

A photograph of a male doctor with a grey beard and glasses, wearing a white lab coat over a blue shirt, with a red stethoscope around his neck. He is looking down at a male patient lying in a hospital bed. The patient is wearing a white hospital gown. The background is a bright, modern hospital room with large windows and greenery visible outside.

**Oncopeptides presenting at
Jefferies 2019 Healthcare Conference
June 7, 2019**

Jakob Lindberg, CEO



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Oncopeptides at a glance

Develops targeted cancer treatments

- Proprietary peptidase-enhanced compounds
- Lead compound Melflufen a peptide conjugated alkylator targeting Multiple Myeloma

Initial focus on Multiple Myeloma

- Significant market opportunity in orphan indication
- Melflufen Phase 2 showed the best MM survival data to date

Application process initiated for accelerated approval in the US

- Target to submit in Q1-20 based on ongoing phase 2 study HORIZON
- Triple-class refractory MM

Phase 3 expected to be fully enrolled in Q1 2020

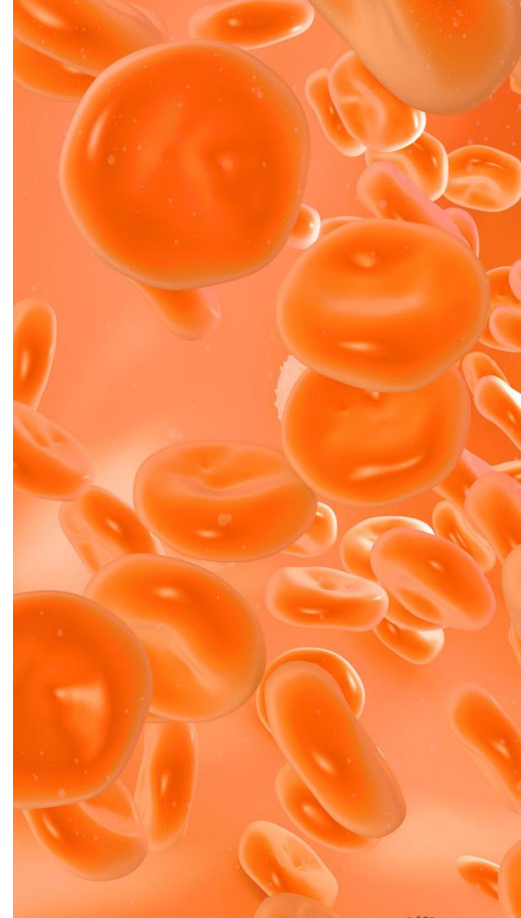
- Approximately 450 patients at 140 sites
- Two additional supporting trials ongoing, additional Phase 3 to be started 2019

Listed on NASDAQ Stockholm, strong financial position

- Market cap: SEK 8.2 B (\$850 M)
- Cash position was SEK 747.5 M (\$77 M) as of March 31, 2019

New indications and NCEs in development

- Clinical trials expected to start in 2019

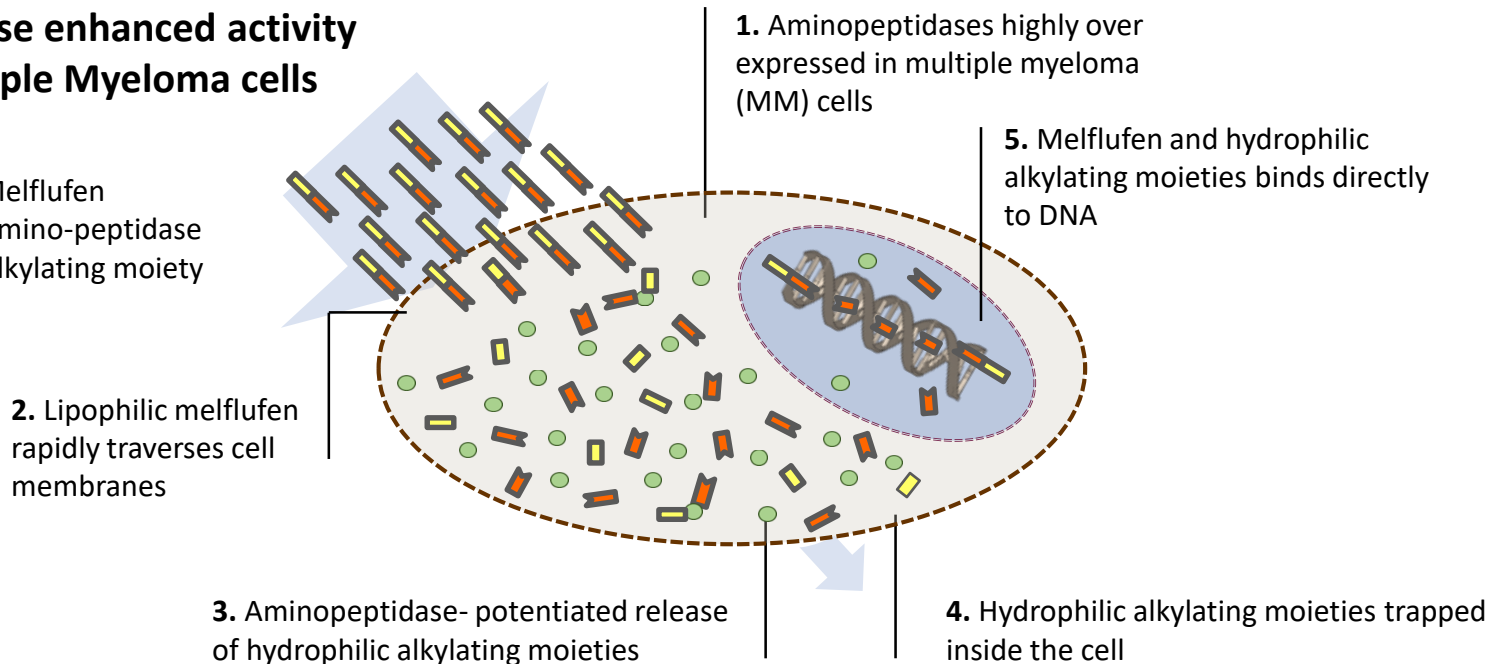


Melflufen is a first in class peptide conjugated alkylator

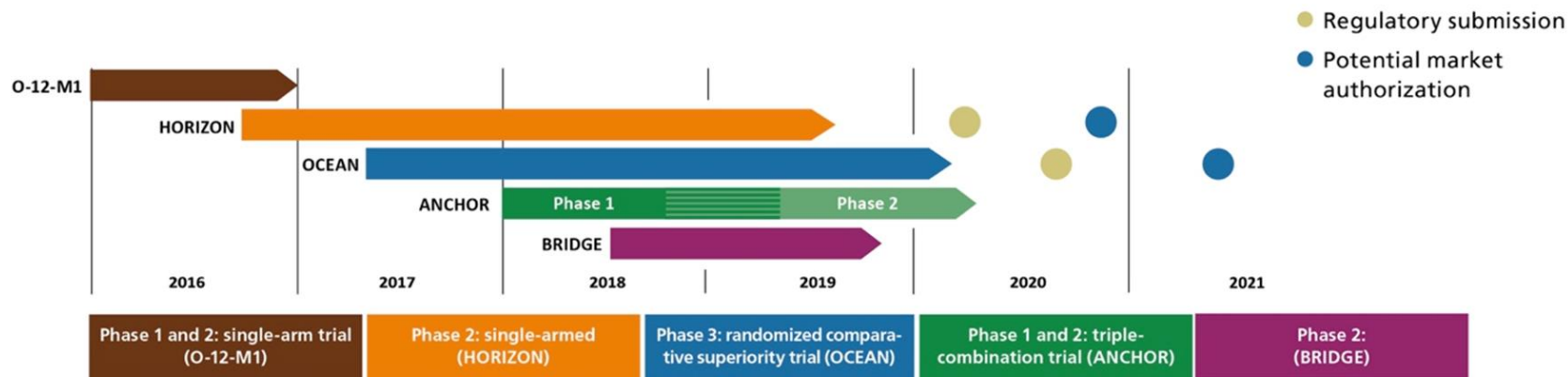
– Aminopeptidase activity increased up to 250x as part of transformation process

Peptidase enhanced activity in Multiple Myeloma cells

-  Melflufen
-  Amino-peptidase
-  Alkylating moiety



Overview of our present clinical development program in multiple myeloma



O-12-M1

Show single-agent activity in RRMM

HORIZON

Show single-agent activity in RRMM

OCEAN

Show single-agent superiority over SoC backbone in RRMM (pomalidomide)

ANCHOR

Show combination synergy and tolerability with daratumumab and bortezomib

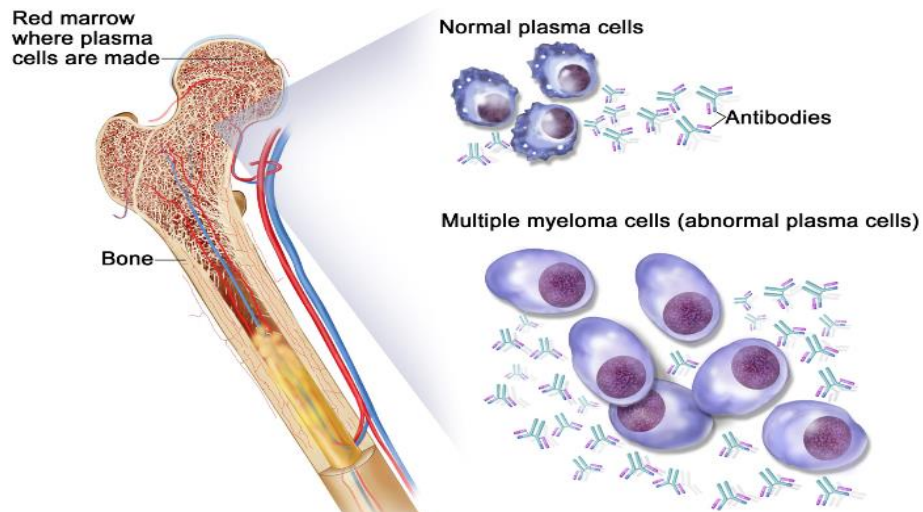
BRIDGE

Show that melflufen can be used in patients with renal impairment

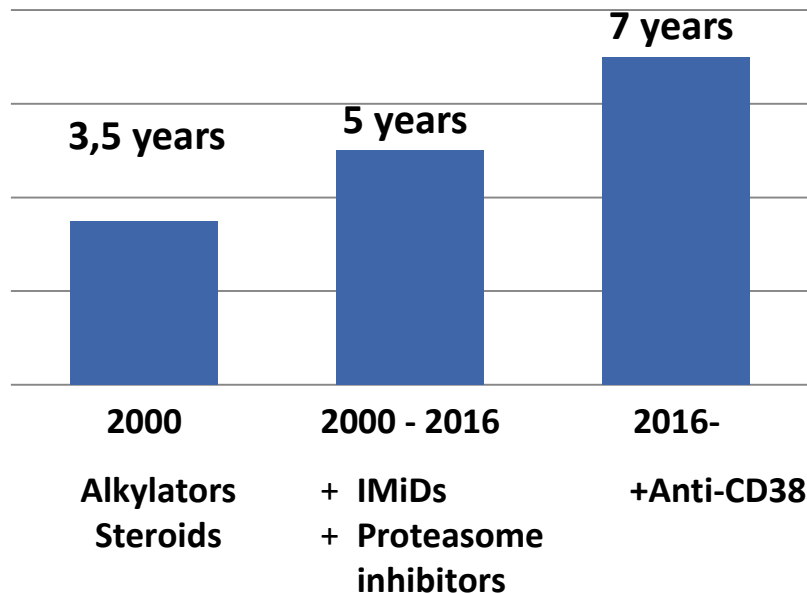


Multiple Myeloma is a hematological cancer without cure

Myeloma – Uncontrolled plasma cell proliferation

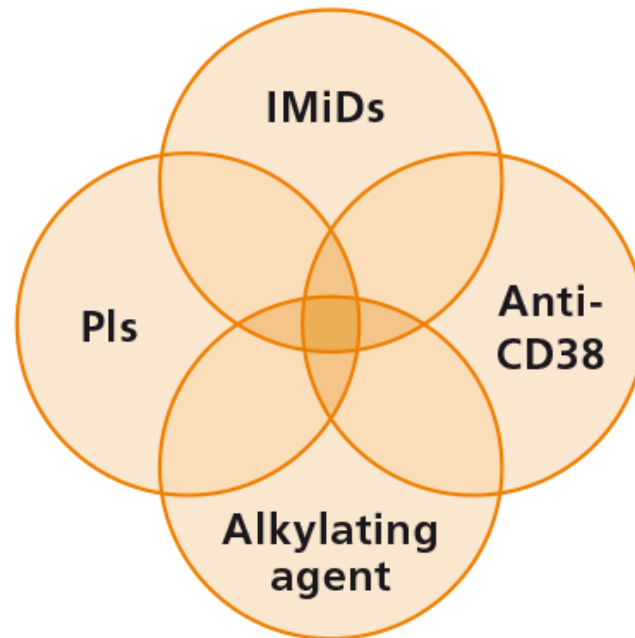


Median Survival increasing with more available treatment options



Significant medical needs remain

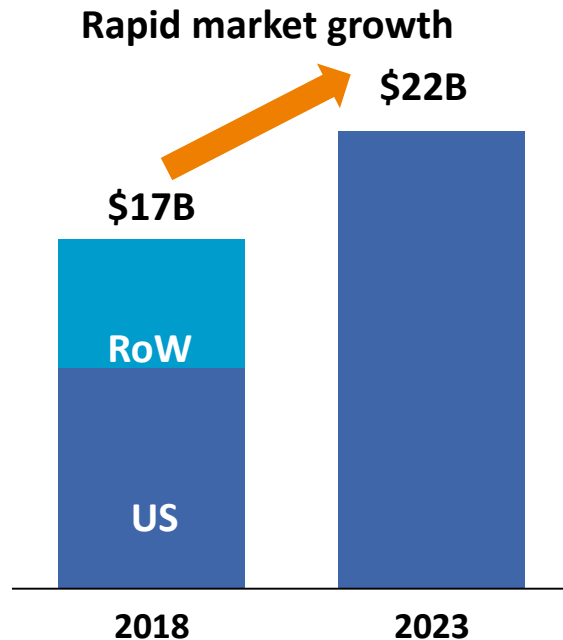
- Four treatment modalities used with inevitable resistance development
- Currently, the majority of patients have been treated with all four modalities after 2-3 lines of therapy with limited treatment options left
- Frequent co-morbidities further compounding the problem with limited treatment options



Multiple Myeloma is a fast growing market

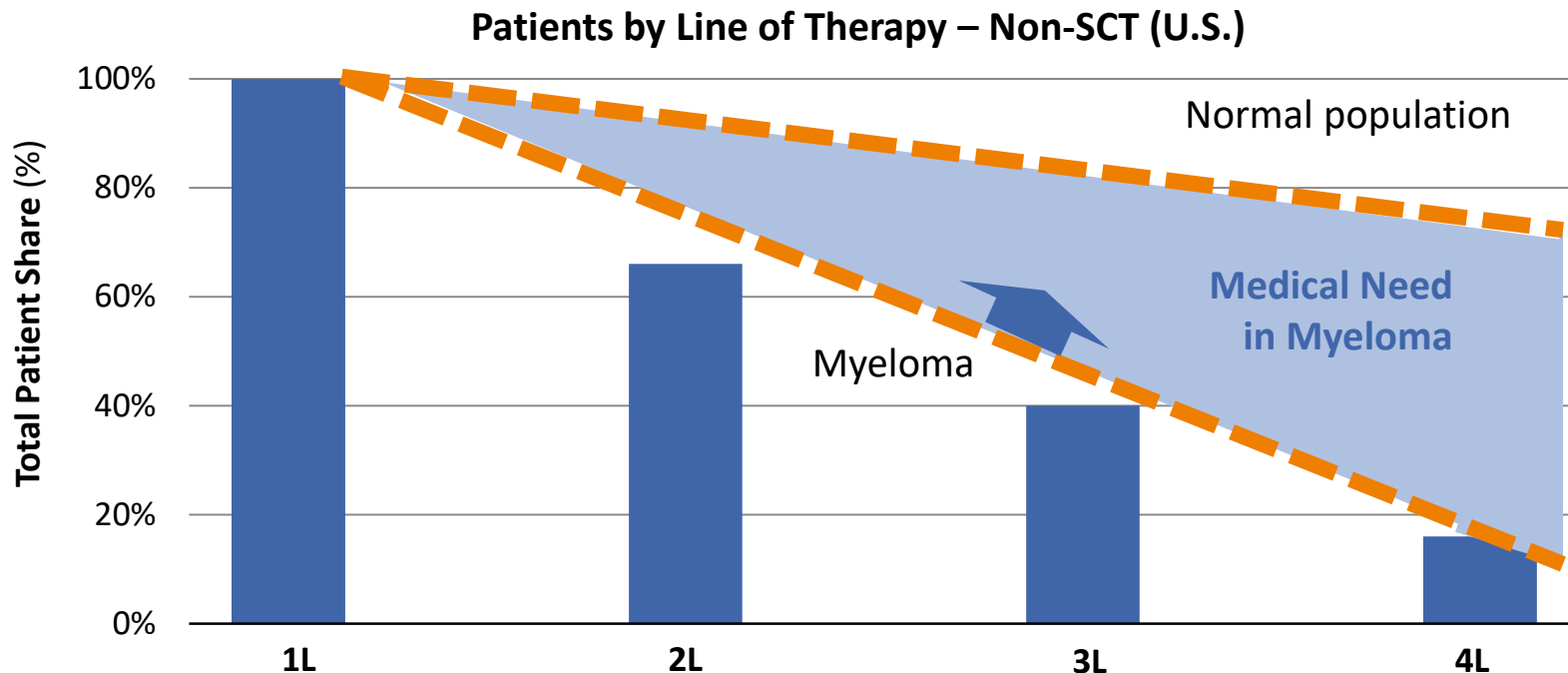
– Approvals of novel agents have expanded market

- IMiDs and PIs will continue to be the foundation of early myeloma care
 - All patients will be treated with these two classes of drugs at least once during the course of disease
 - Revlimid holds majority of the multiple myeloma market in value due to long durations of treatment
- Daratumumab has driven market growth in both number of patients treated and duration on therapy
- Late stage multiple myeloma patient pool is growing due to improved therapies – an increased number of treatment months per patient



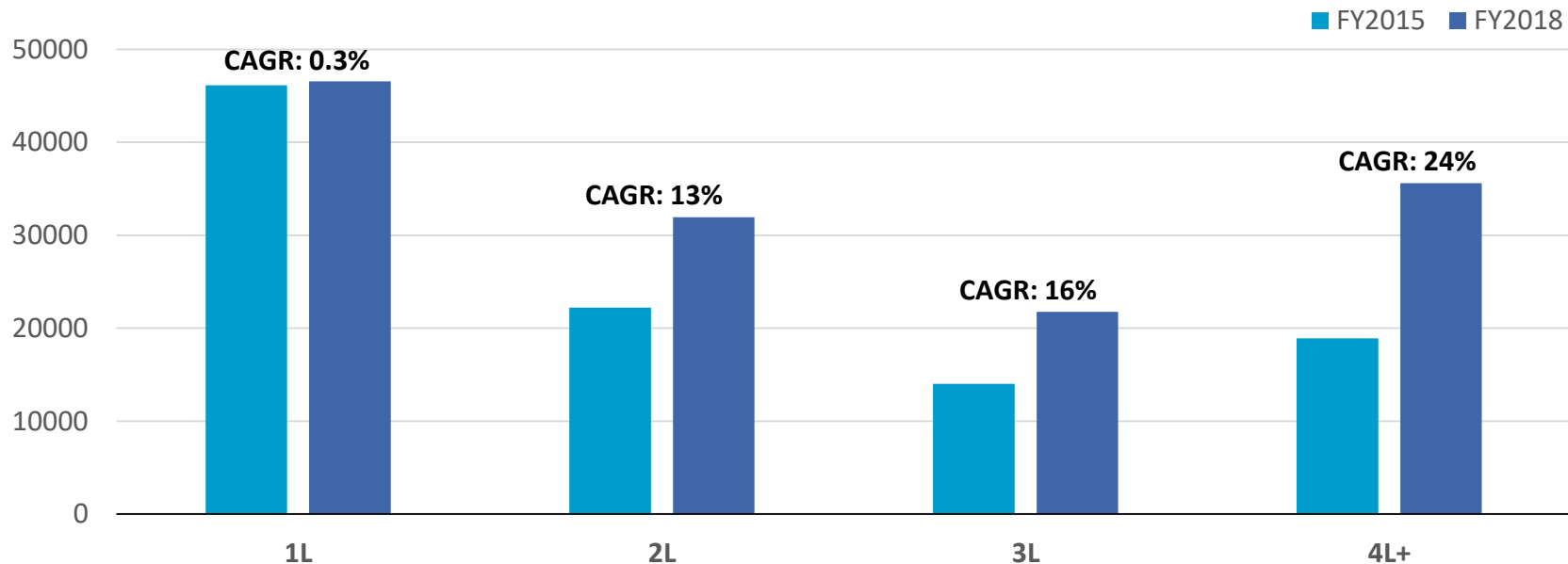
We are still far from making myeloma a chronic disease

- Later line patient population growing with significant need for new treatments



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 Dec 2018, MAT

Note: 3-yr annual growth rate for 2015-2018

Requirements for success in Relapsed Refractory Multiple Myeloma

MUST HAVE CHARACTERISTICS

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

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

Proven single agent activity

Comorbidity or tolerability limitations

Limited to no single agent data

 **Pomalyst**

 **DARZALEX**

 **Kyprolis**

 **FARYDAK**
(panobinostat) capsules
10mg / 15mg / 20mg

 **NINLARO**

 **Empliciti**
(elotuzumab)

Development program for Melflufen is designed to support its potential as a new agent after IMiD and PI failure

MUST HAVE CHARACTERISTICS

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NICE TO HAVE CHARACTERISTICS

Easy administration schedule

MELFLUFEN

O-12-M1 showed an ORR of 31% and HORIZON an ORR of 30% in multi-refractory patients

OCEAN head to head study vs. Pomalyst/dex is designed for approval

ANCHOR shows excellent synergy and good tolerability with daratumumab and bortezomib (early data)

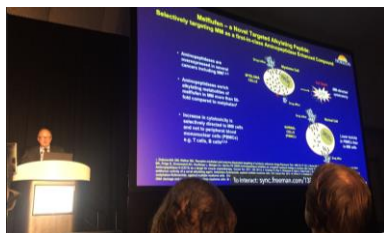
Good QoL with almost no non-hematological AEs

No co-morbidity or drug-drug interactions limitations

One 30 minute infusion every 28 days

Strong data presented at ASH 2018

- Interim HORIZON data in patients with no or limited treatment options presented by Prof. Paul Richardson
- Melflufen in combination with bortezomib and daratumumab presented from the ANCHOR trial



Jim Omet @IMFJimMYELOMA · Dec 5

Good News on the HORIZON: **Melflufen** Induces Response in Heavily Refractory Myeloma ashclinicalnews.org/on-location/go ... via @ASH Clinical News Among all the new novel therapies available for patients, remember that alkylators are still very useful in [#myeloma](https://twitter.com/myeloma) therapy.



Omar Nadeem, MD @DrOmarNadeem · Dec 3

Melflufen with promising activity in refractory population as presented by Dr. Richardson @DanaFarber #ASH18 #mmsm



HematologyTimes.com @HematologyTimes · Dec 3

#Melflufen plus **#dexamethasone** shows "promising activity" in **#multiplmyeloma** patients refractory to **#daratumumab** and/or **#pomalidomide**. **#myeloma** #ASH18 #ASH2018 abstract600



"Good News on the HORIZON: Melflufen Induces Response in Heavily Refractory Myeloma"

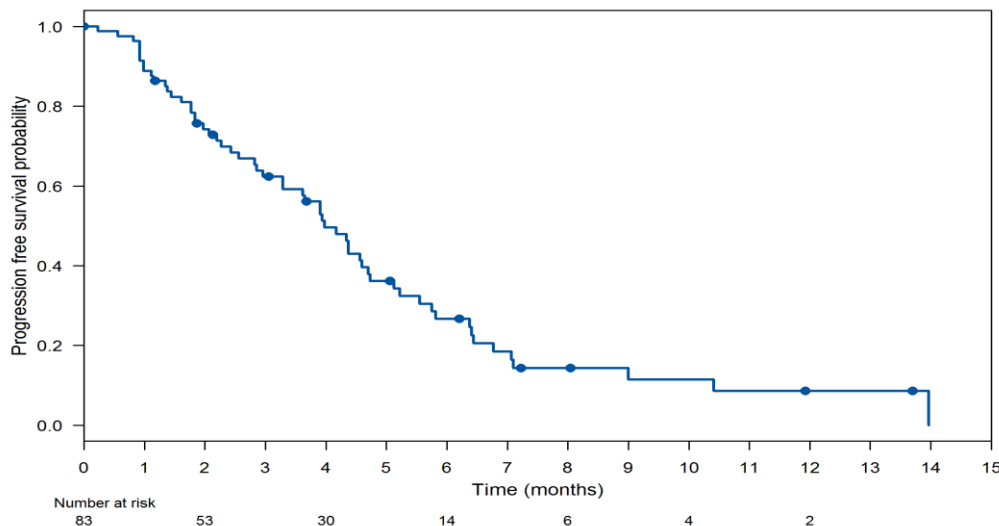
"Safety And Efficacy of Melflufen for Relapsed Refractory Multiple Myeloma Patients"



Promising efficacy data for patients without remaining treatment options presented at ASH

Response	NE	PD	SD	MR	ORR	sCR	VGPR	PR
% (n)	1% (1)	15% (12)	45% (37)	6% (5)	33% (27)	1% (1)	11% (9)	21% (17)

- n=83, 5-6 prior lines of therapy (median of 5)
- Strong overall response rate with 33%
- Median PFS of 4.0 months
- Strong activity in triple refractory (IMiD, PI and daratumumab) refractory patients



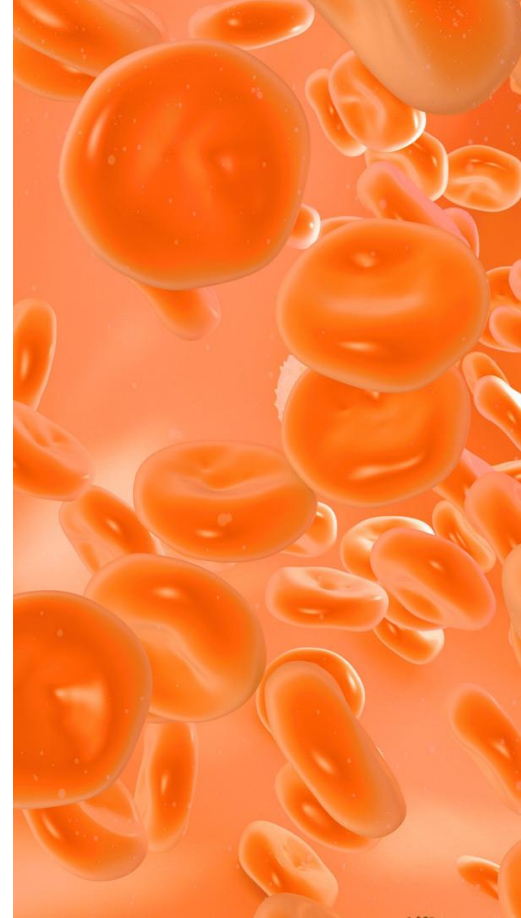
Safety indicates a very good quality of life profile for patients

- Absence of grade 3 and 4 TEAEs outside of the hematological system and infections and infestations
- Low infection rate in comparison with other myeloma drugs
- Hematological toxicity clinically manageable – 73% of patients in HORIZON maintain the full 40mg dose while on treatment despite low bone marrow reserves

Grade 3 and 4 TEAEs occurring in >5% of patients	
	HORIZON
SAE rate	37%
Hematological	
Anemia	26%
Leukopenia	
Lymphopenia	
Neutropenia	55%
Thrombocytopenia	52%
Febrile neutropenia	5%
Infections and infestations	
Pneumonia	5%

Application process initiated for accelerated the US based on HORIZON

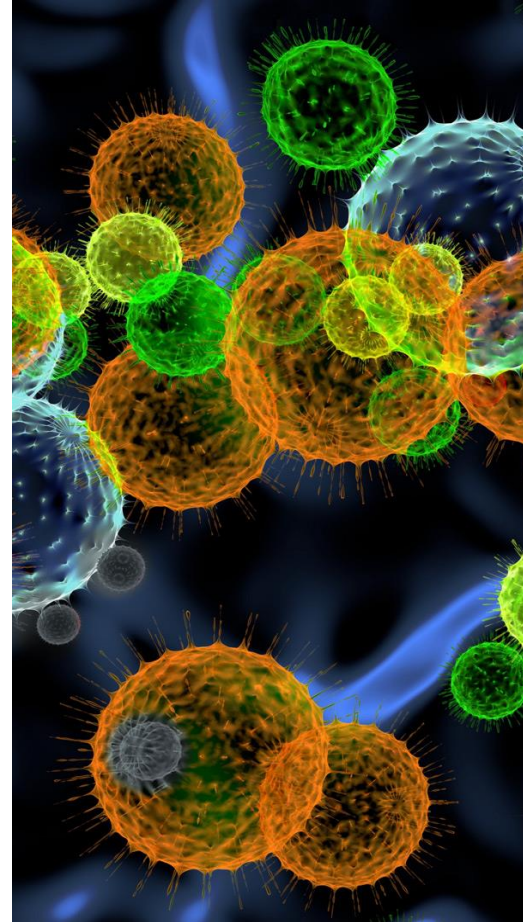
- Oncopeptides has been engaged in dialogue with the FDA during the Spring of 2019 about the HORIZON data
- FDA has had access to all data from our ongoing and completed trials (apart from OCEAN)
- Based on the dialogue, Oncopeptides has now initiated the submission process for accelerated approval in the US
 - Treatment of relapsed refractory multiple myeloma patients whose disease is triple-class refractory (i.e. refractory to one IMiD, one PI and one anti-CD38 Mab)
- Target filing date is Q1 2020



Data indicates synergistic effect of Melflufen+Daratumumab combination

Summary of combination with daratumumab – n=9

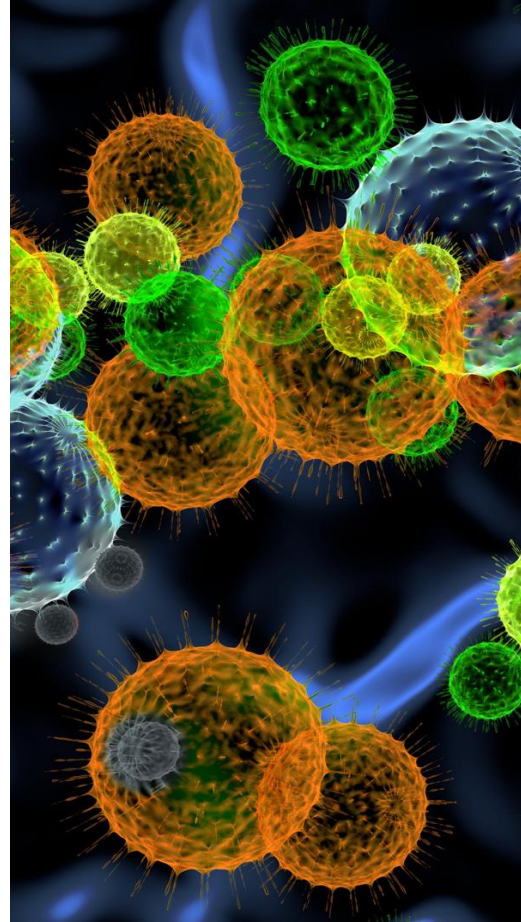
- 2-3 prior lines of therapy
- True RRMM population (not maintenance refractory) – 5/9 had disease progression while on last line of therapy
- 6/7 patients responded to therapy (ORR 86%) with good tolerability and deepening responses. All patients ongoing.



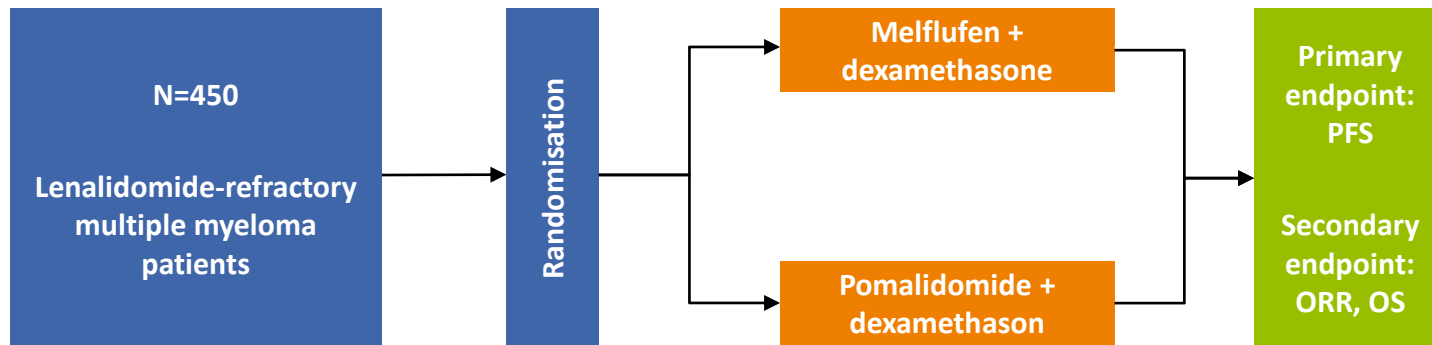
Data indicates synergistic effect of Melflufen+Bortezomib combination

Summary of combination with bortezomib – n=3

- Elderly population – 3 prior lines of therapy
- True RRMM population (not maintenance refractory) – 2/3 had disease progression while on last line of therapy
- 3/3 responded on therapy (ORR 100%) – all pts ongoing with good tolerability



Data to date provide high conviction for success in our phase 3 trial OCEAN



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

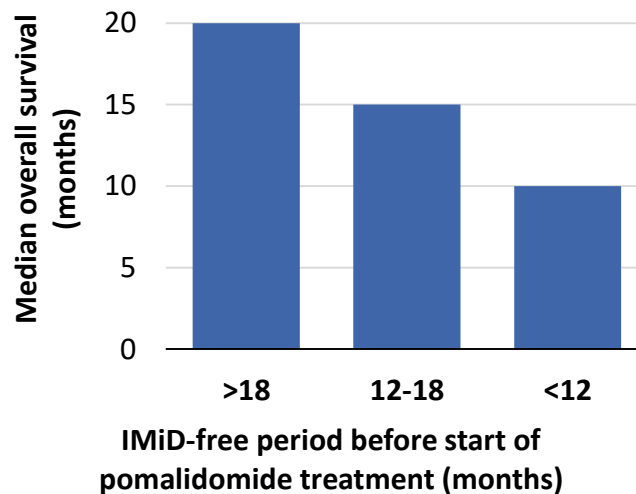
Treatment	ORR	CBR	Median PFS	Median DOR	Median OS
Melflufen + Dexamethasone	31%	49%	5.7 months	8.8 months	20.7 months
Pomalidomide + Dexamethasone	24%	NR	3.6 months	7.0 months	12.4 months

Pomalidomide shares resistance mechanism with lenalidomide

No assumption has been made in OCEAN power calculation about this factor

- Average IMiD free period was 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



Our new pivotal combination trial LIGHTHOUSE of high strategic importance

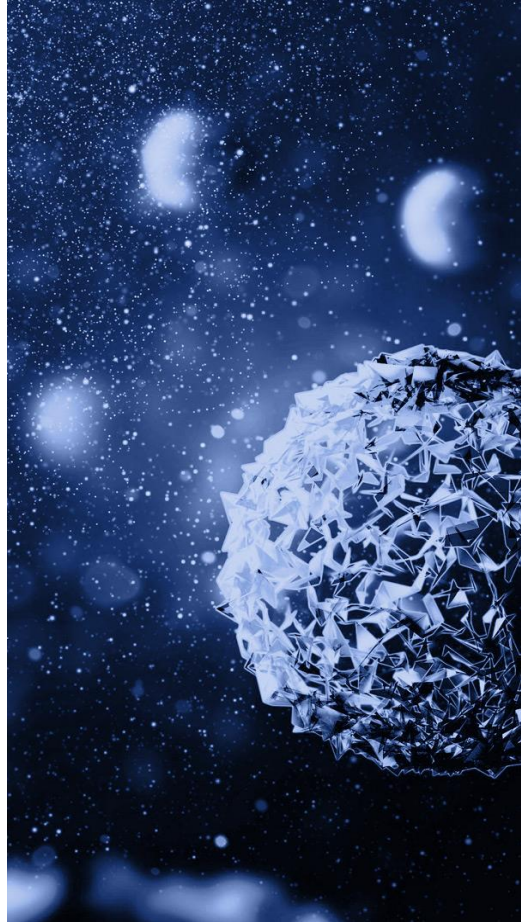
Second pivotal phase III trial with melflufen in multiple myeloma

- Melflufen+daratumumab+dexamethasone vs daratumumab+dexamethasone randomized 2:1

Two objectives:

- Expand market potential in myeloma by label extension to include treatment with melflufen in combination with daratumumab in earlier line patients
- De-risk the melflufen clinical development program in myeloma by adding a third trial that can result in market registration in the EU and US

We are preparing the study and aiming for enrolling the first patient in H2 2019



Our new indication AL Amyloidosis

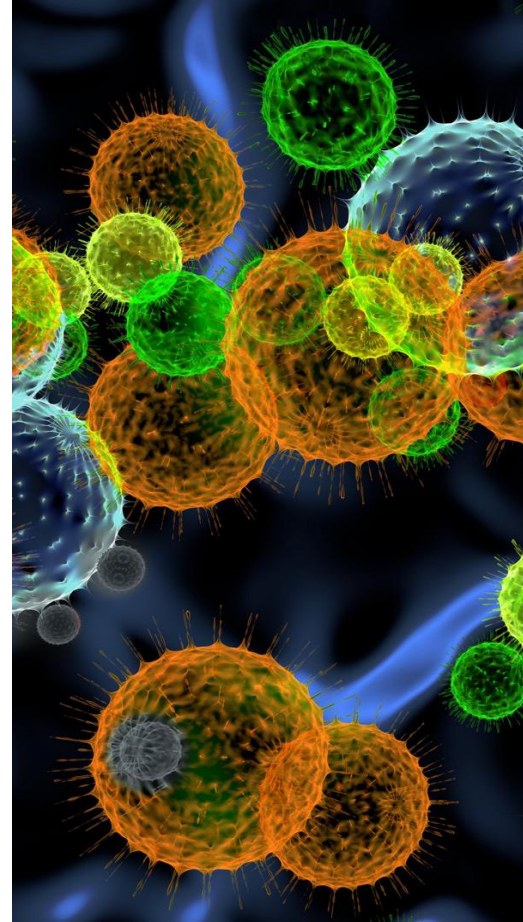
Similar to myeloma, AL amyloidosis is a disease of the B-cell system

- Antibody light-chains misfold and form deposits in multiple organs with organ dysfunction as a result
- Orphan disease - 30-45,000 patients in the USA and the EU¹
- Majority of patients >65 years old

Similar drug use as for myeloma – drugs that are efficacious in myeloma are also most of the time efficacious in AL amyloidosis

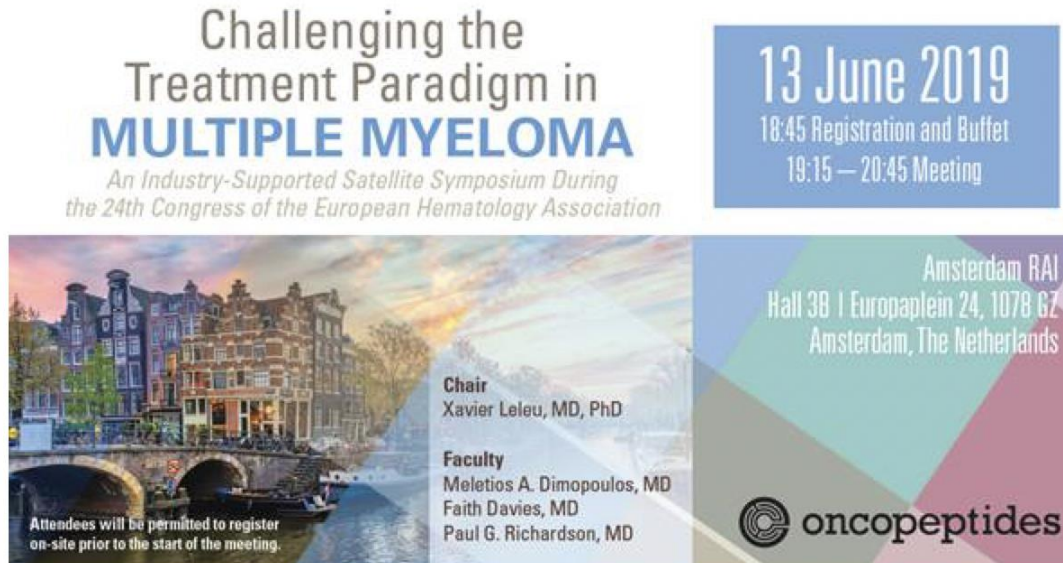
Limited treatment options with median overall survival of 1.5-2.0 years (1995-2013) with a trend towards improved survival (3.5 years for the period 2010-2013)²

Phase I+II study with first-patient-in H2 2019 – up to 30 patients across both phases



EHA is a major event for us

- One oral presentation by Prof. Paul Richardson regarding HORIZON
- Three poster presentations regarding ANCHOR, parameters of health economic importance from O-12-M1 as well as a safety review in RRMM (not only melflufen)
- One satellite symposium (see below)



The poster is divided into several sections. At the top, the title 'Challenging the Treatment Paradigm in MULTIPLE MYELOMA' is displayed in a mix of blue and black fonts. Below it, a subtitle reads 'An Industry-Supported Satellite Symposium During the 24th Congress of the European Hematology Association'. The central part of the poster features a scenic image of a canal in Amsterdam with historic buildings and a bridge. To the right of this image, the date '13 June 2019' is prominently shown in white on a blue background, with the schedule '18:45 Registration and Buffet' and '19:15 — 20:45 Meeting' listed below it. Further down, the location is given as 'Amsterdam RAI, Hall 38 | Europaplein 24, 1078 GZ, Amsterdam, The Netherlands'. The names of the Chair, Xavier Leleu, MD, PhD, and the Faculty members, Meletios A. Dimopoulos, MD; Faith Davies, MD; and Paul G. Richardson, MD, are listed. At the bottom left, a note states 'Attendees will be permitted to register on-site prior to the start of the meeting.' The Oncopeptides logo is at the bottom right.

Challenging the Treatment Paradigm in MULTIPLE MYELOMA
An Industry-Supported Satellite Symposium During the 24th Congress of the European Hematology Association

13 June 2019
18:45 Registration and Buffet
19:15 — 20:45 Meeting

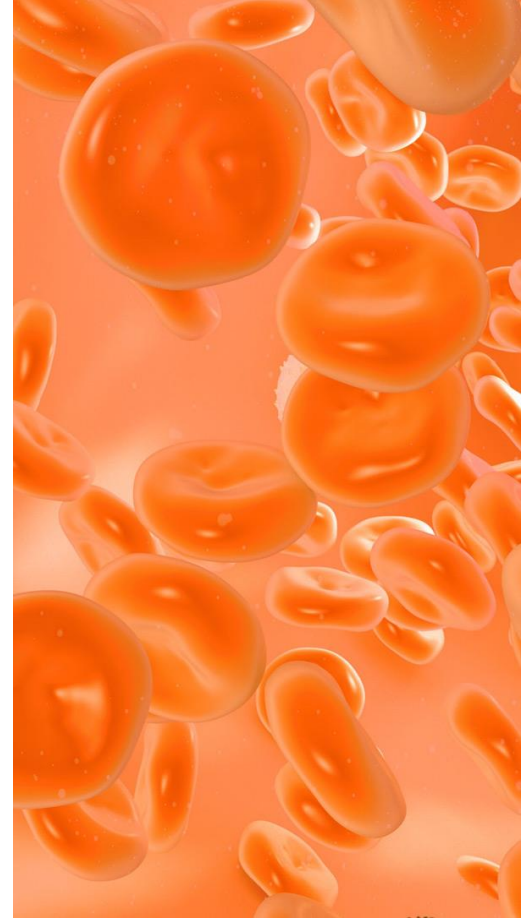
Amsterdam RAI
Hall 38 | Europaplein 24, 1078 GZ
Amsterdam, The Netherlands

Chair
Xavier Leleu, MD, PhD

Faculty
Meletios A. Dimopoulos, MD
Faith Davies, MD
Paul G. Richardson, MD

Attendees will be permitted to register on-site prior to the start of the meeting.

 **oncopeptides**



Upcoming newsflow – highly exciting year ahead of us

H1 2019	H2 2019	H1 2020
Data from ANCHOR and HORIZON at AACR	FPI Amyloidosis Trial	NDA submission
Updated data from ANCHOR and HORIZON at EHA	FPI LIGHTHOUSE	LPI OCEAN
FDA meeting on HORIZON	LPI HORIZON	LPI ANCHOR
O-12-M1 publication	LPI BRIDGE	Top-line results OCEAN
	Updated Data from HORIZON, ANCHOR and BRIDGE at ASH	

Summary

Significant unmet needs in Multiple Myeloma

- \$17 B orphan market

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

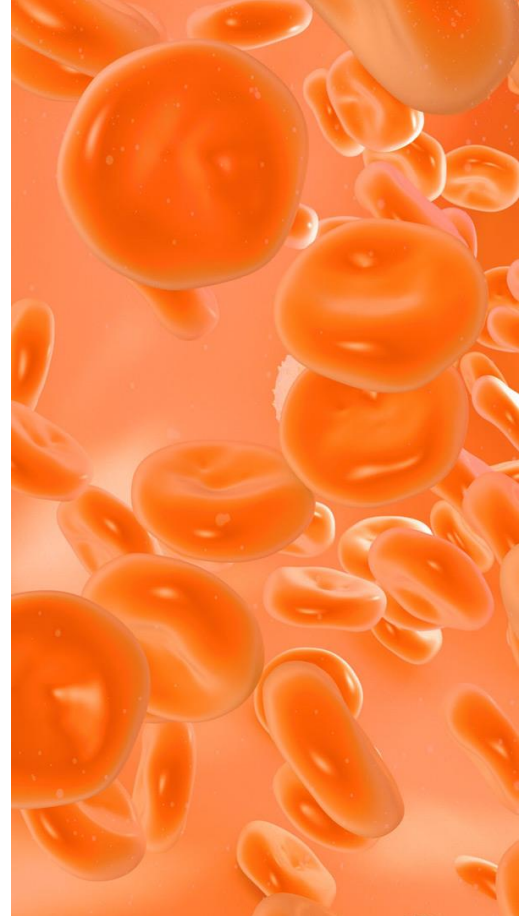
- Phase 2 showed very strong survival data
- Generally well tolerated giving patients good quality of life

Broad development program with multiple ways to get approval

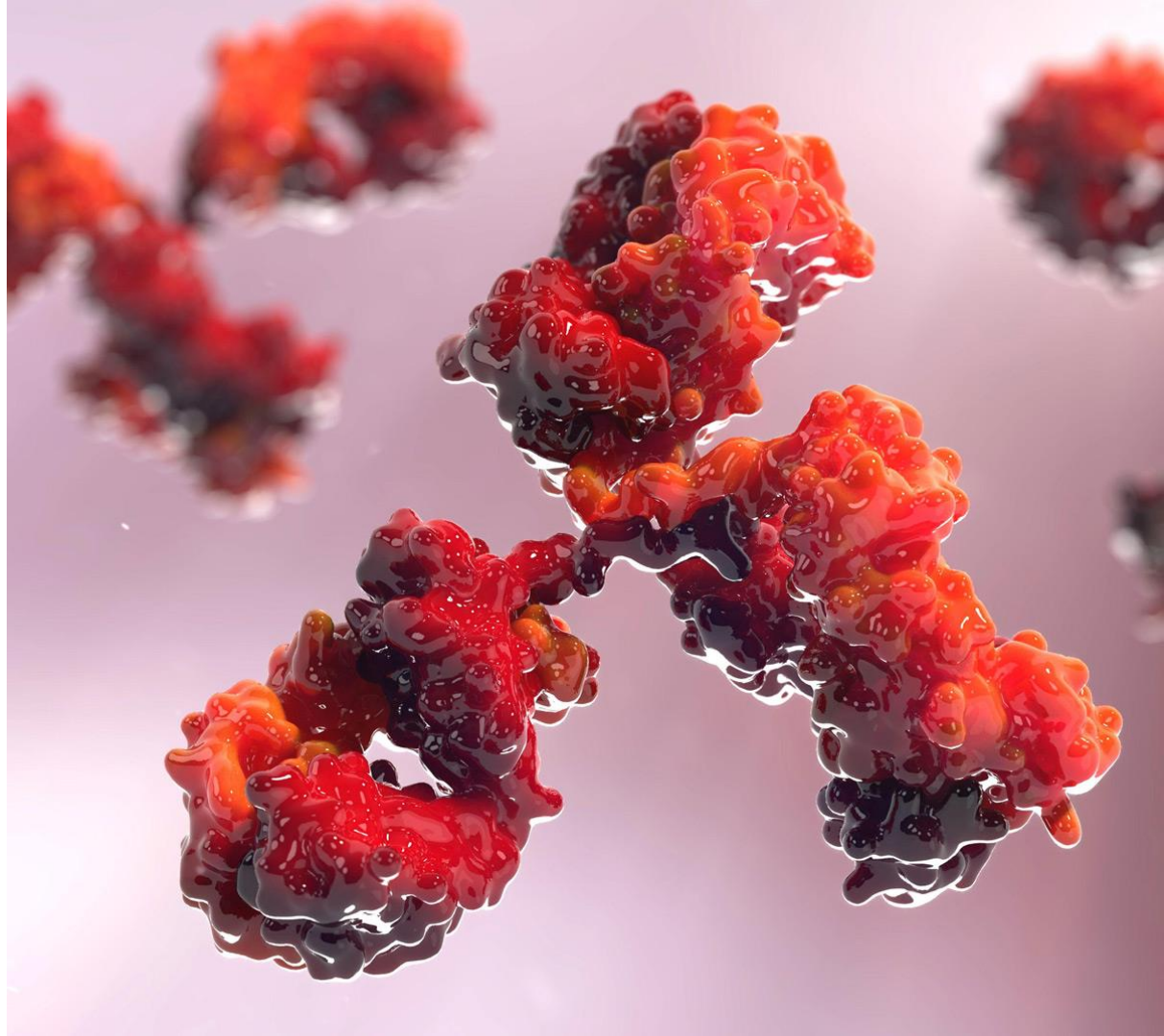
- Submission for accelerated approval for triple-class refractory patients in the US targeted in Q1-20
- Pivotal phase 3 expected to be fully enrolled Q1 2020
- Additional Phase 3 to be started 2019

Strong financial position

- Cash position March 31, 2019: SEK 747.5 M



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



Financial results for the period Jan – Mar 2019



- Operating loss increased to SEK 121.9 M (loss:62.0)
 - R&D increase primarily due to increase in clinical & drug supply: SEK 73.1 M (46.8)
 - OCEAN costs SEK 37.6 M (29.8)
 - ANCHOR costs SEK 13.2 M (3.5)
 - HORIZON costs SEK 11.0 (5.3)
 - Build-up of commercial and medical relations explains increase in M&S costs
- Operating costs include non-cash costs related to incentive programs
 - SEK 7.9 M (2.4) for q1
- Cash flow from operating activities neg. SEK 142.8 M (neg. 40.6)
 - Cash flow from financing activities SEK 514.0 M (295.0)
- Cash position was SEK 747.5 M (664.9) as of March 31, 2019
 - Directed share issue raised SEK 514.8 M after issue costs in January, 2019

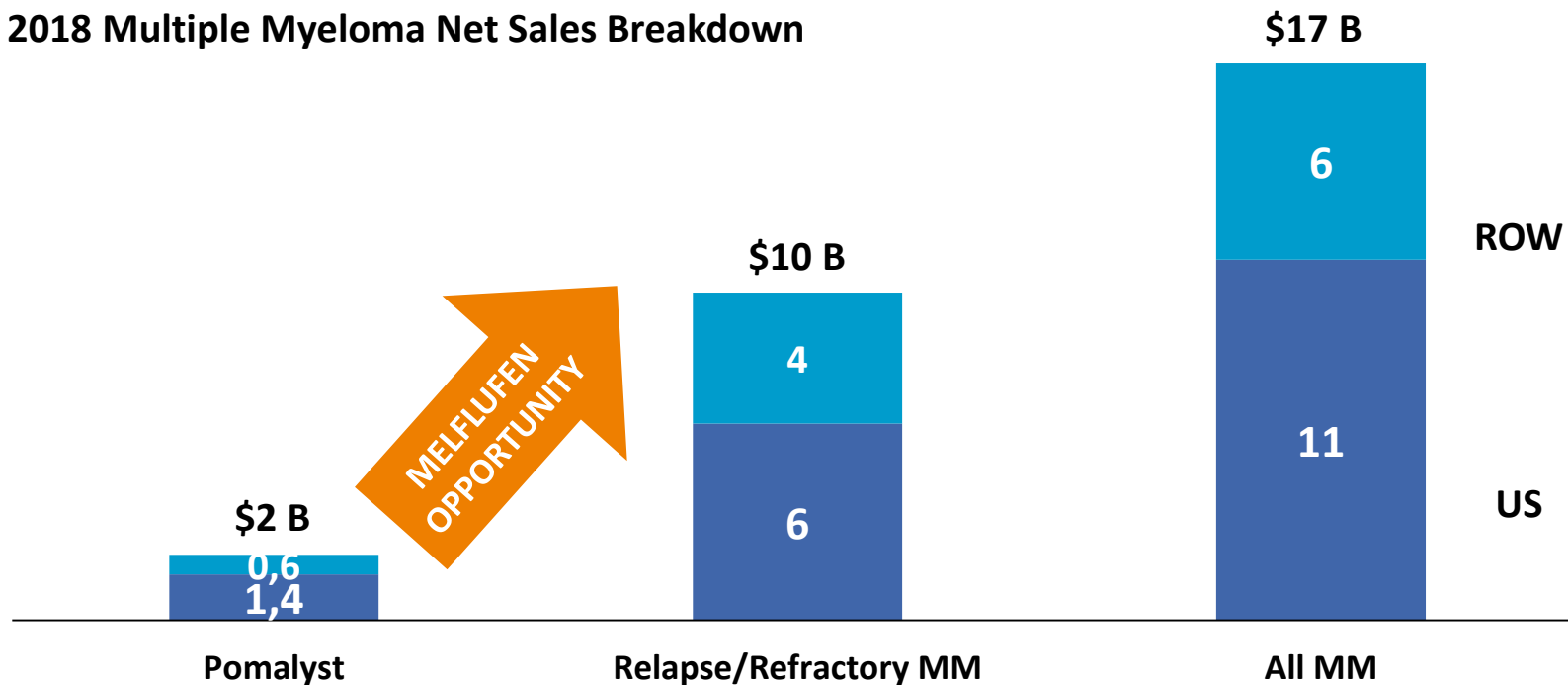
Summary of key late stage development programs in RRMM – all new mechanisms have safety issues

Name	Company	MoA	Phase	Patient population	Efficacy*	Safety	Estimated approval
Daratumumab SC	J&J/ Genmab	aCD38 Mab	III	3+ prior lines (may expand to all Dara IV indications)	ORR: 41% SC vs. 37% IV	No new safety signals vs. IV	1H20
Isatuximab	Sanofi	aCD38 Mab	III	2+ prior lines	ORR: 24% PFS: 18.7mo	Infusion site reactions, cytopenia	1H20
Selinexor	Karyopharm	SINE, XPO1	Filed	Triple refractory	ORR: 26% PFS: 3.7mo	GI toxicity, cytopenia, dose modifications	July 2019 PDUFA
Venetoclax	Abbvie/ Roche	BCL-2	III	1-3 prior lines	ORR: 21%	Deaths, cytopenia	Clinical hold - TBD
bb2121	Bluebird/ Celgene	BCMA CAR-T	II	3+ prior lines	ORR: 85% PFS: 11.8mo	Cytokine release syndrome, cytopenia	2H20
GSK916	GSK	BCMA ADC	II	3+ prior lines	ORR: 60% PFS: 12mo	Blurred vision, cytopenia	2H20

* Latest data cut for single agent + dexamethasone trials

Melflufen opportunity in Relapsed Refractory Multiple Myeloma

– 2018 Multiple Myeloma Net Sales Breakdown



O-12-M1 phase 2 study generated best overall survival data to date in late stage myeloma

	Melflufen	Daratumumab	Pomalidomide*	Carfilzomib
N	45	106	302	266
Year	2017	2016	2013	2012
Population	Refractory to last, exposed to iMiD, PI and alkylator, IMiD and PI refractory	Refractory to last, ≥3 lines with IMiDs and PI, double refractory to PI and IMiD	Refractory to last, at least 2 lines with bort and len and received alkylator	>2 prior for relapsed including Bar, Len or thal, alk or anthra alone or in combo
Time from diag.	5.0 years	4.8 years	5.3 years	5.4 years
High risk Cytog.	44%	19%	~30%	28%
Number of lines	4, 78% ≥3 lines	5, 82% ≥3 lines	5, 94 % ≥2 lines	82% ≥4 lines
Refract. to last	87%	97%	100.0%	94.0%
ORR	31.1%	29.2%	23.5%	23.7%
ORR high risk	25%	20%	–	29.6%
Med. duration treat	3.7 months	-	Progressive Disease or Unacceptable Toxicity	3.0 months
Med. duration response	8.4 months	7.4 months	7.0 months	7.8 months
Median PFS	5.7 months <11.7 in ≥PR)	3.7 months	3.6 months	3.7 months
Median OS	20.7 months	17.5 months	12.4 months	15.6 months

Source: Richardson PG *et al.*, ASH 2017; Usmani SZ *et al.*, 2016; Miguel JS *et al.*, 2013; Siegel DS *et al.*, 2012

* = source FDA label



oncopeptides | 30

Data indicates synergistic effect of Melflufen and Dex in combination with Daratumumab

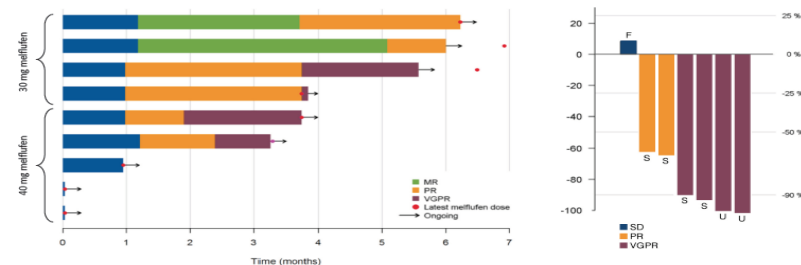
Patient Characteristics

Characteristics	Melflufen + dex + dara (N=9)
Median age, years (range)	63 (35-78)
Median time since diagnosis, years (range)	4.0 (1.8-6.6)
Number of previous lines (range)	2.0 (1-3)
ISS at study entry, n (%)	
I	8 (89)
II	0
III	1 (11)
High-risk cytogenetic risk factor by FISH*, n(%)	3 (33)
Median albumin (range)	4.1 (3.1-4.5)
High LDH (1.5 x UNL)	3 (33)
IMiD refractory, n (%)	6 (67)
PI refractory, n (%)	2 (22)
IMiD + PI refractory, n (%)	1 (11)
Alkylator, n (%)	2 (22)
Last line refractory, n (%)	5 (56)

Manageable hematological AEs and very few non-hematological AEs

	Melflufen+bortezomib+dex (N=9)	
	Grade %, n (%)	Grade 4, n (%)
Any treatment-related AE	7 (78)	4 (44)
Neutropenia	6 (67)	0
Thrombocytopenia	3 (33)	1 (11)
Lymphocyte count decrease	3 (33)	3 (33)
White blood cell count decrease	1 (11)	1 (11)

Overall response rate 86%



Encouraging data for Melflufen+Bortezomib combination presented at ASH

Patient Characteristics

Characteristics	Melflufen+bortezomib+dex (N=3)
Median age, years (range)	81 (70-82)
Median time since diagnosis, years (range)	6.9 (5.7-7.3)
Number of previous lines (range)	3 (2-4)
ISS at study entry, n (%)	
I	3 (100)
II	0
III	0
High-risk, cytogenetic risk factor by FISH*, n (%)	0
Median albumin, n (range)	3.9 (3.6-4.2)
High LDH (1.5 x UNL), n (%)	2 (67)
IMiD refractory, n (%)	3 (100)
Dara refractory, n (%)	1 (33)
Alkylator refractory, n (%)	1 (33)
Last line refractory, n (%)	2 (67)

Few non-hematological AEs

	Melflufen + dex + bortezomib (N=3)	
	Grade 3, n (%)	Grade 4, n (%)
Any treatment-related AE	2 (67)	0
Neutropenia	2 (67)	0
Thrombocytopenia	2 (67)	0
Pneumonia pneumococcal	1 (33)	0

Overall response rate 100%

