company's current expectations and projections relating to its financial condition, results of operations, plans, objectives, future performance and business. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "could" and other words and terms of similar meaning or the negative thereof. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors beyond the Company's control that could cause the Company's actual results, performance or achievements to be materially different from the expected results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Company's present and future business strategies and the environment in which it will operate in the future.

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# **Introduction and Strategy for Value Growth**

Marty J Duvall, CEO Oncopeptides



# WELCOME TO CAPITAL MARKETS DAY

#### **KEY TAKEAWAY MESSAGES**

- Global company with R&D roots in Sweden
- Large unmet needs in multiple myeloma
- Melflufen has potential to become a backbone treatment in relapsed refractory multiple myeloma
- Organization fully ready for US launch
- PDC platform enables us to broaden our portfolio and position
   Oncopeptides as a strong player in hematological diseases





## THE TRANSFORMATION OF ONCOPEPTIDES

# **PROGRAM**

#### Introduction and strategy for value growth

Marty J Duvall, CEO Oncopeptides

#### Myeloma remains one of the largest unmet medical needs within hematology

Assistant Professor Joshua Richter, MD. Icahn School of Medicine at Mount Sinai Hospital, New York

#### Panel discussion - relapsed refractory multiple myeloma - clinical experience with melflufen

- o Dr. Paul Richardson, MD, Dana-Farber Cancer Institute, Boston
- Associate Professor Maria-Victoria Mateos, MD, PhD, University Hospital, Salamanca
- Moderated by Klaas Bakker, MD, PhD, CMO Oncopeptides

#### Clinical development program for melflufen – understanding how melflufen can help patients the most

Jakob Lindberg, CSO Oncopeptides

#### Successfully making melflufen available for patients in the US – overview of US launch

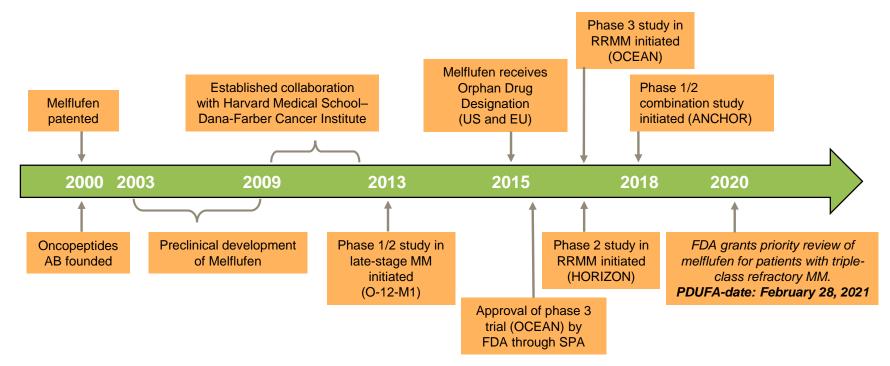
Marty J Duvall, CEO Oncopeptides



# **ONCOPEPTIDES COMPANY HISTORY**

# PEPTIDE DRUG CONJUGATE (PDC) TECHNOLOGY PLATFORM

- Founded in Stockholm, Sweden in 2000
- Focused on anticancer drug development based on PDC platform
- Collaborations with leading cancer research institutions
- US Offices in Boston and San Francisco











# **ONCOPEPTIDES TEAM**

# STRONG AND DIVERSE TEAM UNIFIED AND FOCUSED TO DRIVE VALUE

# Our core values

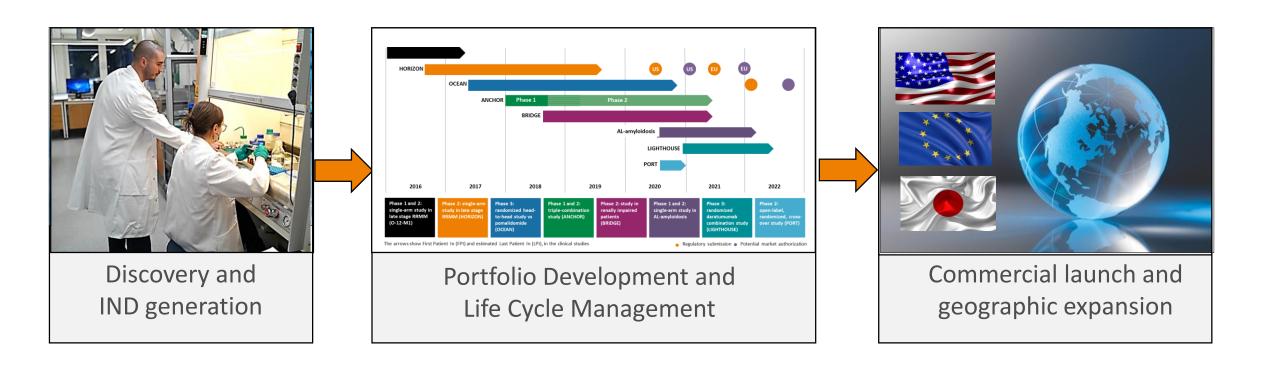
- Science
- Passion
- Collaboration
- Courage
- Trust





# **ONCOPEPTIDES AT A GLANCE**

## TRANSFORMATION INTO A FULLY INTEGRATED BIOPHARMA COMPANY





## PEPTIDE DRUG CONJUGATE

#### PDC TECHNOLOGY PLATFORM

- Drug conjugates use innovative technology that attaches a cytotoxic agent onto a tumor-targeting element.<sup>1</sup>
- The PDC platform allows concentration of a toxic payload into cancer cells by exploiting the difference in peptidase activity between cancer cells and normal cells.
- This approach delivers more and different cytotoxic activity to the cancer cells while protecting the healthy cells.<sup>2</sup>



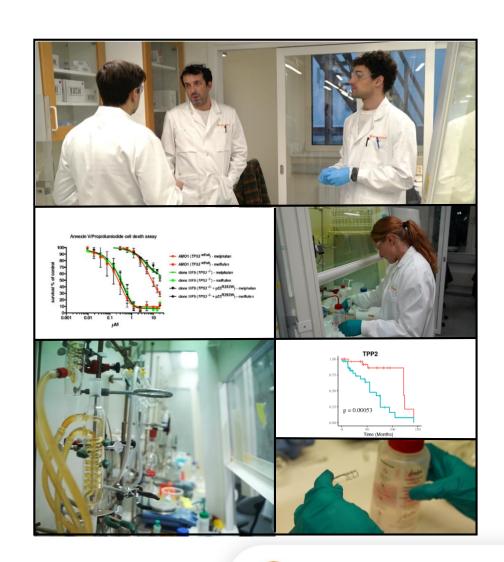
Cytotoxic Agent Peptide Carrier Peptide-drug conjugate Lipophilic peptide bound to a cytotoxic agent

<sup>1.</sup> Vrettos EI, Mező G, Tzakos AG. On the design principles of peptide—drug conjugates for targeted drug delivery to the malignant tumor site. Beilstein J Org Chem. 2018;14:930-954. **2.** Oncopeptides. Annual Report 2019.

# **DISCOVERY AND IND GENERATION**

#### LEVERAGING PDC PLATFORM AND BUILDING A PIPELINE

- Solna-based laboratory acquired in June 2020
- Expanded capabilities to harness the potential of metabolic enzymes in cancer cells
  - Team of passionate and externally focused scientists
  - State of the art medicinal chemistry
  - Modern biophysical and in vitro cell culture
- OPD5 2<sup>nd</sup> PDC drug moving into the clinic
  - IND approval for analogue of melflufen (NCE)
  - Formulated to deliver higher dose toxic payload
  - Phase I trial dose escalation study of safety and tolerability as myeloablative conditioning regimen followed by stem cell transplant in RRMM patients

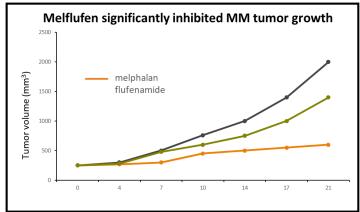


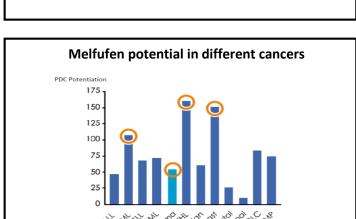


# PORTFOLIO DEVELOPMENT AND LIFE CYCLE MANAGEMENT

#### LEAD PROGRAM EXPANDING IN MULTIPLE MYELOMA AND BEYOND

- Strong differentiation versus other alkylators
- Broad pre-clinical activity
- Multiple Myeloma focus
  - Triple-class refractory or heavily pre-treated patients
  - Earlier lines of therapy
  - Combination trials
- AL- Amyloidosis first TA beyond myeloma
- Additional hematologic malignancies









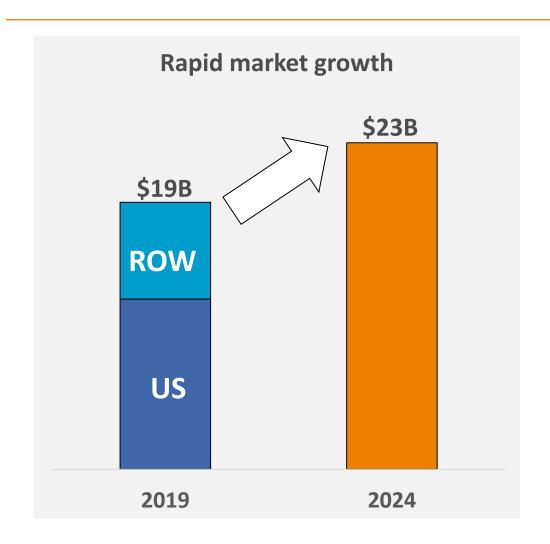






# LAUNCH INVESTMENT AND GEOGRAPHIC EXPANSION

# MULTIPLE MYELOMA - A HEMATOLOGICAL CANCER WITH NO CURE



# Significant unmet needs remain

- Survival increasing with new drug classes
- Most patients are treated with
  - Immunomodulatory drugs (IMiD)
  - Proteasome inhibitors (PI)
  - Anti-CD38 monoclonal antibodies (CD38)
- Many get all three in combination in first two lines of therapy, inevitably developing resistance
- New classes needed to overcome resistance



Source: IntrinsiQ and Kantar Health from 2019

# LAUNCH INVESTMENT AND GEOGRAPHIC EXPANSION

#### DRIVEN TO MAXIMIZE VALUE FOR SHAREHOLDERS AROUND THE GLOBE



# **Launch Phase**

- "Go at it alone" strategy
- Boston-based HQ for US
- San Francisco regional office
- Team fully recruited
- Launch-ready
- PDUFA date February 28



# **Regulatory Phase**

- "Go at it alone" strategy
- Targeting "conditional approval" (HORIZON)
- Rapporteur/Co-rapporteur
- Stockholm HQ to be leveraged
- Recruiting leadership



# **Early Reg Phase**

- Likely partnering strategy
- Gap analysis underway to determine regulatory needs
- Engaging with KOLs
- Local congress activity
- More to come

Actively exploring special licensed sales opportunities in other geographies ...



# Myeloma Remains one of the Largest Unmet Medical Needs Within Hematology Assistant Professor Joshua Richter MD, Icahn School of Medicine at Mount Sinai Hospital,

New York





Relapsed refractory multiple myeloma and melflufen – clinical experience with melflufen

**Panel discussion** 



# RELAPSED REFRACTORY MULTIPLE MYELOMA AND MELFLUFEN

## CLINICAL EXPERIENCE WITH MELFLUFEN



Klaas Bakker, M.D. Ph.D.
Chief Medical Officer
Oncopeptides AB
Moderator



Maria-Victoria Mateos, M.D. Ph.D. Associate Professor of Medicine University of Salamanca Salamanca, Spain



Paul G. Richardson, M.D.
R.J. Corman Professor of Medicine
Harvard Medical School
Dana-Farber Cancer Institute
Boston, Massachusetts





# Understanding how melflufen can help patients the most

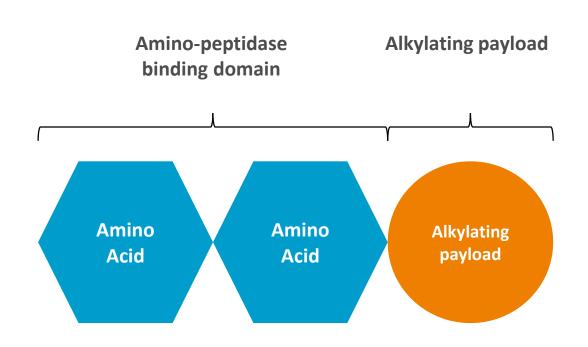
The PDC platform and the clinical development program for melflufen

Jakob Lindberg, CSO Oncopeptides



# **MELFLUFEN - A FIRST IN CLASS DRUG CANDIDATE**

#### A PEPTIDE-DRUG CONJUGATE TARGETING AMINOPEPTIDASES



#### PDC mechanism has potential to add several benefits

- 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

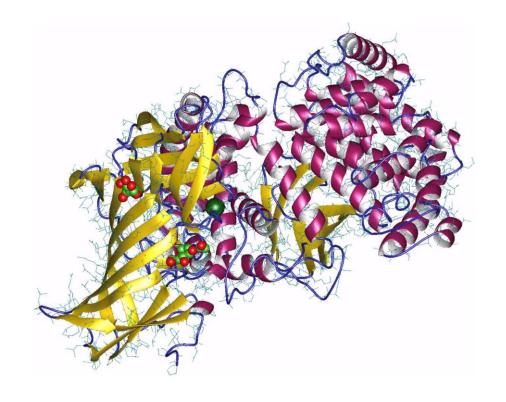


# AMINOPEPTIDASES ARE EXCELLENT CANCER TARGETS

# 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

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

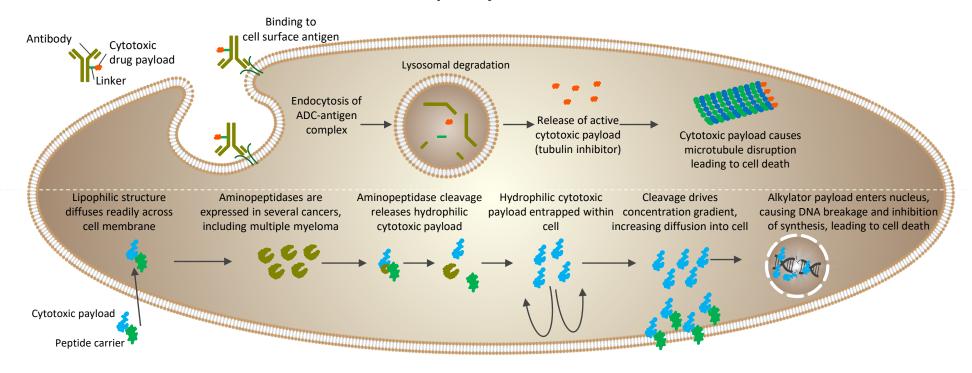




# NOVEL DRUG CONJUGATES TARGETING MULTIPLE MYELOMA TWO DIFFERENT TECHNOLOGIES TO ACHIEVE SAME OBJECTIVE

1 Antibody—drug conjugate

#### Multiple myeloma cell



# Peptide-drug conjugate

1. Bonello F, et al. Cancers (Basel). 2019;12(1). pii: E15; 2. Wickström M, et al. Oncotarget 2017;8(39):66641-55.



# THE EVOLVING MYELOMA LANDSCAPE – A FEW YEARS AGO...

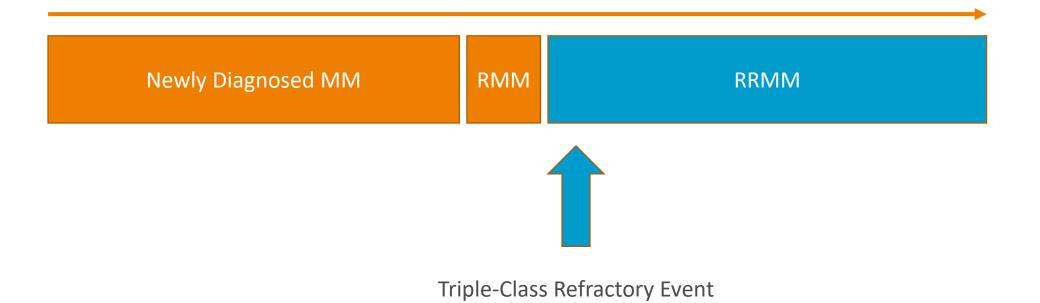
NEWLY DIAGNOSED MARKET DOMINANT – 3x RRMM EVENT LATE





# THE EVOLVING MYELOMA LANDSCAPE – CURRENT

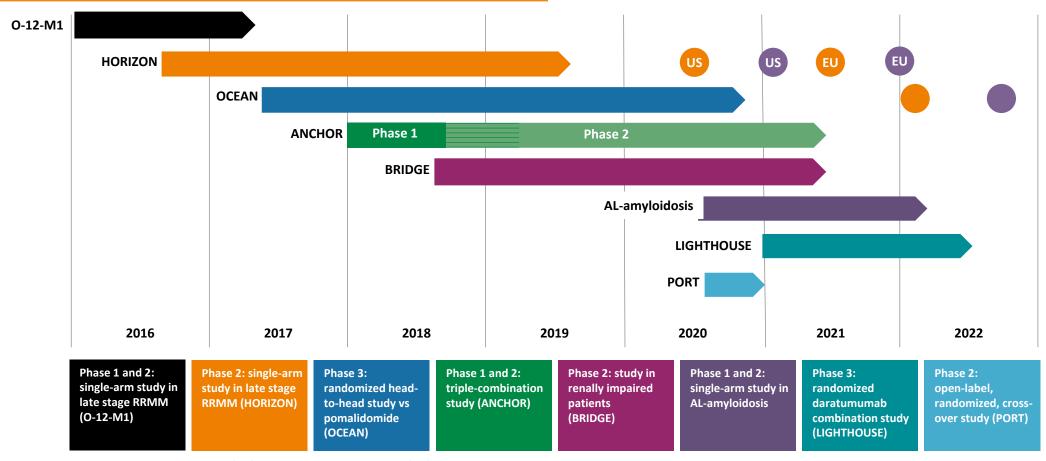
RRMM GROWING WITH MAJORITY OF PATIENTS BEING 3x RRMM





# **MELFLUFEN – CURRENT CLINICAL DEVELOPMENT PROGRAM**

#### FULL CLINICAL DEVELOPMENT PROGRAM IN RRMM



The arrows show First Patient In (FPI) and estimated Last Patient In (LPI), in the clinical studies

Regulatory submission
 Potential market authorization



# **DETAILS – MELFLUFEN CURRENT CLINICAL STUDIES**

O-12-M1











PHASE 3





**sEAPort** 

#### PHASE 2 SINGLE-ARM STUDY

Study O-12-M1, a single-arm, openlabel, phase 1/2, multicenter study of melflufen plus dexamethasone in RRMM patients with >2 prior therapies including IMiD and PI (N=75) PHASE 2

Study OP-106 (HORIZON), a single-arm, openlabel, phase 2, multicenter study of melflufen plus dexamethasone in **RRMM** patients who are refractory to pomalidomide and/or daratumumab (N=157)

PHASE 3 **RANDOMIZED COMPARATIVE** SINGLE-ARM STUDY SUPERIORITY STUDY

> Study OP-103 (OCEAN), a randomized. controlled, OL, phase 3, multicenter study of melflufen plus dexamethasone compared with pomalidomide plus dexamethasone in patients with RRMM (ref to len) (N=450)

PHASE1/2 **TRIPLE** COMBINATION **STUDY** 

Study OP-104 (ANCHOR), a parallel, open-label, phase 1/2, multicenter study of melflufen plus dexamethasone with either bortezomib or daratumumab in patients with RRMM (N=80)

PHASE 2 SINGLE-ARM STUDY

Study OP-107 (BRIDGE), a PK study in RRMM patients with renal impairment (N=25)

**RANDOMIZED COMPARATIVE** SUPERIORITY STUDY

Study OP-108 (LIGHTHOUSE), a randomized 2:1, phase 3 study of melflufen. with daratumumab and dexamethasone vs daratumumab in RRMM, with >3 prior lines incl. IMiD and PI (N=240)

PHASE 1/2 SINGLE-ARM STUDY IN AL AMYLOIDOSIS

Study OP201, a PK phase 1/2, openlabel study of melflufen plus dexamethasone in patients with AL amvloidosis and >1 prior therapy (N=46)

PHASE 2 TWO-PERIOD STUDY

A randomized cross over study comparing peripheral versus central intravenous administration of melflufen in RRMM (N=20)

**Expanded Access** 

Program (EAP)

Study OP-110 (sEAPort), a multicenter, openlabel EAP protocol to address an unmet medical need by providing access to melflufen for patients with RRMM (N=up to 200 [planned])



# **PLANNED NEW STUDIES IN 2021 - RRMM**

RRMM patients with EMD

- RRMM patients with extramedullary disease (EMD) represents one of the largest unmet medical needs in multiple myeloma
- Melflufen showed highly encouraging data in EMD patients in HORIZON
- Planned study start during 2021

**OPD5** for ASCT

- Strong clinical interest in exploiting PDCs with alkylating payloads in the stem-cell transplant setting
- OPD5 is an analog of melflufen specifically designed for the high-dose setting, i.e. the stem-cell transplant setting
- IND for OPD5 recently approved in the US planned study start in 2021



# MELFLUFEN DEVELOPMENT

#### DESIGNED TO SUPPORT USE AFTER IMID AND PI FAILURE

#### **MUST HAVE CHARACTERISTICS**

Single agent +/- steroid **activity** in multi-refractory patients of >20% Overall Response Rate (ORR)

Single agent +/- steroid **approval** in refractory patients

**Efficacy synergy** in combination with other main myeloma drugs with good tolerability

No major quality of life tolerability issues

No **co-morbidity** limitations

#### **NICE TO HAVE CHARACTERISTICS**

Easy administration schedule



**O-12-M1** showed an ORR of 31%, **HORIZON** an ORR of 29% in multi-refractory patients

OCEAN pivotal head-to-head study versus pomalidomide + dexamethasone will read out H1-21

**ANCHOR** shows excellent synergy and good tolerability with daratumumab and bortezomib (early data). Next combination study **LIGHTHOUSE** to commence shortly

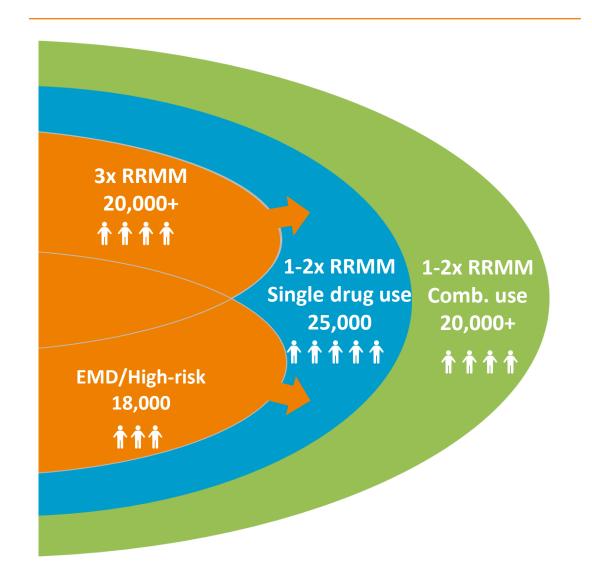
**Good QoL** with almost no non-hematological AEs

No **co-morbidity** or drug-drug interactions limitations

One **30-minute infusion** every 28 days

# **DEVELOPING MELFLUFEN FOR RRMM PATIENTS**

# US MARKET – CURRENT PATIENT NUMBERS



# **Clinical Program Drives Label Expansion**



Anticipated label in triple-class refractory patients



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



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



# 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%*	
Dose reduction, % of patients	24%		49%		29%	
Gr3/4 bleeding events, % of patients	3.8%		3.0%		2.1%	
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%	Keratopathy Decreased Visual Acuity Pneumonia Pyrexia	44% 28% 7% 6%

# **PIVOTAL TRIALS**OCEAN AND LIGHTHOUSE



- Head-to-head comparison with the most used drug in RRMM pomalidomide
- Pomalidomide is perceived as the drug with the best combination of efficacy and safety in RRMM
- Both non-inferiority and superiority outcome from OCEAN is a positive



- Based on good combination data from the ANCHOR trial
- Combination therapy between melflufen and daratumumab (anti-CD38)
- Targets patients that are not receiving anti-CD38 in the front-line setting and patients receiving anti-CD38 as a retreatment in later lines with novel combination partner (both in patients exposed to as well as refractory to anti-CD38 therapy)

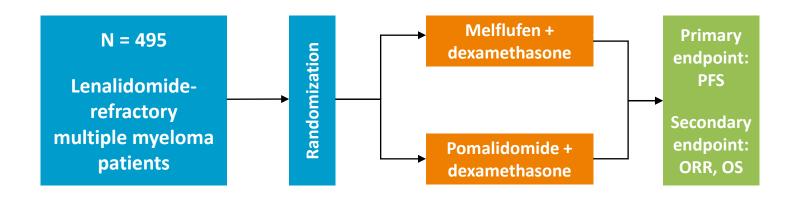


# **ENROLLMENT COMPLETED IN PHASE 3 OCEAN STUDY**



#### 495 PATIENTS RECRUITED – TOP-LINE RESULTS IN H1 2021

#### Head to Head study versus pomalidomide



#### RRMM data from pomalidomide FDA label and O-12-M1 study

Treatment	ORR	CBR	Median PFS	Median DOR	Median OS
Melflufen + Dexamethasone	31%	49%	5.7 months	8.8 months	20.7 months
Pomalidomide+ Dexamethasone	24%	NR	3.6 months	7.0 months	12.4 months



# POMALIDOMIDE SHARES RESISTANCE MECHANISM WITH LENALIDOMIDE



# Average IMiD free period significant in pomalidomide registration study

Only 29% received lenalidomide as last treatment

#### Lenalidomide used more aggressively today

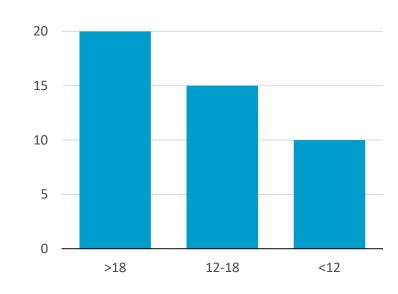
Median maintenance duration 24 months instead of 10 months

# In OCEAN all patients have failed on lenalidomide within 18 months

Vast majority has lenalidomide as last treatment

# No assumptions have been made in OCEAN power calculation to account for increased cross resistance

# Pomalidomide efficacy decreases for recent lenalidomide failures



Median overall survival (months)

IMiD-free period before start of pomalidomide treatment (months)



# **PHASE 3 OCEAN STUDY**



#### TWO WAYS TO MEET PRIMARY ENDPOINT

- OCEAN meets its primary endpoint with a superiority or non-inferiority result
- Pomalidomide is the largest treatment option in RRMM with very good physician perception

OCEAN OUTCOME	FDA	EMA
Primary endpoint met - Superiority	✓	✓
Primary endpoint met – Non-inferiority	?	✓
Primary endpoint <b>not</b> met	×	×



# **LIGHTHOUSE STUDY - BASED ON POSITIVE ANCHOR DATA**



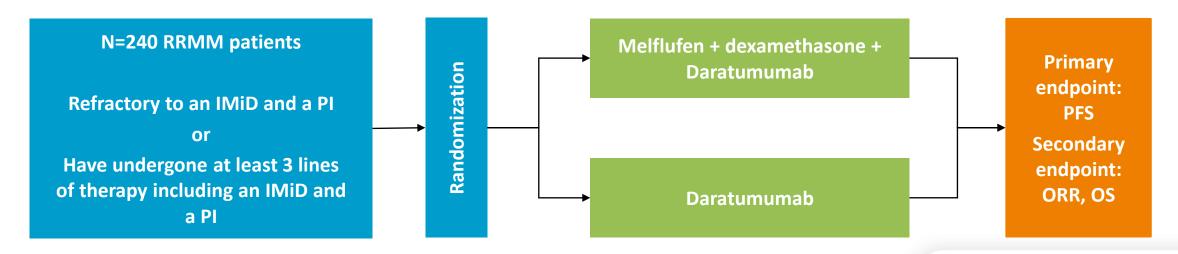
#### CONFIRMATORY PHASE 3 STUDY – AWAITING GO-AHEAD

#### Phase 3 study with melflufen in multiple myeloma

- Melflufen + daratumumab vs daratumumab randomized 1:1
- Subcutaneous version of daratumumab

#### **Objectives**

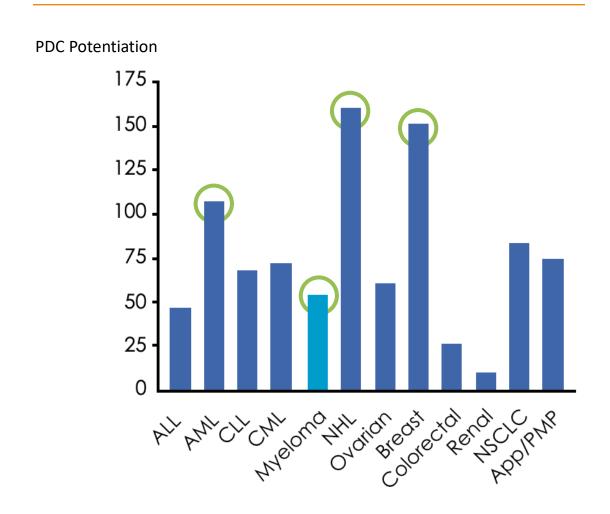
Expand market potential – expand label for melflufen in combination with daratumumab





# PEPTIDE DRUG CONJUGATE PLATFORM

## THERAPEUTIC ACTIVITY IN MOST CANCERS



- 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



# PLANNED NEW CLINICAL STUDIES 2021 OUTSIDE MULTIPLE MYELOMA

#### **KEY AREAS OF EXPLORATION**

Relapsed/refractory AML patients

- Significant unmet medical need in AML
- Strong pre-clinical data with melflufen in AML
- Phase I/II trial planned to be initiated in 2021

DLBCL patients with high-risk features

- Significant unmed medical need in sub-groups of DLBCL patients
- Strong pre-clinical data with melflufen in NHL/DLBCL
- Phase I/II trial planned to be initiated in 2021



# **DEVELOPING PEPTIDE-DRUG-CONJUGATE PLATFORM**

# FROM PRE-CLINICAL TO CLINICAL DEVELOPMENT 2020/21

	EXPLORATORY DEVELOPMENT	LATE PRECLINICAL DEVELOPMENT	PHASE 1	PHASE 2	PHASE 3	REGISTRATION	MARKET
Melflufen							
OPD 5							
New CD							





# Successfully Making the Drug Available for Patients in the US

Overview of US launch of melflufen

Marty J Duvall, CEO Oncopeptides



## MELFLUFEN PRODUCT POSITIONING

## ASPIRATIONAL POSITIONING IN MULTIPLE MYELOMA

Melflufen, used alone and in combination, is a first in class peptide-drug conjugate that leverages aminopeptidases and rapidly releases alkylating agents into tumor cells

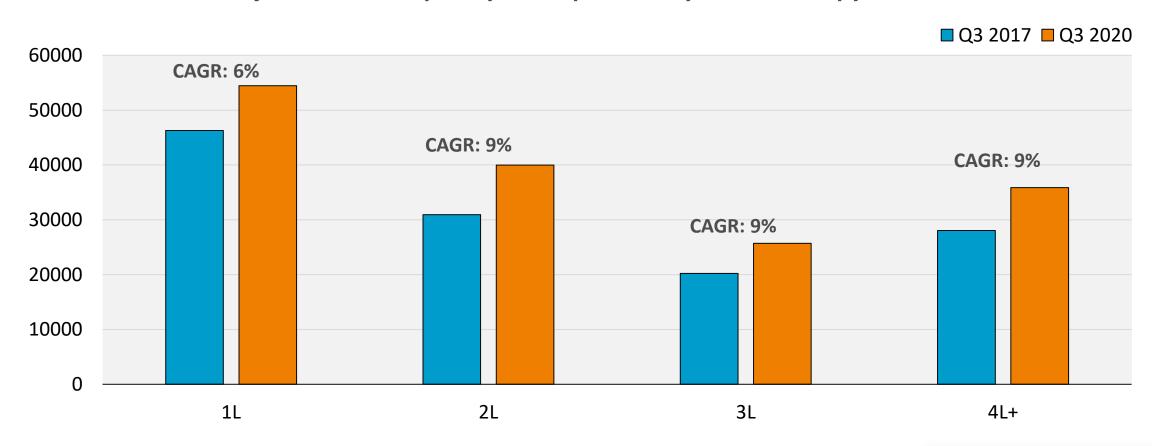
- "First in class" supports a novel product and differentiated positioning
- "PDC" leverages the clinical and commercial success of "ADC" drugs which resonates externally
- "leverages aminopeptidases" Aminopeptidase expression is upregulated in cancer cells relative to normal tissue. In multiple myeloma cells, increased expression of aminopeptidases is associated with advanced disease and tumor mutational burden. Thus, targeting aminopeptidases results in selective activity in cancer cells, sparing healthy cells and resulting in a strong benefit to risk profile
- "rapidly releases" suggests highly active and effective
- "alkylating agents" boldly asserts a differentiated "payload" of alkylators

The first and only PDC that leverages aminopeptidases which are highly expressed in myeloma cells



# IMPROVED OUTCOMES LEAD TO FAST GROWTH IN NUMBER OF TREATED PATIENTS IN LATER LINES OF THERAPY

## Projected US multiple myeloma patients by line of therapy



Source: Intrinsiq MAT Q3 2020

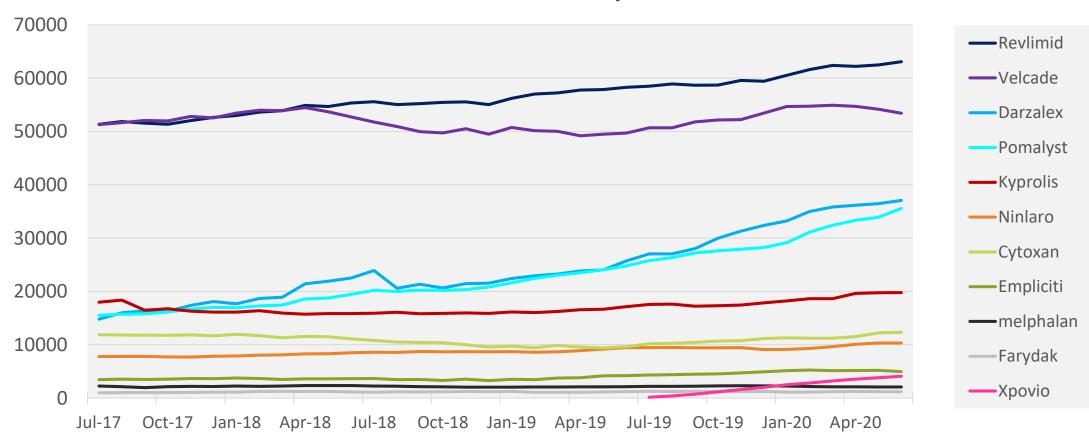
Note: 3-yr annual growth rate for 3Q2017-3Q2020

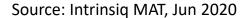


## NEWER PRODUCTS ON TOP OF OLDER AS SURVIVAL IMPROVES

## **NEED OF NEW TREATMENT OPTIONS**

## **US MM # of Total Patients by Product**



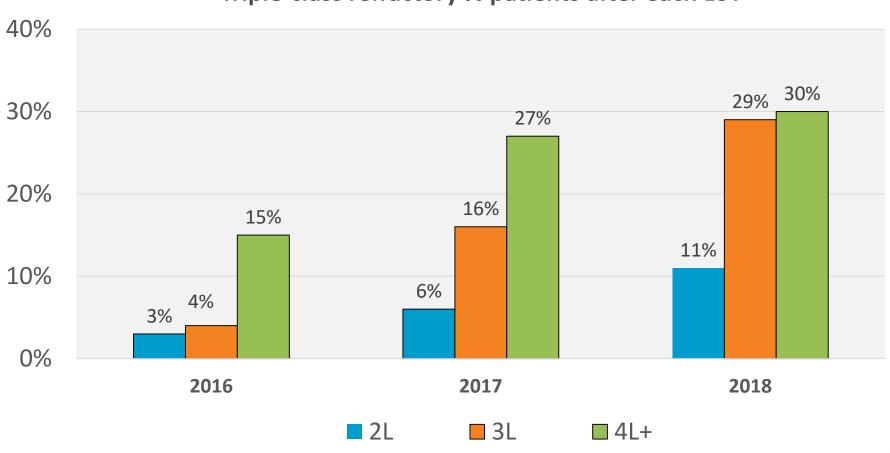




## TRIPLE-CLASS REFRACTORY MULTIPLE MYELOMA

## AN INDICATION WITH GROWING UNMET MEDICAL NEED

## Triple-class refractory % patients after each LoT



Estimated
>20,000 Tripleclass refractory
patients in the
US and
growing

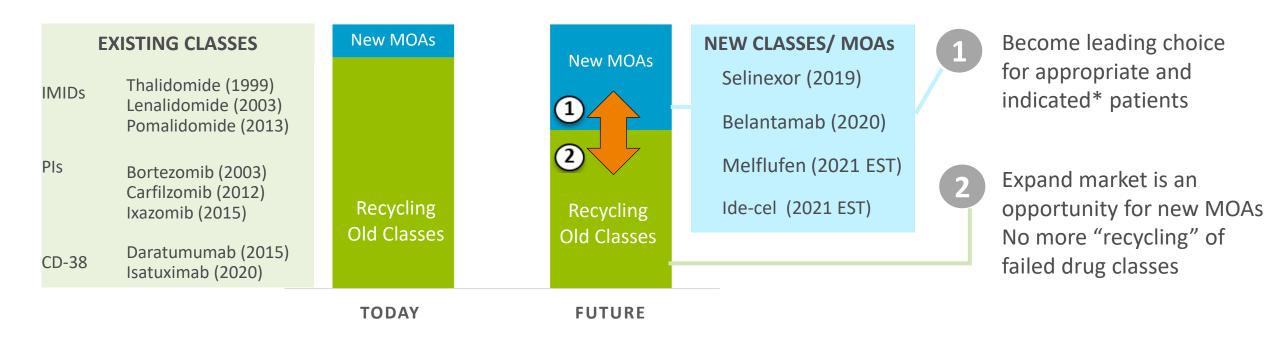


## BECOME A LEADING CHOICE IN TRC MM AND EXPAND MARKET

## TWO-PRONGED STRATEGIC APPROACH

## Driving change in today's RRMM treatment paradigm

Common Practice to "recycle" drugs within existing classes as patients progress



<sup>\*</sup> based on final FDA approved label



## PAVING THE WAY FOR A SUCCESSFUL LAUNCH ... THE TEAM US LEADERSHIP ORGANIZATION WITH SIGNIFICANT ONCOLOGY LAUNCH EXPERIENCE



#### Mohamed Ladha, General Manager US Business Unit

17 years in industry with extensive oncology launch expertise

Led/built commercial functions at 7 pharma or biotech companies for in-line/ launch products including Schering Plough, Merck, ARIAD,



#### Chris Black, Head of Sales and Training

21 years of industry experience with 17 years in oncology which include Pfizer, EMD Serono and Nanostring.

Involvement in 7 product launches in oncology and part of 2 buildouts and expansions for the promotion of in-line and launch onco brands



#### Sarah Donovan, Head of Marketing

20 years of industry experience in sales, analytics; patient advocacy, US and Global Marketing, 10 years of experience in oncology

Led and built marketing functions for launches and inline brands



#### **Matt Smith, Head of Market Access**

20 years of commercial biotech experience which includes 10 years in oncology

Strong track record of leadership success and building market access functions from the ground up while part of 5 launches and supporting 10+ line extensions



#### Paula O'Connor, MD, Head of Medical Affairs US

17 years industry experience with 30 years oncology experience

Led Clin Dev programs at 3 companies and established Medical Affairs organizations at 3 companies



#### Jacob Lai, Head Business Strategy and Planning

17 years of industry experience with 10 years in oncology

Has played key roles in the strategic planning and growth of biotech companies with expertise in the areas of commercial analytics, commercial development and pipeline strategy



#### **Nick Holsman, Head of Commercial Operations**

18 years of industry experience with 5 focused in oncology

Led and built commercial operations functions at 5 biotech and diagnostic companies for both in-line marketing and launch brands









































## ONCOPEPTIDES IS PAVING WAY TO ENSURE BEST CUSTOMER EXPERIENCE

## "ONE ONCOPEPTIDES" TEAM IN MOTION



- An integrated and coordinated field force team
- Oncology Account Managers spearhead the tactical execution and pulls in appropriate resources
- Cross functional in nature with one objective: meet customer needs
- The team operates as an area level business
- All planning and execution at local level
- The team is empowered to execute the go to market strategy and be the external face of Oncopeptides



## PUTTING PATIENTS FIRST BY ELIMINATING BARRIERS TO THERAPY

## PROVIDING CONTINUOUS SUPPORT ALONG THE PATIENT JOURNEY



#### **ACCESS – No Patient Left Behind**

- Payer engagement for "prior authorization"
- Support any "appeals" processes
- Uninsured patients (Free Drug program)
- Quickstart program

### **AFFORD – Reduce Patient Expense**

- Co-Pay Cards
- Connections to additional resources

## **ADHERE – Remain on Therapy**

- Patient outreach and support
- Educational materials



## **ENGAGING WITH PAYERS REPRESENTING >95% OF COVER MEDICAL LIVES**

## MARKET ACCESS TEAMING WITH MEDICAL AFFAIRS TO LAY THE GROUNDWORK

UnitedHealth Group/OPTUM
Anthem
Aetna & CVS Caremark
CVS
Cigna and Express Scripts
Express Scripts
Health Care Service Corporation (PRIME/ppt)
Centene (Health Net and Wellcare)
Kaiser Permanente
Humana
Highmark
BlueCross BlueShield Michigan
Horizon BCBS of New Jersey (Magellan)
Florida Blue (Magellan)
EmblemHealth
BlueShield California
Blue Cross and Blue Shield of Alabama (PRIME/ppt)
CareFirst
BlueCross BlueShield Tennessee
BlueCross BlueShield Minnesota
BlueCross BlueShield Massachusetts
Harvard-Pilgrim (Tufts)

BlueCross BlueShield North Carolina
Cambia Health Solutions (Regence)
Molina Healthcare
Medical Mutual
Medica (MN)
Lifetime Healthcare (Excellus) (Magellan)
Haven Health (JPMorgan, Berkshire, and Amazon)
Premera Blue Cross
Independence Blue Cross
BlueCross BlueShield South Carolina
University of Pittsburgh Medical Center
Capital BlueCross
Intermountain Healthcare
Henry Ford Health System
BlueCross BlueShield Kansas
Sentara Health
Magellan (Excellus/Horizon/FL Blue/BCBST)
Remedy One (Empire/BCBSVT)
Walgreens PRIME Alliance (Same as PRIME)
Geisinger Health System

- Medical Affairs leads melfufen clinical profile characterization: feedback is positive
- Stakeholder feedback from recently-approved other agents: focus on GIrelated and ocular toxicities of other in-class competitor agents
- Experienced hem-onc
   Market Access teams in
   place to address potential
   coverage, reimbursement
   issues post-launch



## **DISTRIBUTION AND SUPPLY CHAIN SLIDE**

### US ORGANIZATION SET FOR LAUNCH

Supply Chain and distribution strategy aims to optimize access, control and customer support







Product Supply imported from Cenexi in Brussels, Belgium

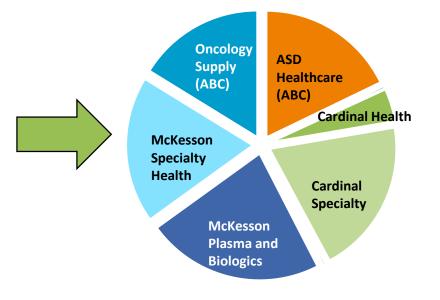
Third Party Logistics (3PL) in place to ensure supply and distribution of Melfufen to market





Finished and labelled product stored at Cardinal Health 3PL

Traditional Specialty Distributor model familiar to end-customers (IDNs, Community Oncology) using RRMM agents



Contracts with distributors estimated to provide product to 99.9% of customers in the RRMM market



## MATERIALS READY AND TAILORED FOR TARGETED CUSTOMERS\*



Product X + dexamethasone showed clinically significant response in heavily pretreated patients.<sup>1</sup>

**EFFICACY RESULTS** 





## DRIVE BROAD AWARENESS APPROVAL OF NOVEL TREATMENT OPTION FOR MM

- Now approved in relapsed or refractory multiple myeloma
- The first and only anticancer peptide-drug conjugate

#### HIGHLIGHT EFFICACY RESULTS IN DIFFICULT TO TREAT PATIENTS

- Clinically significant response in heavily pretreated patients (ORR, DOR, PFS, OS); Median of 5 prior lines of treatment
- EMD patient reponses consistent with overall study population

#### **CLARIFY AE PROFILE AND GUIDANCE FOR MANAGEMENT**

- Most common AEs; Clinical implications of cytopaenias
- Safety profile consisted primarily of hematologic AEs

#### PROVIDE GUIDANCE ON HOW AES WERE MANAGED

 Adverse events clinically manageable with dose modifications and supportive care

#### HIGHLIGHT CONVIENIENT DOSING SCHEDULE

• Convenient dose schedule; Once monthly 30-minute infusions

\*Messages tailored to target audience and subject to approved labelling from the FDA

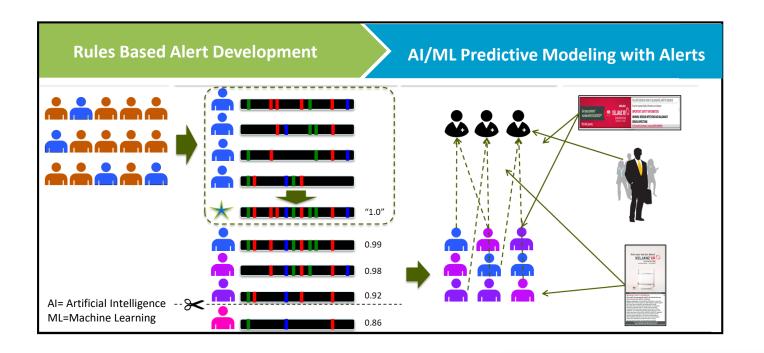


## **CUSTOMER INFORMATION MANAGEMENT SYSTEM**

## PROVIDING REAL-TIME CUSTOMER INSIGHTS TO IMPROVE SERVICE

Leveraging integrated healthcare patient-level data and delivering weekly insights

300M +**Unique Patients** Across virtually all\* providers, HCOs, and IDNs Over a decade of history updated weekly **Multiple Myeloma Focused All Prescription Drugs All Geographies** \*99% of HCPs; 98% of health systems; 86% of outpatient facilities; 89% of hospitals





## **MEDICAL AFFAIRS**

## US ORGANIZATION SET FOR LAUNCH

Medical Information & Communication	Scientific Exchange	Data Generation
<ul> <li>Call Center</li> <li>Compendia &amp; dossiers</li> <li>Publications (abstracts &amp; manuscripts)</li> <li>Continuing Medical Education support</li> </ul>	<ul> <li>MSL and Nurse Educator Teams</li> <li>Local-Regional-National Education</li> <li>Insight gathering</li> <li>OCP Trial &amp; EAP support</li> </ul>	<ul> <li>Investigator Initiated Trial (IIT) program</li> <li>Real World Evidence (RWE) program</li> <li>Expanded Access Program (EAP)</li> </ul>
Patient Advocacy		

- Majority of KOLs and Large Community practices engaged and profiled
- Unmet Need insights defined
- Scientific engagements with current and future studies
- Participation in advisory boards
- EAP Participation







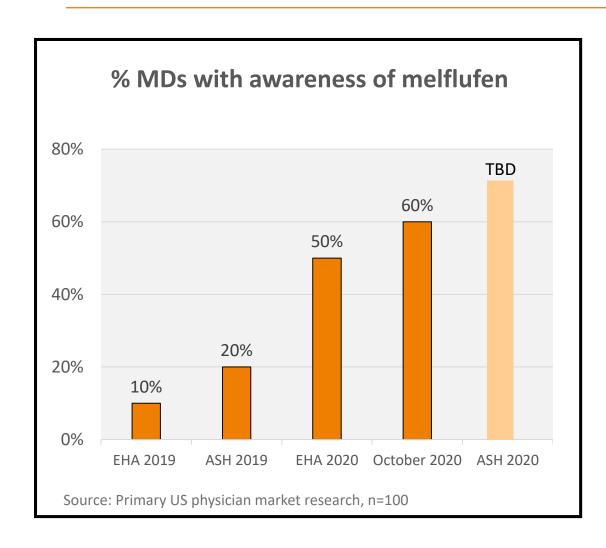


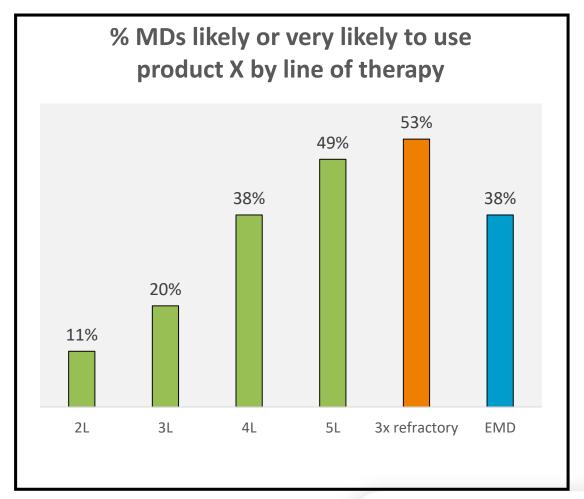




## MELFLUFEN AWARENESS CONTINUES TO INCREASE IN US

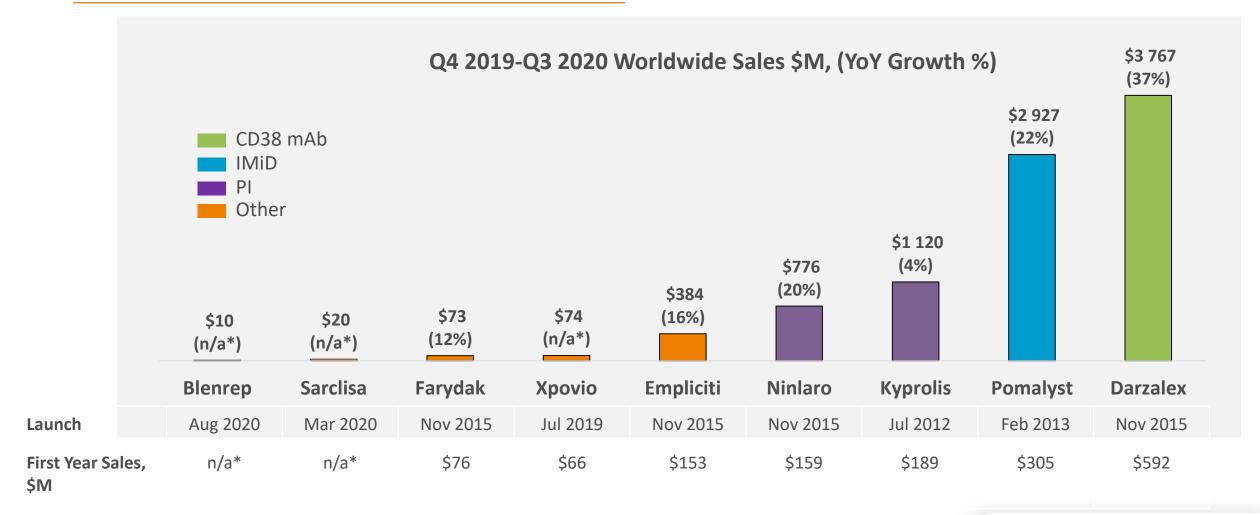
## MOMENTUM IS GROWING AFTER SCIENTIFIC MEETINGS







# EFFECTIVE RRMM DRUGS WITHOUT MAJOR SIDE EFFECTS OR COMORBIDITY LIMITATIONS HAVE A SIGNIFICANT POTENTIAL



<sup>\*</sup> Newly approved products without full year sales for YoY comparison Source: EvaluatePharma, company earnings



## **NEWS FLOW**

## VALUE DRIVERS AND MAJOR MILESTONES

Q3 2020

First patient in PORT study

First patient in Amyloidosis study

FDA Feedback PDUFA date

OCEAN patient enrollment completed

Q4 2020

**Expanded Access Program (US) opened** 

Intent to file for EU conditional approval

Loan agreement with EIB for € 40 M

**IND filing OPD5** 

ASH abstract including ANCHOR data

**Virtual CMD** 

HORIZON publication
Journal Clin Onc

ANCHOR presentation at ASH

Q1 2021

First patient in LIGHTHOUSE

First patient in OPD5

**Results from PORT** 

Potential accelerated approval in US

Commercial launch in the US

Q2 2021

EU-submission conditional approval

Top-line results OCEAN

**EHA data update** 

Last patient in ANCHOR

Last patient in BRIDGE

H2 2021 / H1 2022

Potential conditional approval in EU

**Final results ANCHOR** 

Results BRIDGE

Last patient in LIGHTHOUSE

Potential sNDA submission OCEAN

Extension of EU indication on OCEAN



## **IN SUMMARY**KEY TAKEAWAY MESSAGES

Global company with R&D roots in Sweden

Large unmet needs in multiple myeloma

 Melflufen has the potential to become a backbone treatment in relapsed refractory multiple myeloma

Organization fully ready for US launch

PDC platform enables us to broaden our portfolio and position Oncopeptides as a strong player in hematological diseases



## Q/A session



