Oncopeptides

Presentation at Avanza lunch meeting

Jakob Lindberg, CEO

27 November, 2019

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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 study, O-12-M1, 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

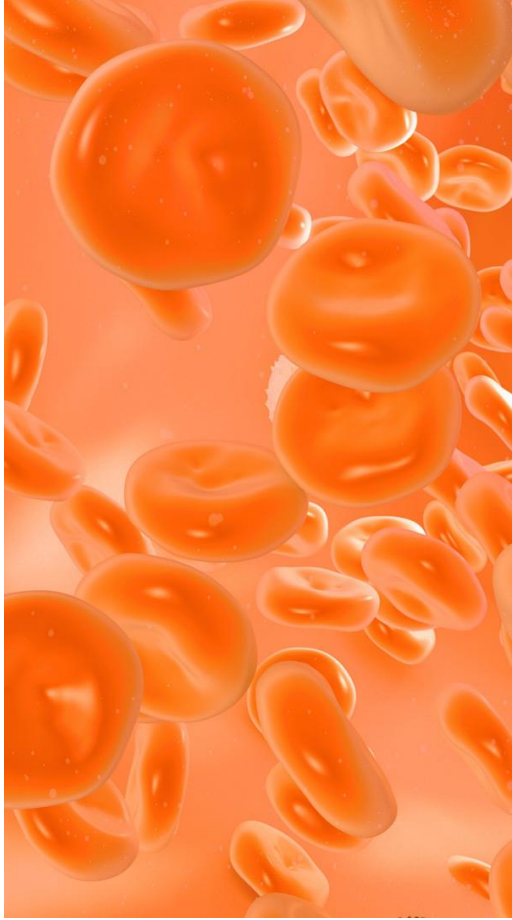
- Approximately 450 patients at 140 sites
- Two additional supporting trials ongoing, additional Phase 3 called LIGHTHOUSE will start early 2020

New indications and NCEs in development

- A Phase 1/2 study addressing AL amyloidosis to start shortly

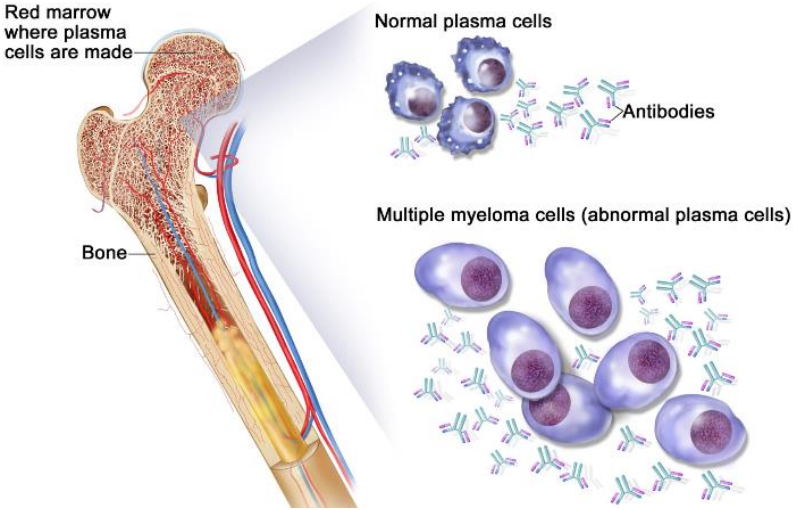
Listed on NASDAQ Stockholm, strong financial position

- Market cap: SEK 7.0 B ($ 725 M)
- Cash position: SEK 1,122 M ($ 116 M) as of September 30

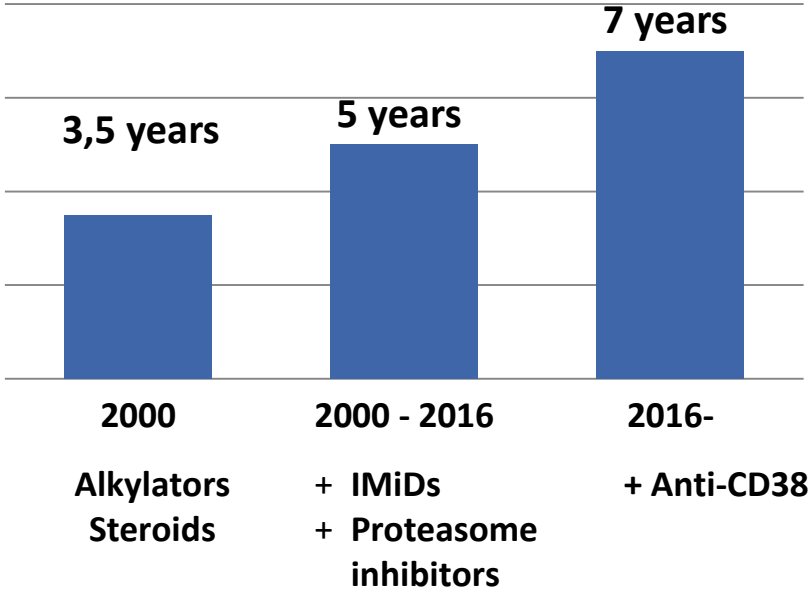


Multiple Myeloma is a hematological cancer without cure

Myeloma – Uncontrolled plasma cell proliferation



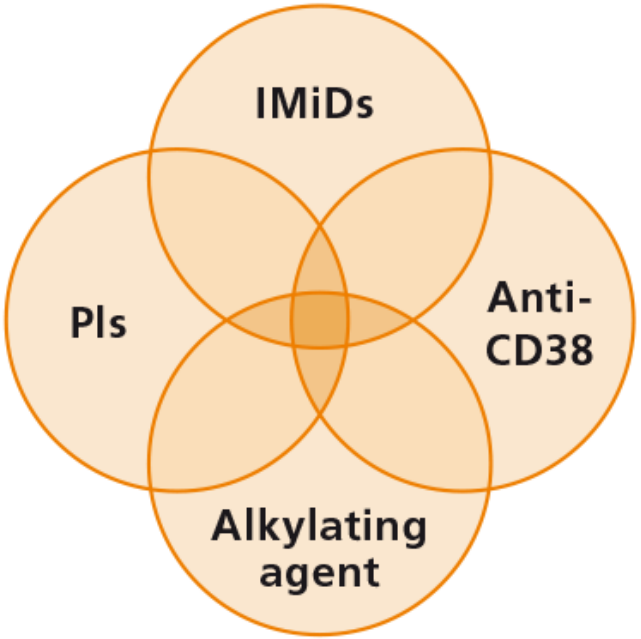
Median Survival increasing with more available treatment options



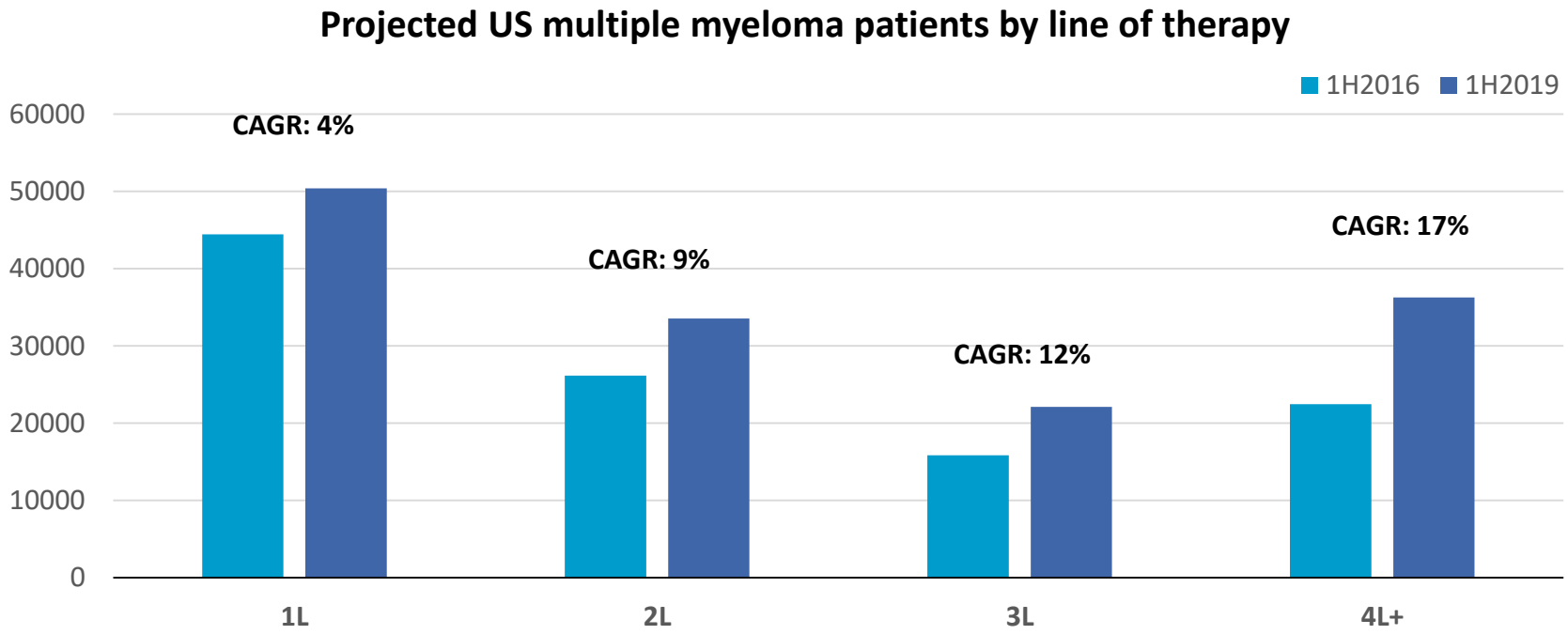
Source: IntrinsiQ and Kantar Health.

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

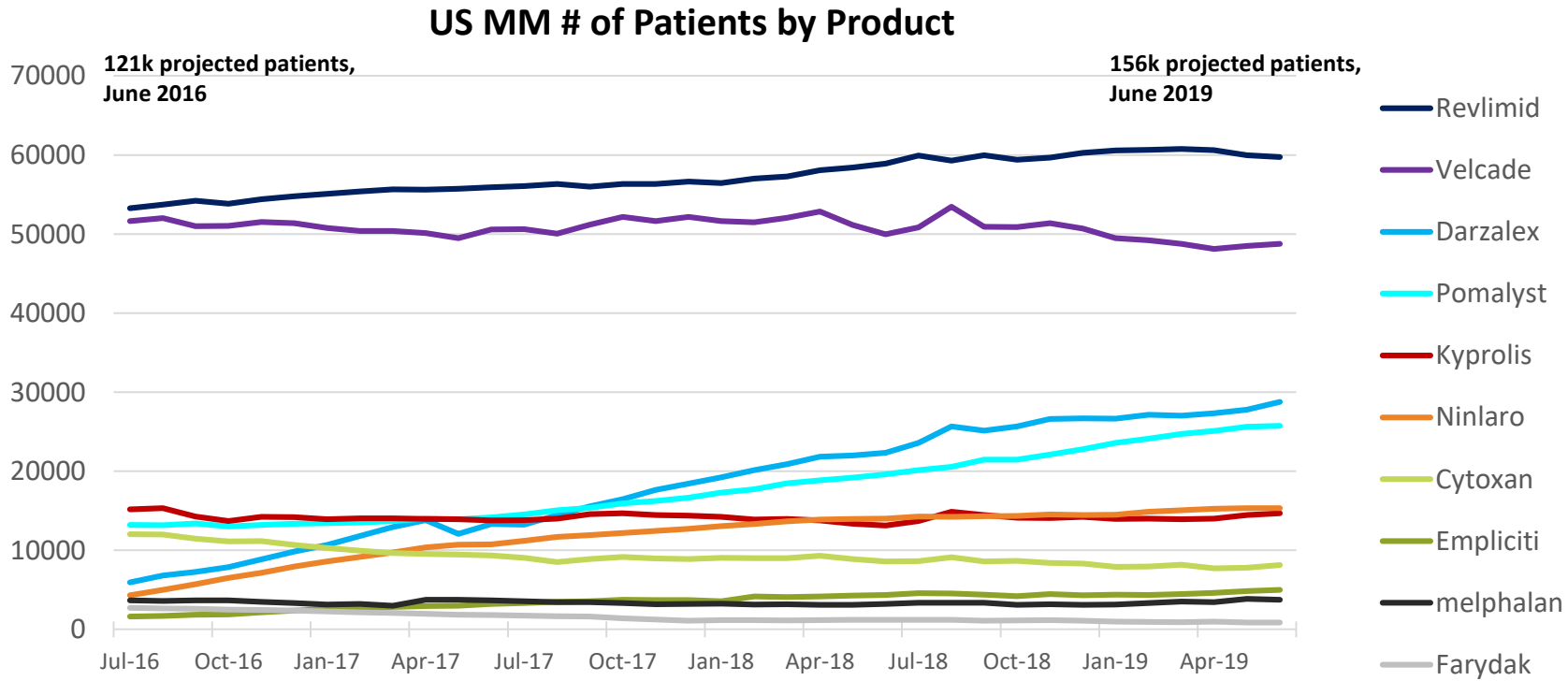


Improved outcomes lead to fast growth in number of treated patients in later lines of therapy



Source: Intrinsiq MAT, June 2019
Note: 3-yr annual growth rate for 1H2016-2H2019

Newer products used in addition to, not in place of, older products as survival increases



Source: Intrinsiq MAT, June 2019

Melflufen is a first in class peptide-drug conjugate

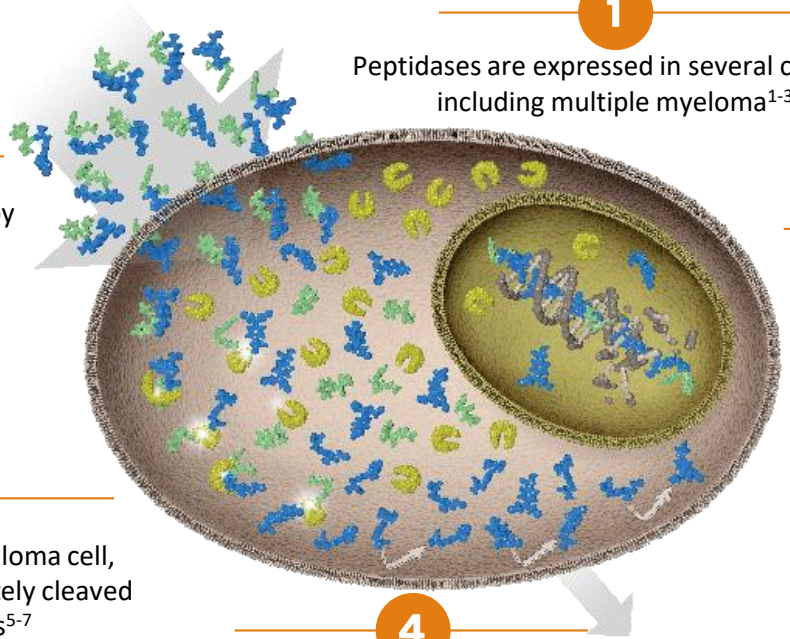
- Uses high peptidase levels to target myeloma cells

1

Peptidases are expressed in several cancers, including multiple myeloma[1-3]

2

Melflufen is rapidly taken up by myeloma cells due to its high lipophilicity[4,5]



3

Once inside the myeloma cell, melflufen is immediately cleaved by peptidases[5-7]

4

The hydrophilic alkylator payloads are entrapped[5-7]

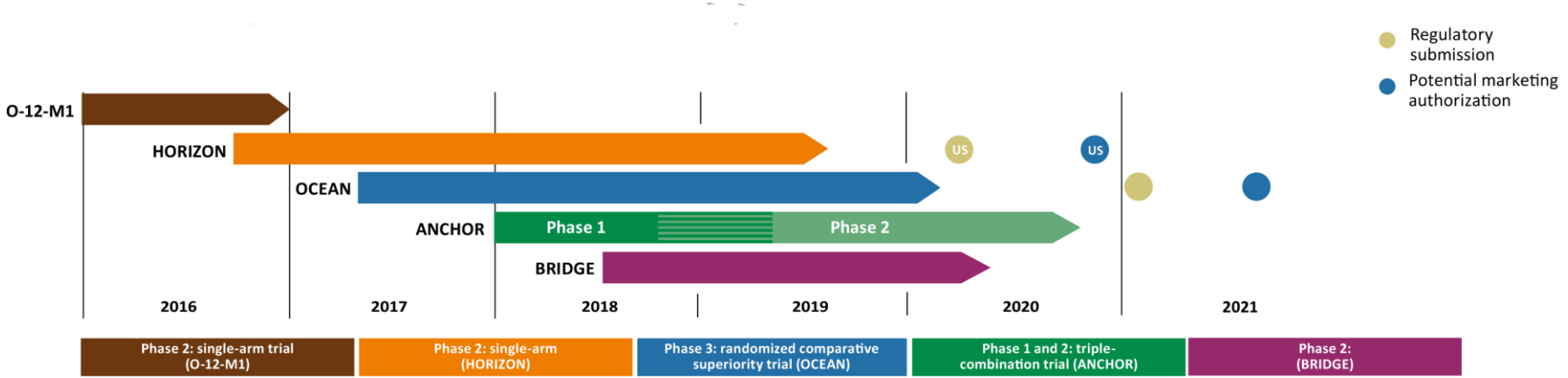
5

Melflufen rapidly induces irreversible DNA damage, leading to apoptosis of myeloma cells[4,8]

- Melflufen
- pFPhe (carrier)
- Peptidase
- Alkylator payload

Sources: 1. Hitzerd SM, et al. *Amino Acids.* 2014;46:793-808. 2. Moore HE, et al. *Mol Cancer Ther*. 2009;8:762-770. 3. Wickström M, et al. *Cancer Sci.* 2011;102:501-508. 4. Chauhan D, et al. *Clin Cancer Res.* 2013;19:3019-3031. 5. Wickström M, et al. *Oncotarget*. 2017;8:66641-66655. 6. Wickström M, et al. *Biochem Pharmacol.* 2010;79:1281-1290. 7. Gullbo J, et al. *J Drug Target.* 2003;11:355-363. 8. Ray A, et al. *Br J Haematol.* 2016;174:397-409.

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)

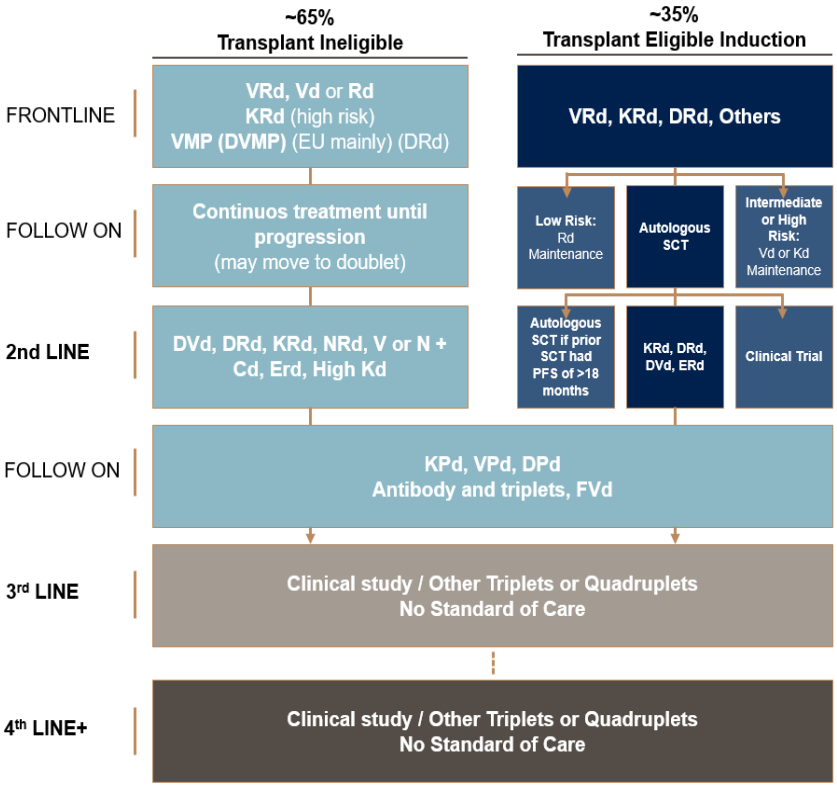
ANCHOR

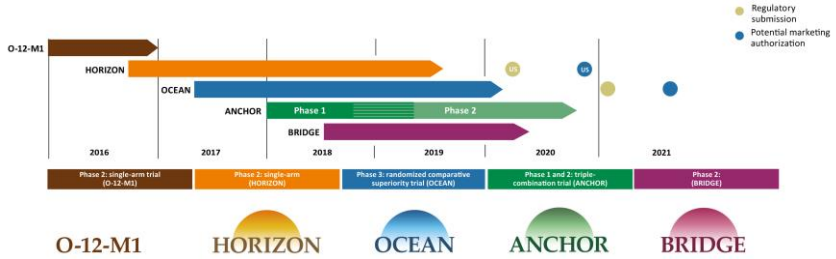
Show combination synergy and tolerability with daratumumab and bortezomib

BRIDGE

Show that melflufen can be used in patients with renal impairment

Clinical program covers entire relapsed setting





ANCHOR

LIGHTHOUSE

OCEAN ANCHOR

HORIZON OCEAN ANCHOR

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

Pomalyst

DARZALEX

Comorbidity or tolerability limitations

Kyprolis

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

Limited to no single agent data

NINLARO

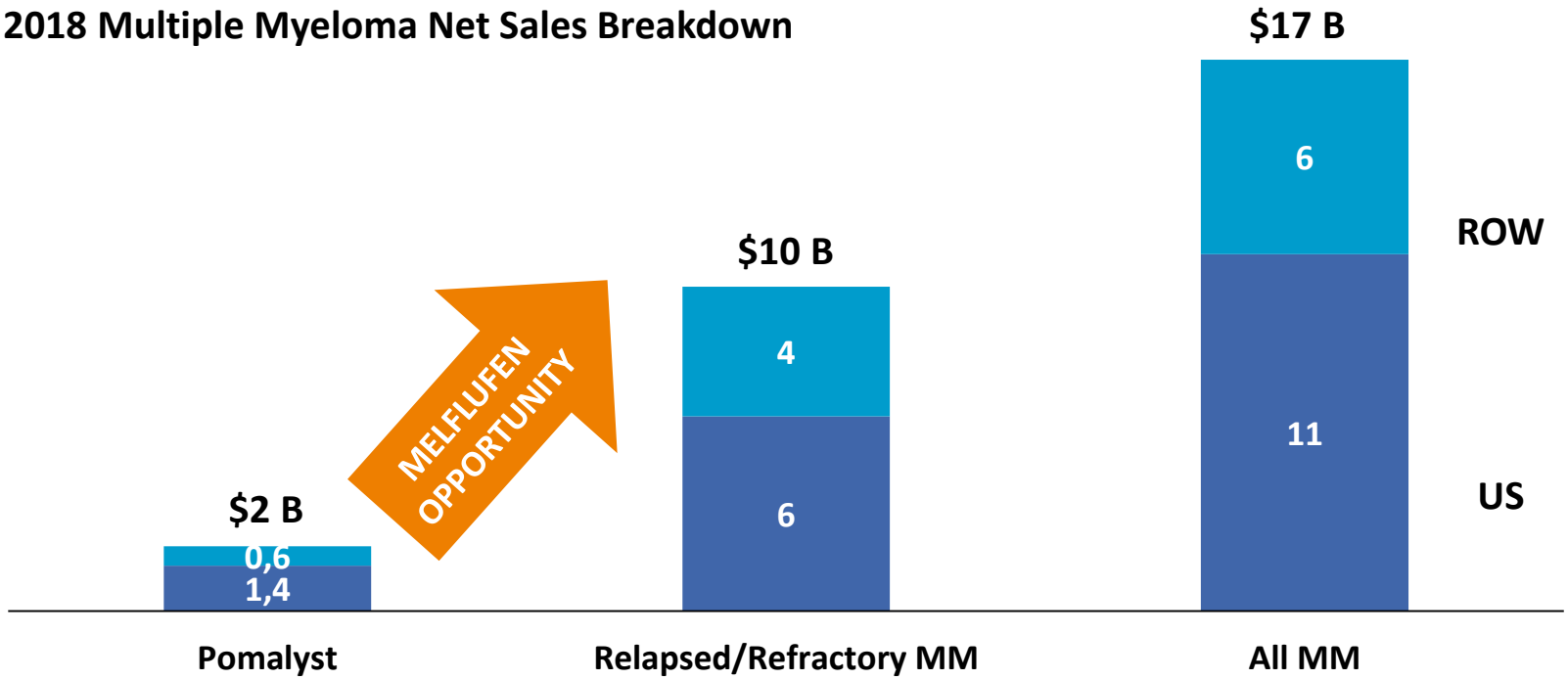
Empliciti (elotuzumab)

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

MUST HAVE CHARACTERISTICS	MELFLUFEN
Single agent +/- steroid activity in multi-refractory patients of >20% Overall Response Rate	O-12-M1 showed an ORR of 31% and HORIZON an ORR of 27% in multi-refractory patients
Single agent +/- steroid approval in refractory patients	OCEAN head to head study vs. Pomalyst/dex is designed for approval
Efficacy synergy in combination with other main myeloma drugs with good tolerability	ANCHOR shows excellent synergy and good tolerability with daratumumab and bortezomib (early data)
No major quality of life tolerability issues	Good QoL with almost no non-hematological AEs
No co-morbidity limitations	No co-morbidity or drug-drug interactions limitations
NICE TO HAVE CHARACTERISTICS	
Easy administration schedule	One 30-minute infusion every 28 days

Melflufen opportunity in Relapsed Refractory Multiple Myeloma

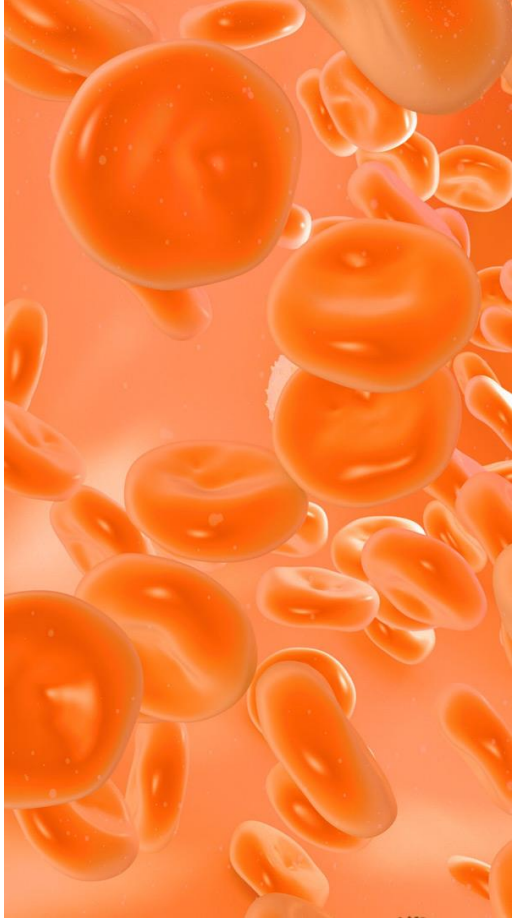
– 2018 Multiple Myeloma Net Sales Breakdown



Source: EvaluatePharma, Intrinsiq, company analysis

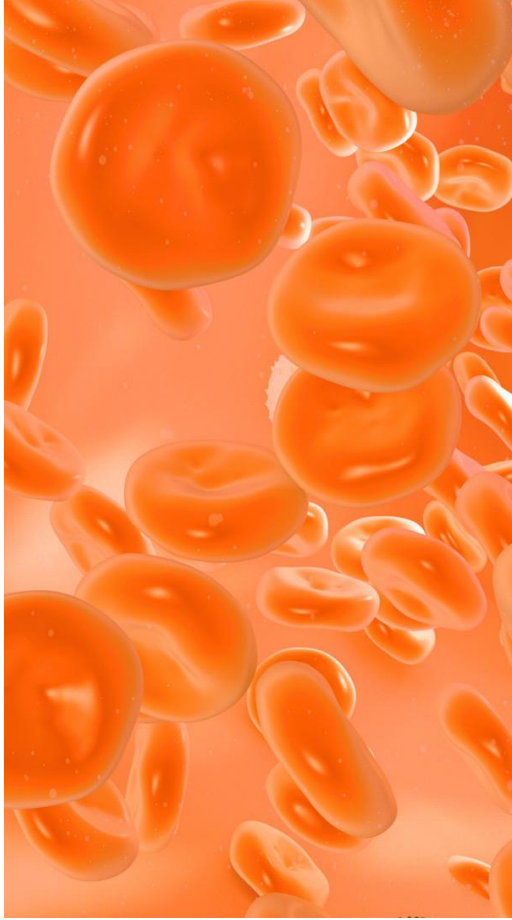
Recent highlights

- The last patient in the pivotal Phase 2 HORIZON trial was enrolled in September
- The application process for accelerated approval in the US based on HORIZON data is on track with submission planned late Q1 2020
  - US launch is expected late 2020, assuming a positive outcome in the regulatory process with FDA
- Promising HORIZON data for RRMM patients with extramedullary disease (EMD) presented at the International Myeloma Workshop (IMW) in September
- In the ANCHOR combination trial, enrollment in the cohort with melflufen plus daratumumab was completed sooner than expected in September
  - Enrollment in the melflufen+bortezomib arm expected to be completed in 2020
- The BRIDGE trial has been expanded to include patients with severe renal impairment
  - Last patient to be enrolled in the study is expected during spring 2020.
- Klaas Bakker, MD, PhD, started as Chief Medical Officer in early November



ASH in December will be of high interest

- Six poster presentations in total at ASH Annual Meeting December 7 – 10 including:
  - Efficacy and safety data from HORIZON after long term follow-up, i.e. the data that the submission for accelerated approval will be based on
  - First data for progression free survival (PFS) for melflufen in combination with daratumumab from the ANCHOR combination trial
- Will also monitor data presented by other companies focused on multiple myeloma
  - The data around BCMA of special interest



Strong activity in relapsed patients with extramedullary disease presented at IMW September 2019

HORIZON

Extramedullary disease occurs when myeloma cells form tumors outside the bone marrow

- Outcomes remain very poor for patients with EMD
- Incidence approximately 10-15% reported at relapse, increasing with reported rates up to 40%

Other studies have failed to demonstrate substantial response in relapsed EMD

- Only daratumumab and pomalidomide have shown any responses
- ORRs of 17% and 9%, respectively in less ill patients

EMD data from HORIZON presented at IMW, Sep 15

- 44 EMD patients, largest EMD cohort ever
- Late stage patients, median of 5 prior lines and 5.5 years since diagnosis

High response rate and highly relevant responses

- 23% ORR for EMD patients, similar to non-EMD
- Survival benefit >12 months for EMD responders vs non-responders

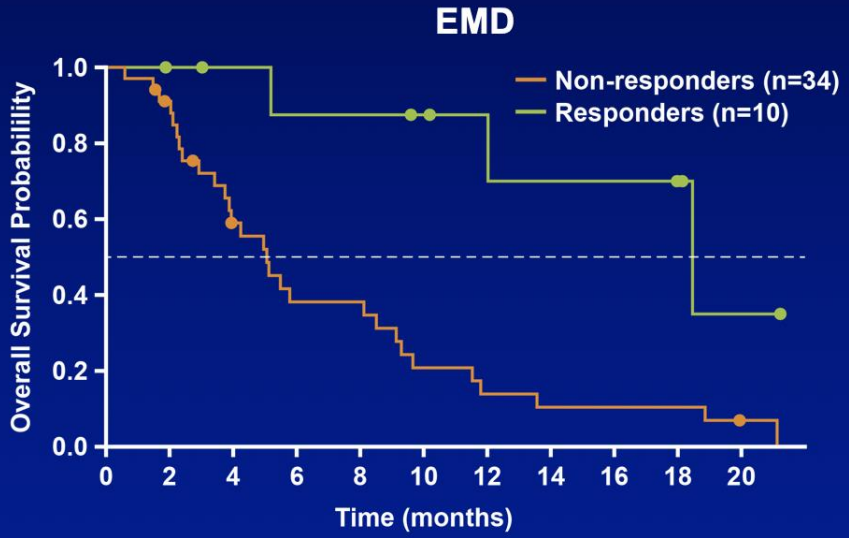
HORIZON data presented at IMW Sep, 2019 (n=128)

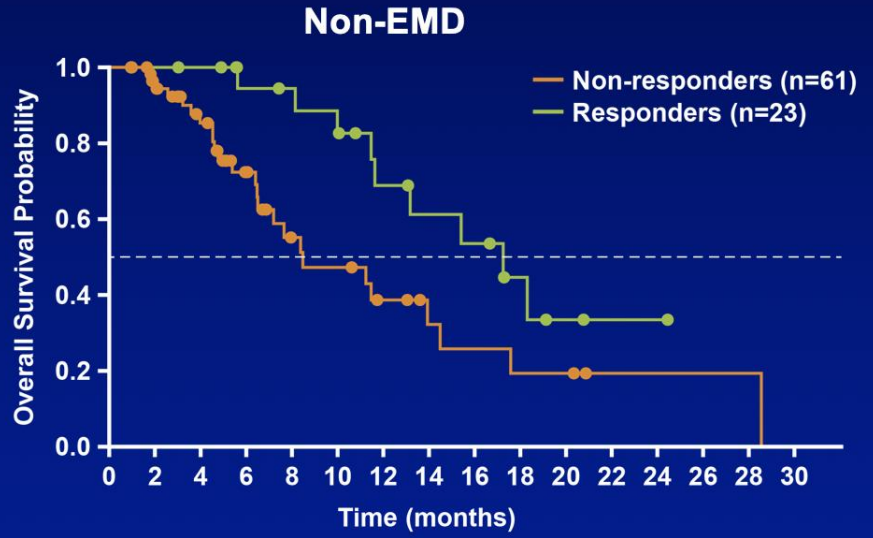
	EMD-relapsed patients (n=44)	Non-EMD relapsed patients (n=84)
Overall response rates, %	23	27
Duration of response, months	3.4	4.4
Median overall survival responders, months	18.5	17.2
Median overall survival non-responders, months	5.1	8.5

Source: IMW presentation September 2019, Haematologica 2014.

OS in EMD and Non-EMD Pts Stratified by Response

HORIZON





- Median OS in EMD responders vs. non-responders: 18.5 vs. 5.1 mos
- Median OS in Non-EMD responders vs. non-responders: 17.2 vs. 8.5 mos
  - Similar trend for PFS in responders vs. non-responders: 4.8 vs. 2.2 mos in EMD pts; 6.4 vs. 3.8 mos in non-EMD pts
- 54% of ITT pts received subsequent therapy with no significant difference in outcome between EMD vs. non-EMD pts[1]

Data cutoff 30 July 2019.

1. Gandhi UH, et al. *Blood*. 2018;132(suppl 1):Abstract 3233.

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
  - 78% of patients in HORIZON maintain the full 40 mg dose despite low bone marrow reserves

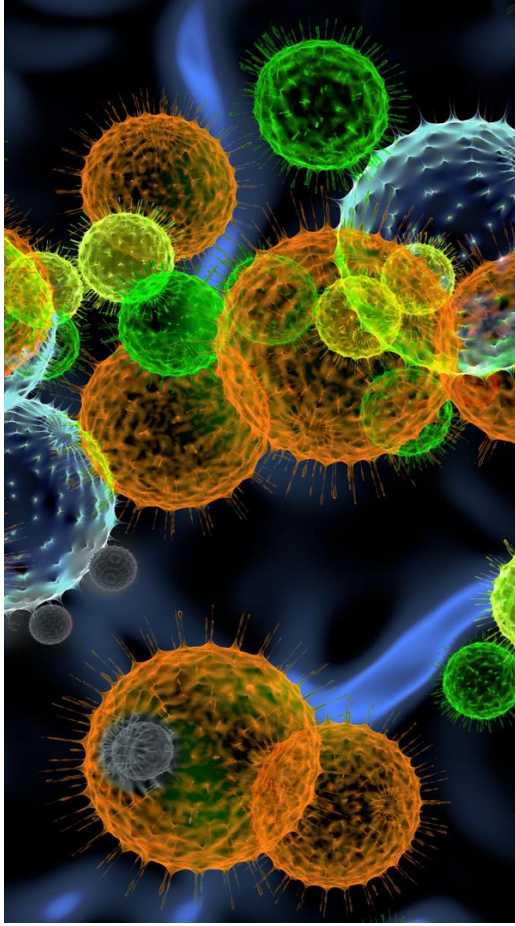
Grade 3 and 4 TEAEs occuring in >5% of patients	HORIZON
SAE rate	40%
Hematological	
Anemia	30%
Neutropenia	57%
Thrombocytopenia	58%
Febrile neutropenia	7%

Source: EHA June 2019

Encouraging data for Melflufen+Daratumumab combination presented at EHA in June 2019 indicates synergistic effect

Summary of combination with daratumumab – n=24

- 2-3 prior lines of therapy
- True RRMM population (not maintenance refractory) – 50% had disease progression while on last line of therapy and 37% high-risk cytogenetics
- **ORR of 82%** with good tolerability and deepening responses
- Median PFS not reached with longest patient on treatment for 12 months. All patients apart from one ongoing.

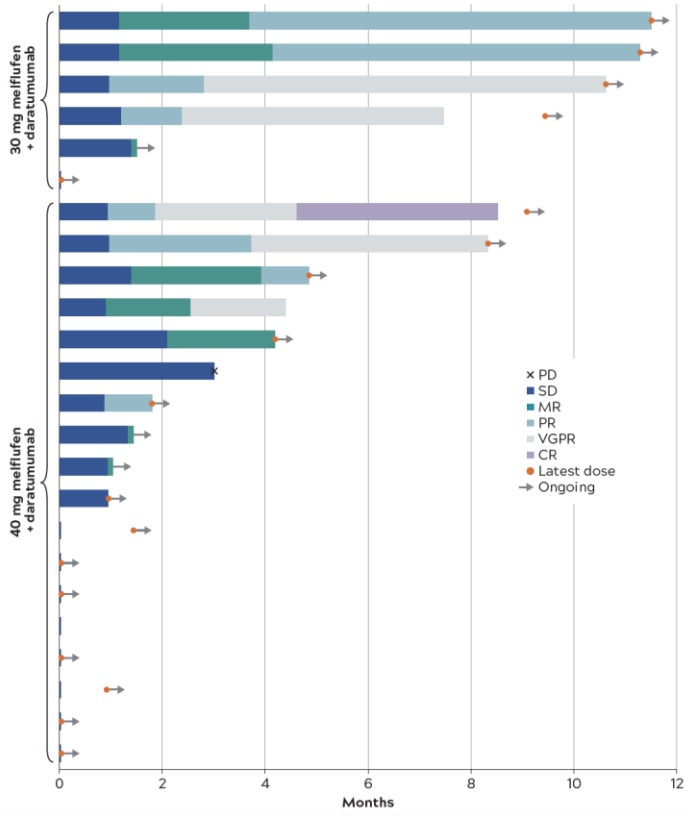


ANCHOR

Data presented at EHA in June 2019, will be updated at ASH presentation in December

ANCHOR

Deepening responses – all but one patient ongoing



Patient characteristics

Characteristics	30 mg[a] (n=6)	40 mg (n=18)
Median age, years (range)	57.0 (49-78)	62.0 (35-77)
Gender, n (%) Male/female	3 (50)/3 (50)	13 (72)/5 (27)
Median time since diagnosis, years (range)	3.1 (1.9-8.0)	4.4 (0.7-8.2)
Median number of previous lines (range)	2.5 (1-3)	2 (1-4)
Prior ASCT/ alkylator exposed, n (%)	5 (83)/ 3 (50)	14 (78)/ 10 (56)
Alkylator refractory, n (%)	1 (17)	4 (22)
IMiD refractory, n (%)	3 (50)	11 (61)
PI refractory, n (%)	0	10 (56)
Last-line refractory, n (%)	2 (33)	10 (56)
IMiD + PI refractory, n (%)	0	8 (44)
ISS at study entry,[b] n (%) I/II/III	6 (100)/0/0	13 (76)/2 (12)/2 (12)
High-risk cytogenetic by FISH,[c] n (%)	2 (40)	5 (36)
Median albumin level, g/dL (range)	4.1 (3.1-4.5)	3.9 (3.1-4.9)

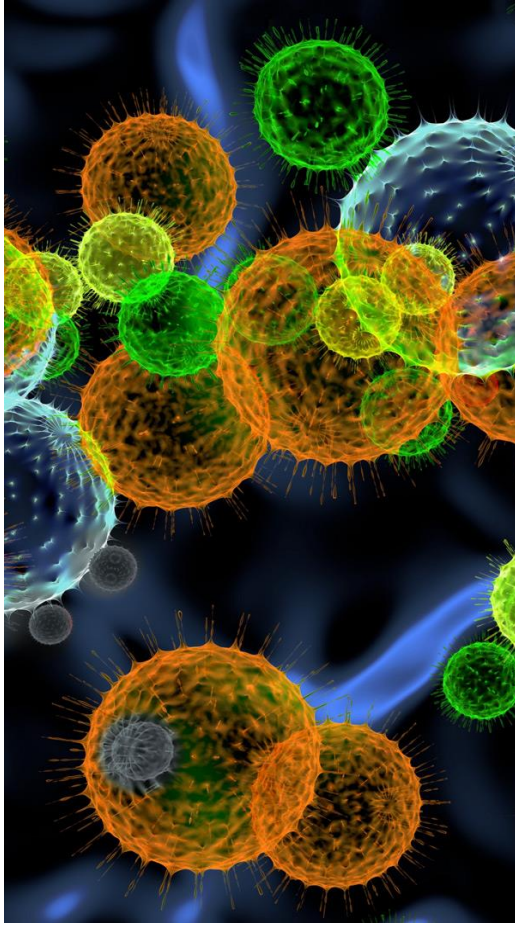
Treatment-related Grade 3/4 AEs

Preferred term	No. of Patients (%) 30 mg (n=6)	40 mg (n=18)
Any AE	5 (83)	14 (78)
Neutropenia[a]	5 (83)	10 (56)
Thrombocytopenia[a]	3 (50)	11 (61)
Anemia	2 (33)	1 (6)
Febrile neutropenia	1 (17)	0
Fatigue	0	1 (6)
Agitation	0	1 (6)
Muscular weakness	0	1 (6)

Encouraging data for Melflufen+Bortezomib combination presented at EHA in June 2019, indicates synergistic effect

Summary of combination with bortezomib – n=5

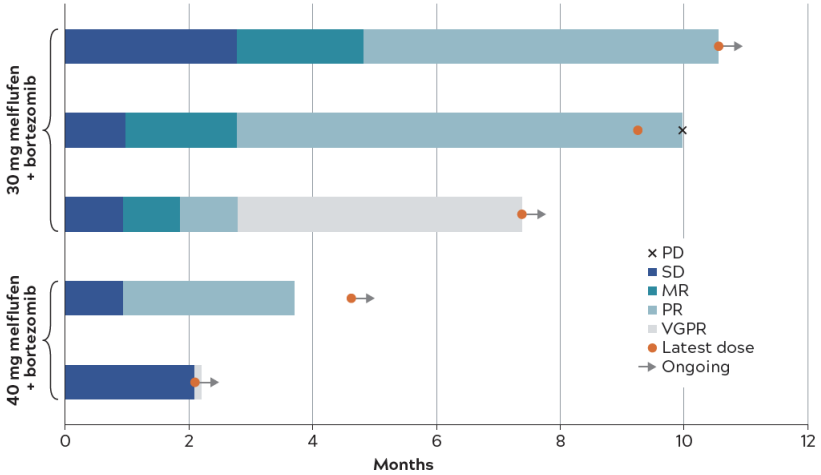
- Elderly population – 2-3 prior lines of therapy
- True RRMM population (not maintenance refractory) – 50% had disease progression while on last line of therapy
- 5/5 responded on therapy (**ORR 100%**) – all pts ongoing apart from one with good tolerability
- Median PFS not reached with the longest patient on treatment for 11 months



Data presented at EHA in June 2019, will be updated at ASH presentation in December

ANCHOR

Deepening responses – all but one patient ongoing



Patient characteristics

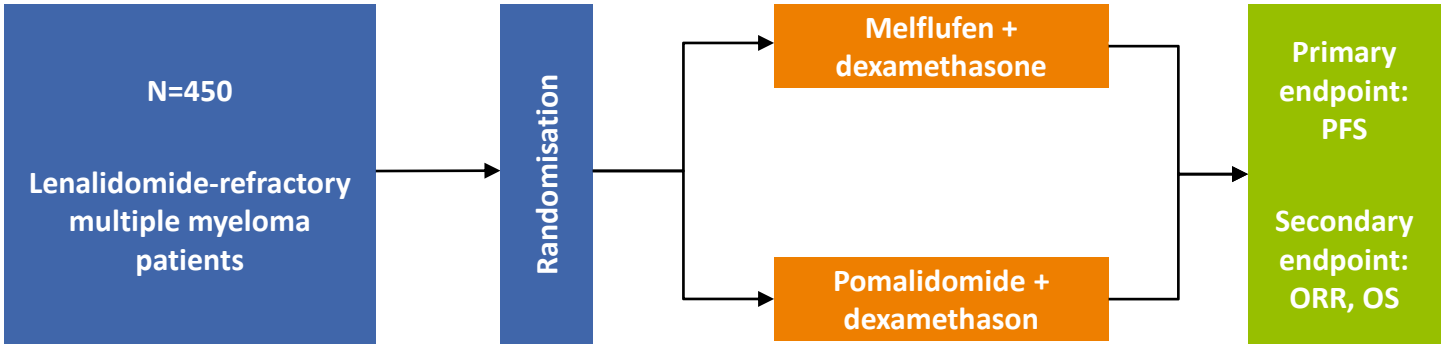
Characteristics	n=5[a]
Median age, years (range)	73.0 (63-82)
Gender, n (%) Male/female	3 (60)/2 (40)
Median time since diagnosis, years (range)	5.8 (1.2-7.4)
Median number of previous lines (range)	2 (2-4)
Prior ASCT/alkylator exposed, n (%)	1 (20)/4 (80)
Alkylator refractory, n (%)	1 (25)
PI exposed, n (%)	5 (100)

Treatment-related Grade 3/4 AEs

Preferred Term	No. of Patients (%)	
	30 mg (n=3)	40 mg (n=2)
Any AE	2 (67)	1 (50)
Thrombocytopenia[a]	2 (67)	1 (50)
Neutropenia[a]	2 (67)	0
Pneumonia[a]	1 (33)	0

Source: EHA June 2019.

Data to date provide high conviction for success in our ongoing 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

Average IMiD free period was significant in pomalidomide registration study

- Only 29% received lenalidomide as last treatment

Lenalidomide used more aggressively today

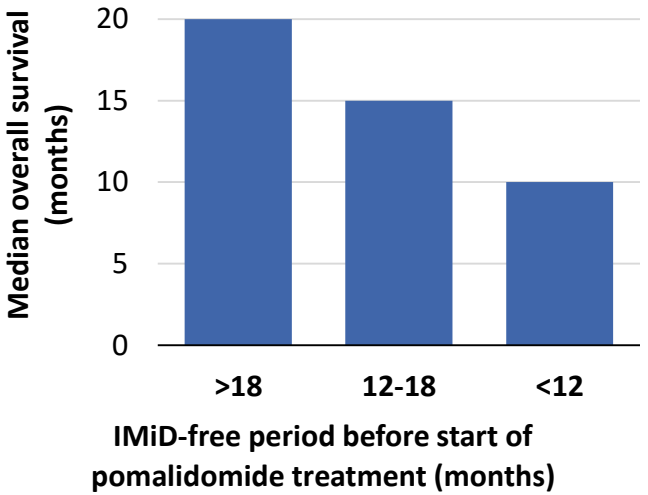
- Median maintenance duration 24 months instead of 10 months

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



Source: Pomalidomide with Low Dose Dexamethasone Is Effective Irrespective of Primary or Secondary Resistance to Lenalidomide but the IMiD-Free Interval Is Important (Dimopoulos et. al. ASH poster 2016).

The phase 3 combination trial LIGHTHOUSE will be of high strategic importance

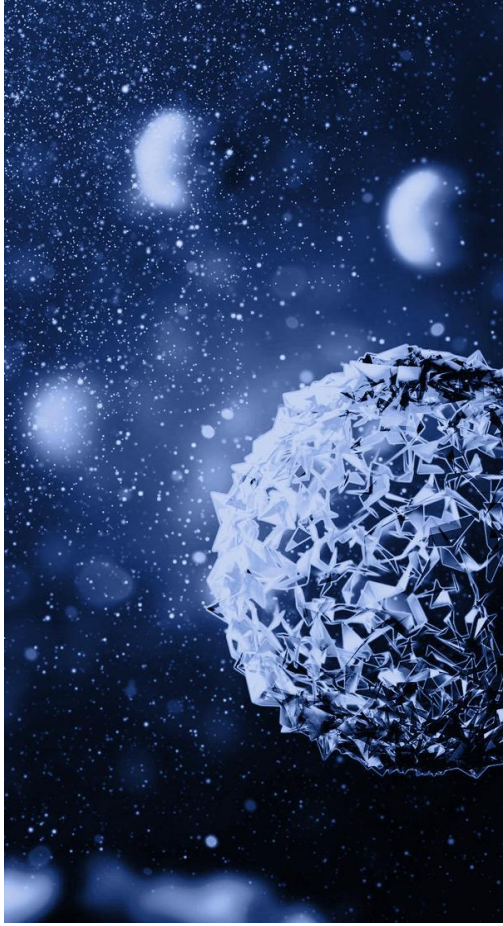
Second phase 3 trial with melflufen in multiple myeloma

- Melflufen + daratumumab vs daratumumab randomized 2:1

Two objectives:

- Expand market potential – extend label with melflufen in combination with daratumumab in earlier line patients
- De-risk the development program – add a third trial that can result in market registration in the EU and US

We are in final preparations of the study and aim to start the study early 2020



LIGHTHOUSE

Our new indication AL Amyloidosis

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

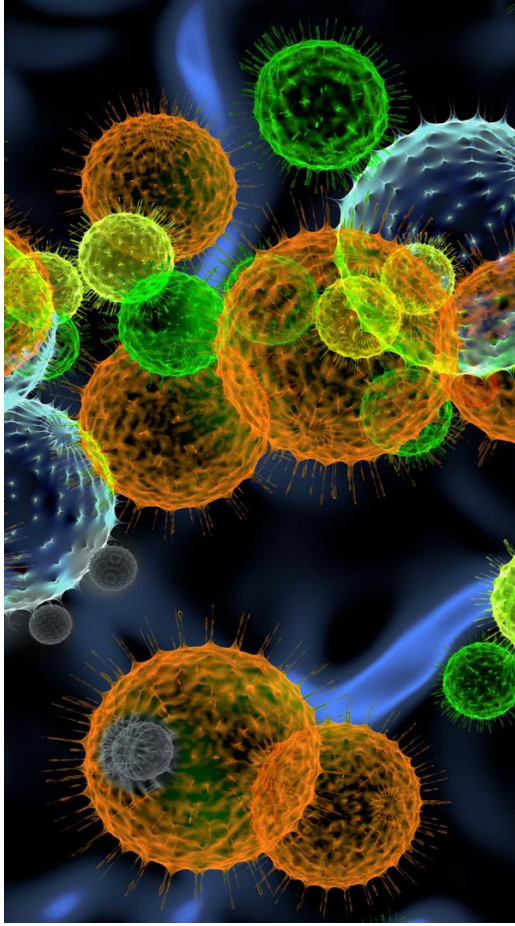
- Antibody light-chains misfold and form deposits in multiple organs with organ dysfunction as a result
- Orphan disease - 30-45,000 patients in the USA and the EU[1]
- Majority of patients >65 years old

Similar drug use as for myeloma – drugs that are efficacious in myeloma are most of the time also used 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 around year end 2019 – up to 40 patients across both phases

The study to start in the coming month



Source: 1) Quock et. al, Blood Advances, May 2018, 2) Weiss et. al, Blood, 2016

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The coming quarters will be very information rich

Dec 2019	Q1 2020	Q2 2020	Q3 2020	Q4 2020
Data from HORIZON, ANCHOR at ASH	FPI LIGHTHOUSE	LPI BRIDGE	Top-line results OCEAN	Potential accelerated approval in US
FPI Amyloidosis Trial	LPI OCEAN	New data and updates at EHA	LPI ANCHOR	Potential Launch in US
	NDA submission			

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

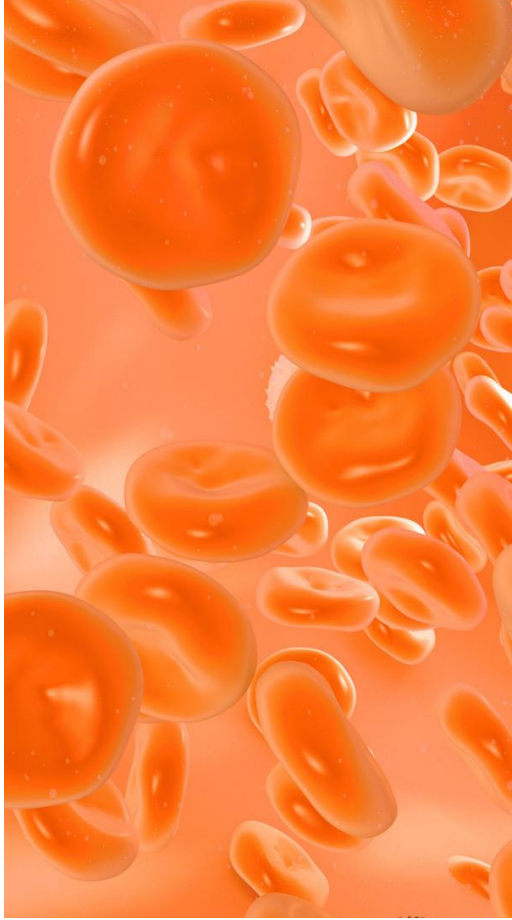
- Phase 2 study, O-12-M1, showed very strong survival data
- Both phase 2 studies, HORIZON and ANCHOR show strong overall response (ORR) data and competitive profile for progression free survival (PFS)
- Generally well tolerated giving patients good quality of life

Late stage development program with multiple ways to get approval

- Submission for accelerated approval for triple-class refractory patients in the US targeted in Q1-20 based on HORIZON data
- Phase 3-trial OCEAN expected to be fully enrolled Q1 2020
- Additional Phase 3-trial, LIGHTHOUSE will start early 2020

Strong financial position

- Cash position SEK ~1.1 B ($ 116 M) end September



Thank you for your attention!

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