oncopeptides

Nomenclature

International non-proprietary name (INN)
Melphalan flufenamide

Chemical name
4-[Bis-(2-chloroethyl)amino]-L-Phenylalanine-4-fluoro-L-phenylalanine ethyl ester hydrochloride

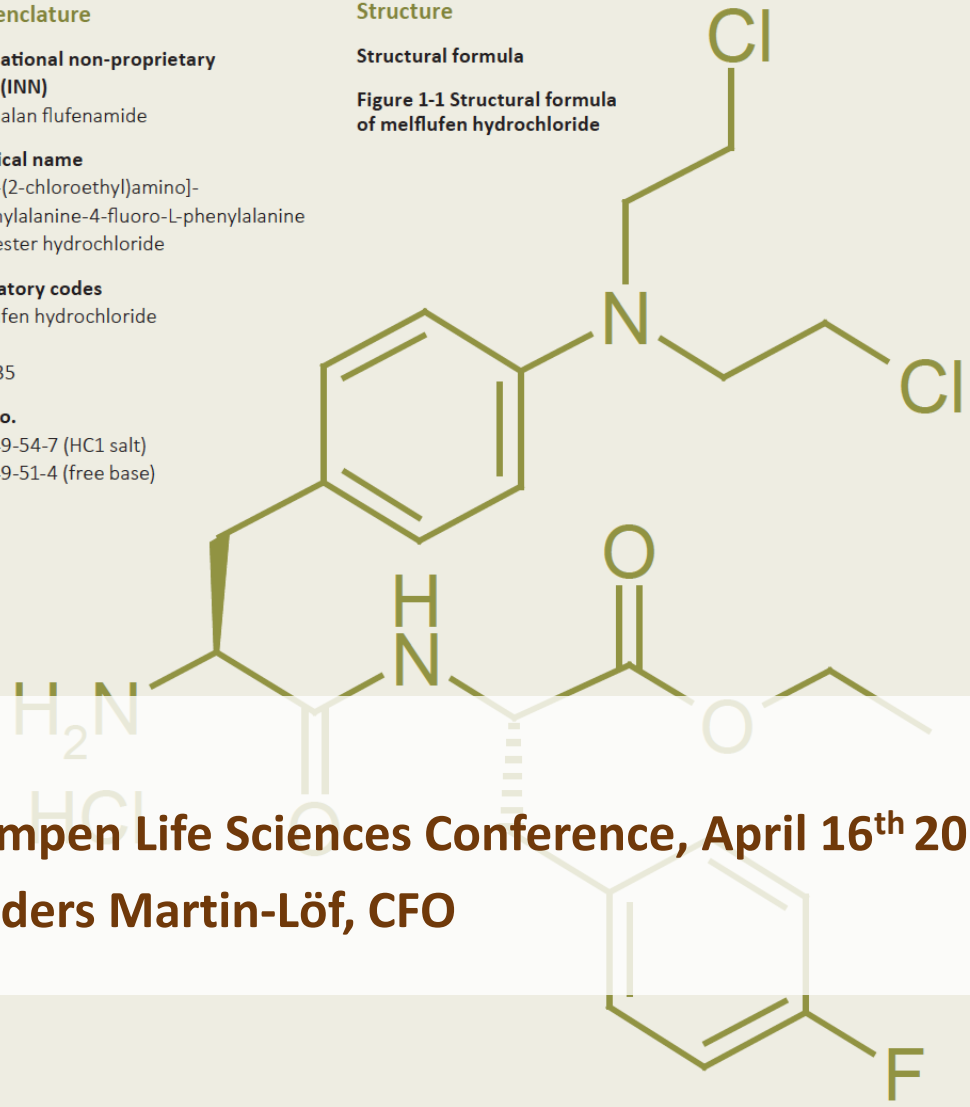
Laboratory codes
Melflufen hydrochloride
J1
CK 1535

CAS No.
380449-54-7 (HC1 salt)
380449-51-4 (free base)

Structure

Structural formula

Figure 1-1 Structural formula of melflufen hydrochloride

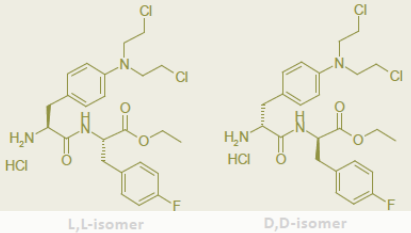


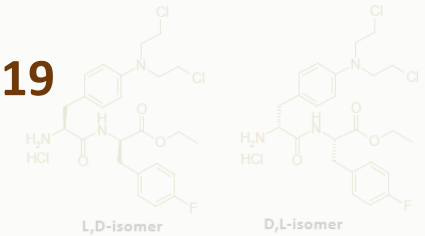
Molecular formula
C24 CH31C13FN3O3 (HC1 salt)

Molecular weight
534.9 (HC1 Salt)

Stereochemistry
Melflufen hydrochloride contains two stereogenic centers giving rise to four possible stereoisomers. Melflufen hydrochloride drug substance is the L,L-isomer. The structures are outlined in Figure 1-2.

Figure 1-2 Structure of melflufen hydrochloride isomer





General properties

Appearance
White to slightly yellowish powder

Solubility
Melflufen hydrochloride is soluble in most organic solvents. The solubility in water and buffers is limited.

Partition coefficient
ClogP = 4.04 (tecken) 0.66, calculated using ACD logP DB, v.6.0 (from Advanced Chemistry Development)

Dissociation constant
pKa 10.0 (determined in ethanol solution)

Optical rotation
[α]D 5.2° (c 1.9, CH3OH) at 20°C

Thermal behaviour
Differential scanning calorimetry (DSC) was performed using a Mettler Toledo DSC 822 instrument and a scanning rate of 2(tecken)C/minute. The melting temperature was measured using batch GF404528 and determined from the DSC thermogram to be 205.4°C, as shown in Figure 1-3.

Kempen Life Sciences Conference, April 16th 2019

Anders Martin-Löf, CFO

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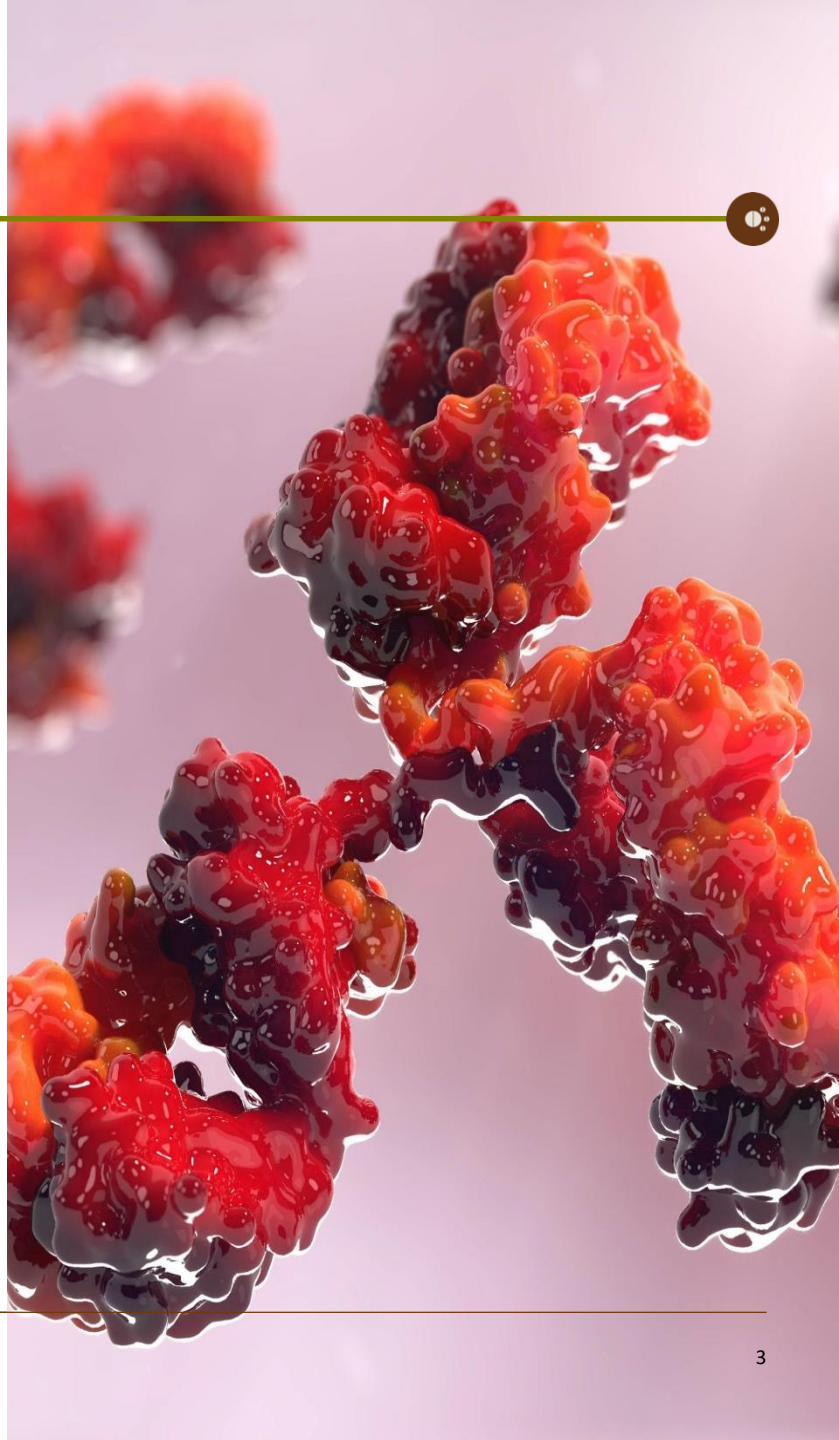
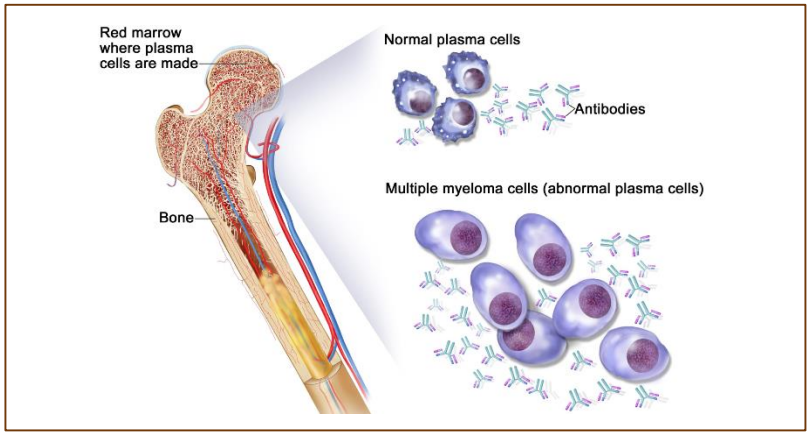
Oncopeptides at a glance

- **Develops targeted cancer treatments**
  - Proprietary peptidase-enhanced compounds
  - Lead compound Melflufen a peptide conjugated alkylator
- **Initial focus on Multiple Myeloma**
  - Significant market opportunity in orphan indication
  - Melflufen Phase 2 showed the best MM survival data to date
- **Phase 3 expected to be fully enrolled in the summer of 2019**
  - Approximately 450 patients at 140 sites
  - Three additional supporting trials ongoing, additional Phase 3 to be started 2019
- **Listed on NASDAQ Stockholm, strong financial position**
  - Market cap: ~$730 M
  - Cash position Dec. 31, 2018: $40 M, raised an additional $55 M in January
- **New indications and NCEs in development**
  - Clinical trials expected to start in 2019

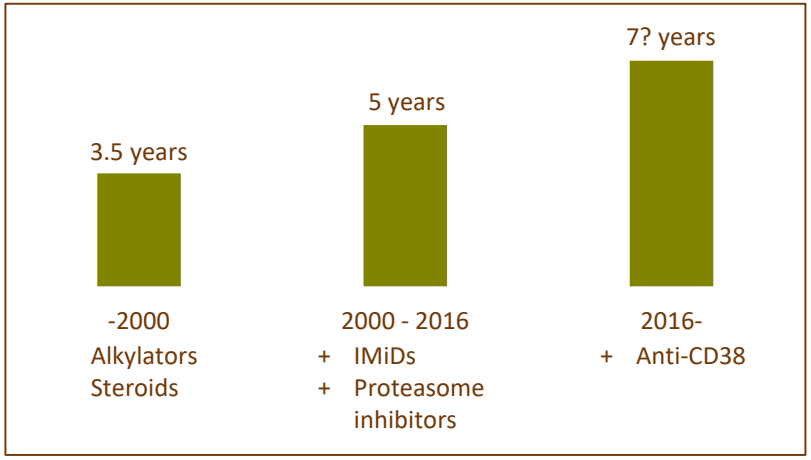


Multiple Myeloma is a hematological cancer without cure and significant medical needs remain

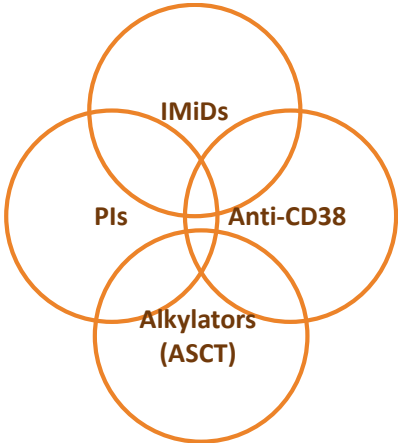
Myeloma – Uncontrolled plasma cell proliferation



Median Survival increasing with more available treatment options



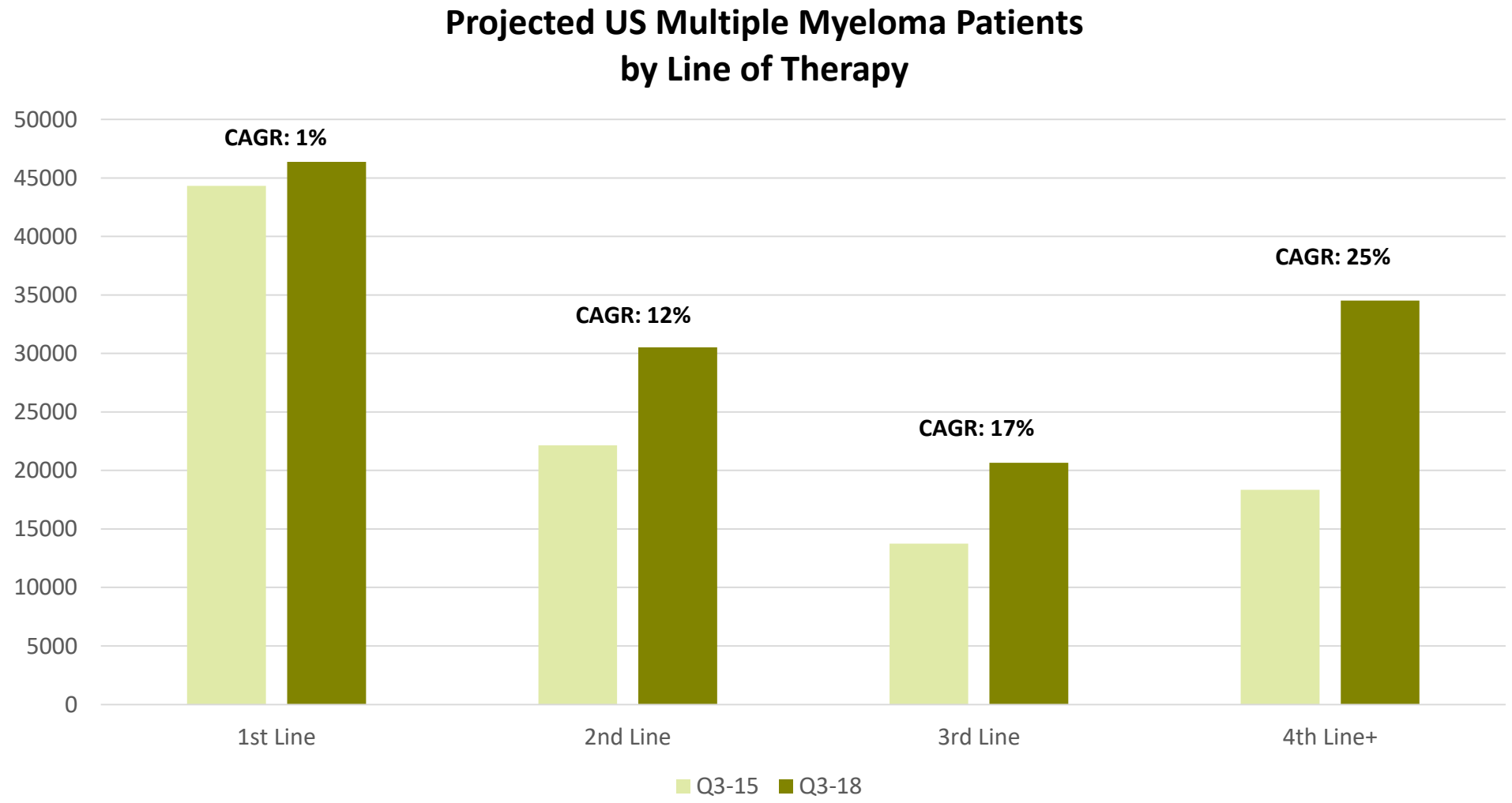
- Four treatment modalities used with inevitable resistance development



- 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

Source: IntrinsiQ and Kantar Health.

Improved outcomes lead to fast growth in number of treated patients in later lines of therapy with great need of new treatment options



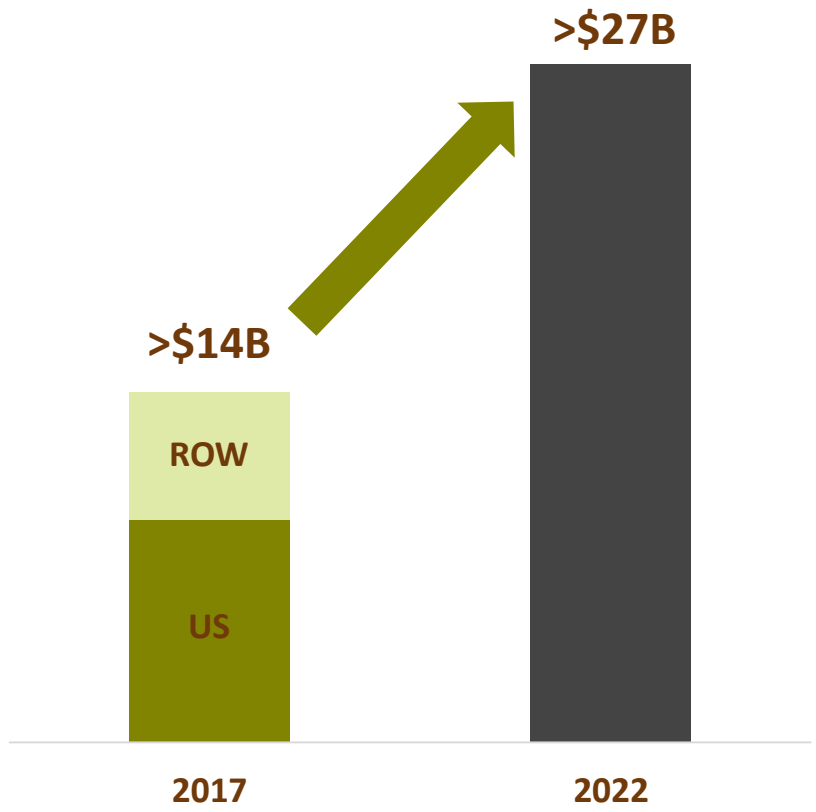
Source: Intrinsiq Oct 2018, MAT
Note: 3-yr annual growth rate for 3Q15-3Q18

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
- 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
- The multiple myeloma market is expected to almost double in size before Revlimid patent expiry

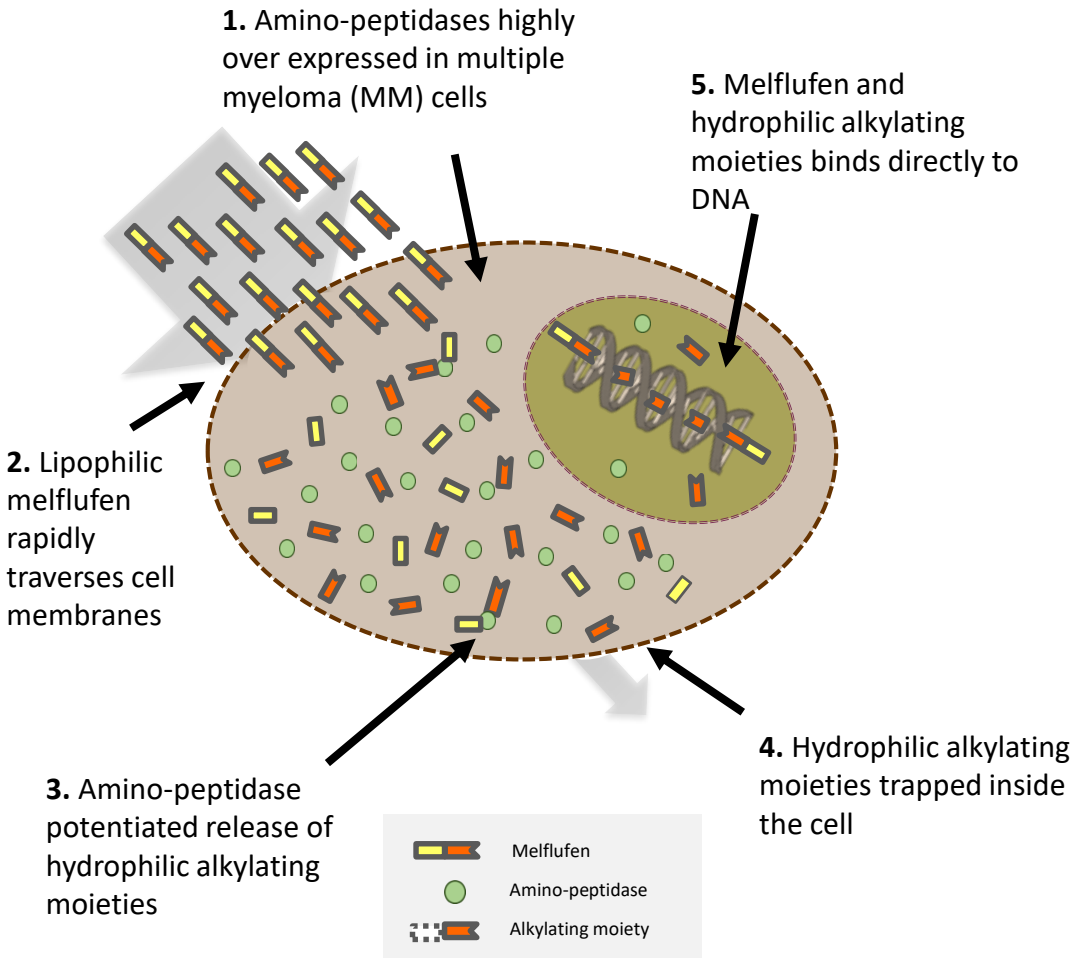
Market Value Expected to Double



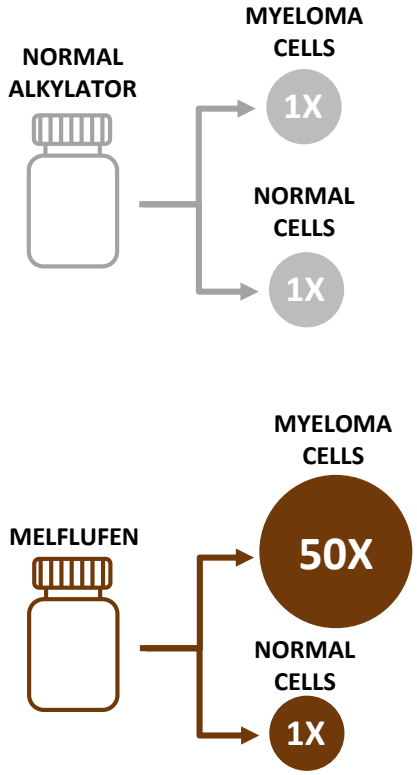
Source: EvaluatePharma

Melflufen is a first in class peptide conjugated alkylator –
Aminopeptidases activity increased up to 250x as part of transformation process

Peptidase enhanced activity in Multiple Myeloma cells



Results in 50-fold higher potency



Requirements for success in Relapsed Refractory Multiple Myeloma

Must have characteristics

- Single agent +/- steroid activity in multi-refractory patients of >20% ORR
- Single agent +/- steroid approval in refractory patients
- Efficacy synergy in combination with other main myeloma drugs with good tolerability
- No major QoL 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

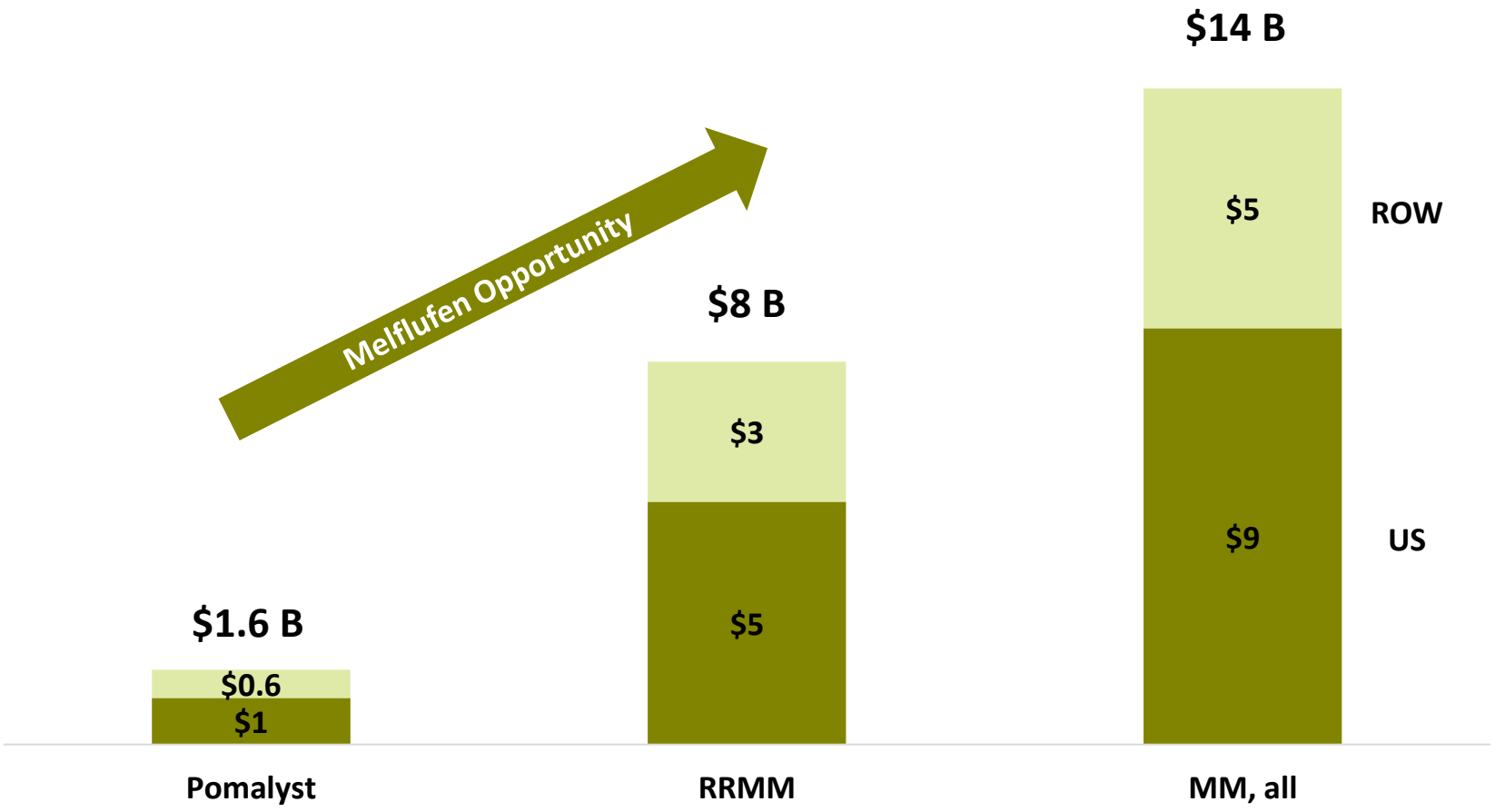
NINLARO®

Empliciti™ (elotuzumab)

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

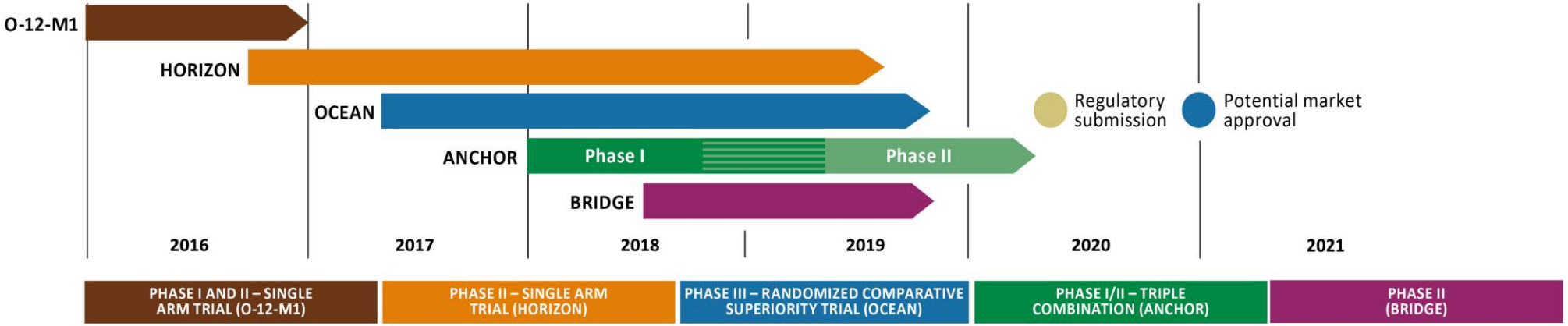
Must have characteristics	Melflufen
• Single agent +/- steroid activity in multi-refractory patients of >20% Overall Response Rate	• O-12-M1 showed an ORR of 31% and HORIZON an ORR of 33% in multi-refractory patients
• Single agent +/- steroid approval in refractory patients	• OCEAN head to head study 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 (limited number of patients so far)
• No major QoL 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 –
2017 Multiple Myeloma Net Sales Breakdown



Source: EvaluatePharma, Intrinsiq, company analysis

Overview of our present clinical development program in relapsed refractory multiple myeloma



O-12-M1	HORIZON	OCEAN	ANCHOR	BRIDGE
Show single-agent activity in RRMM	Show single-agent activity in RRMM	Show single-agent superiority over SoC in RRMM (pomalidomide)	Show combination synergy and tolerability with daratumumab and bortezomib	Show that melflufen can be used in patients with renal impairment

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 alklylator	>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

Strong data presented at ASH 2018

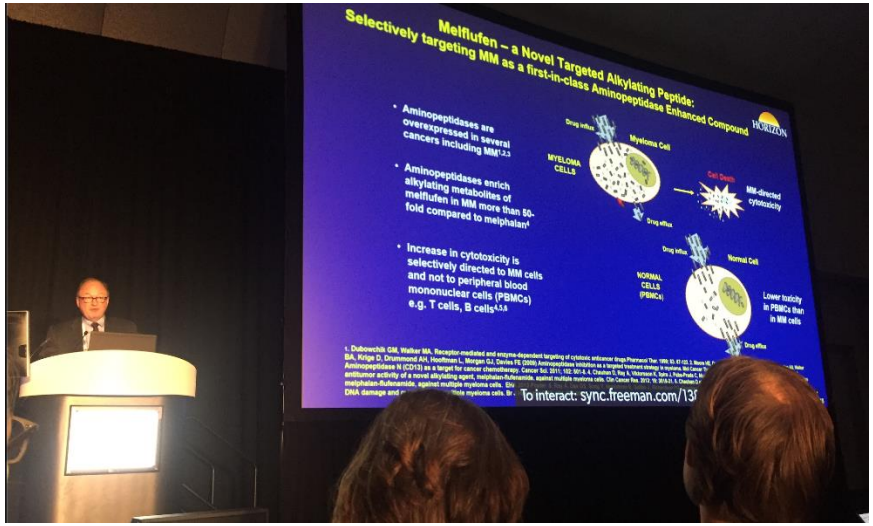
HORIZON ANCHOR

- 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

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

ASH Clinical News

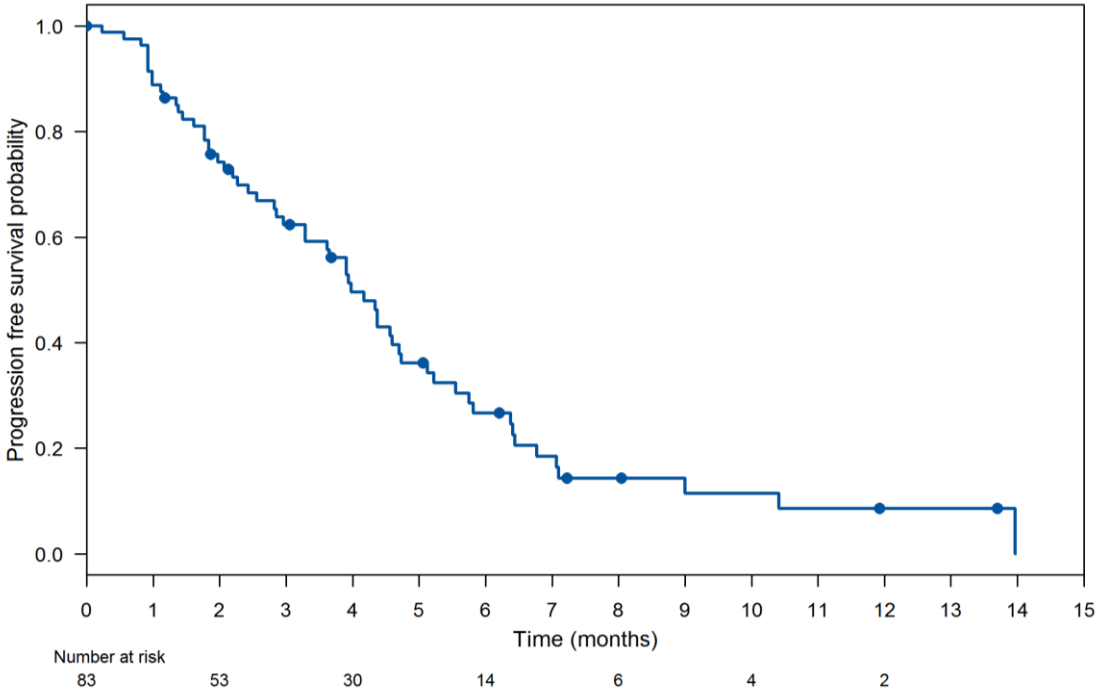
Safety And Efficacy of Melflufen for Relapsed Refractory Multiple Myeloma Patients



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

Response	NE	PD	SD	MR	ORR
% (n)	1% (1)	15% (12)	45% (37)	6% (5)	33% (27)

sCR	*VGPR*	*PR*
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

Source: ASH December 2018.

Safety indicates a very good quality of life profile for patients

HORIZON

Grade 3 and 4 TEAEs occuring 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%

- Absence of grade 3 and 4 adverse events outside of the hematological system and infections and infestations
- Low infection rate in comparison with other myeloma drugs
- Hematological toxicity clinically manageable

Upcoming discussion with the FDA with regard to HORIZON data

- HORIZON is a study in myeloma patients with no or limited treatment options
- Potential for accelerated approval path in the USA – but not certain
- ODAC meeting regarding selinexor (a competitor) on February 26th confirmed the target population and efficacy hurdle in late-stage myeloma (i.e. triple-class refractory myeloma patients)
- FDA meeting before the summer regarding HORIZON will guide Oncopeptides for the possibility to apply for accelerated approval

Encouraging data for Melflufen in combination with PI bortezomib presented at ASH

ANCHOR

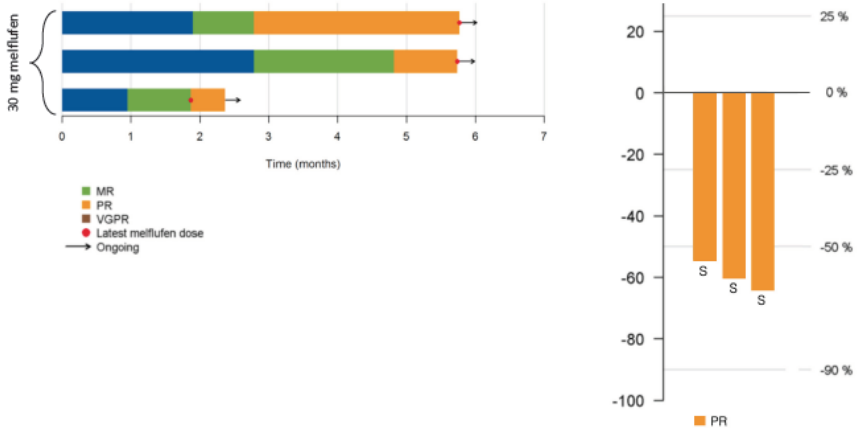
Summary of combination with bortezomib – n=3

- Elderly population – 3 prior lines of therapy
- 3/3 responded on therapy (ORR 100%)
- All patients ongoing with good tolerability

Few non-hematological AEs

CHARACTERISTICS	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%



Source: ASH December 2018.

Data indicates synergistic effect of Melflufen in combination with CD38 inhibitor daratumumab

ANCHOR

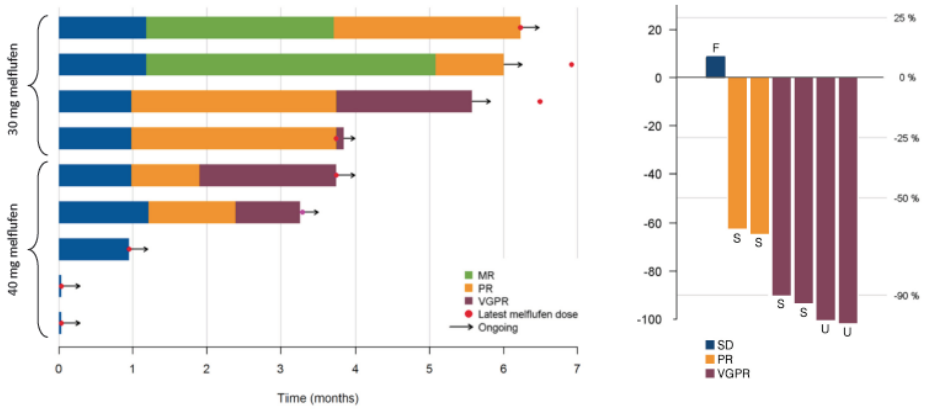
Summary of combination with daratumumab – n=9

- 2-3 prior lines of therapy
- 6/7 patients responded to therapy (ORR 86%)
- All patients ongoing with good tolerability and deepening responses

Manageable hematological AEs and very few non-hematological AEs

CHARACTERISTICS	MELFLUFEN+BORTEZOMIB+DEX (N=9) GRADE 3/4 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%

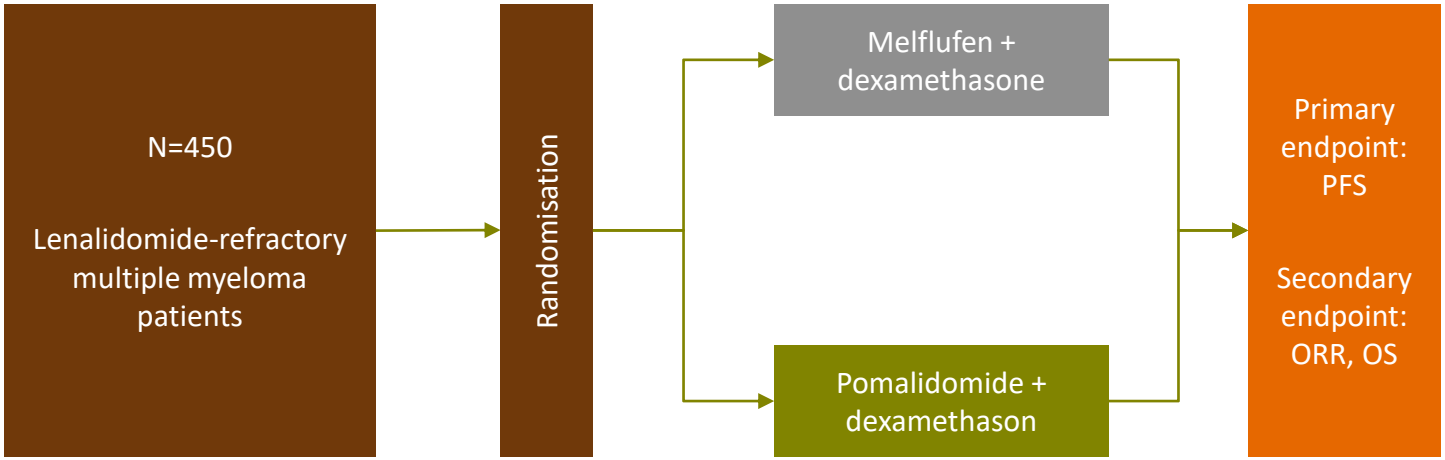


Source: ASH December 2018.

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 having the first patient in H2 2019

Data to date provide high conviction for success in pivotal trial OCEAN

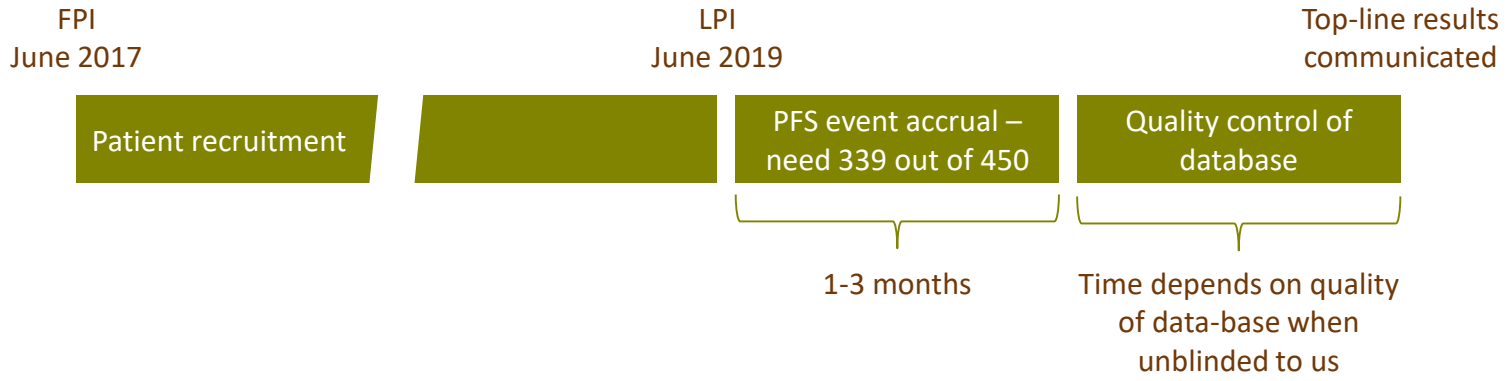


RRMM data from pomalidomide FDA label and O-12-M1 study

Treatment	ORR	Median PFS	Median OS
Melflufen + Dexamethasone	31%	5.7 months	20.7 months
Pomalidomide + Dexamethasone	24%	3.6 months	12.4 months

OCEAN recruitment update

- Last patient in (LPI) estimated for summer of 2019 (no change)
- Previous communication has stated that there is an increased risk of delay to last patient in
  - More than 40 hospitals added to the trial to increase patient recruitment
  - Amendment discussions ongoing with the FDA
- Early 2019 has performed well in terms of patient recruitment
- Process and time-line from last patient in to top-line results:

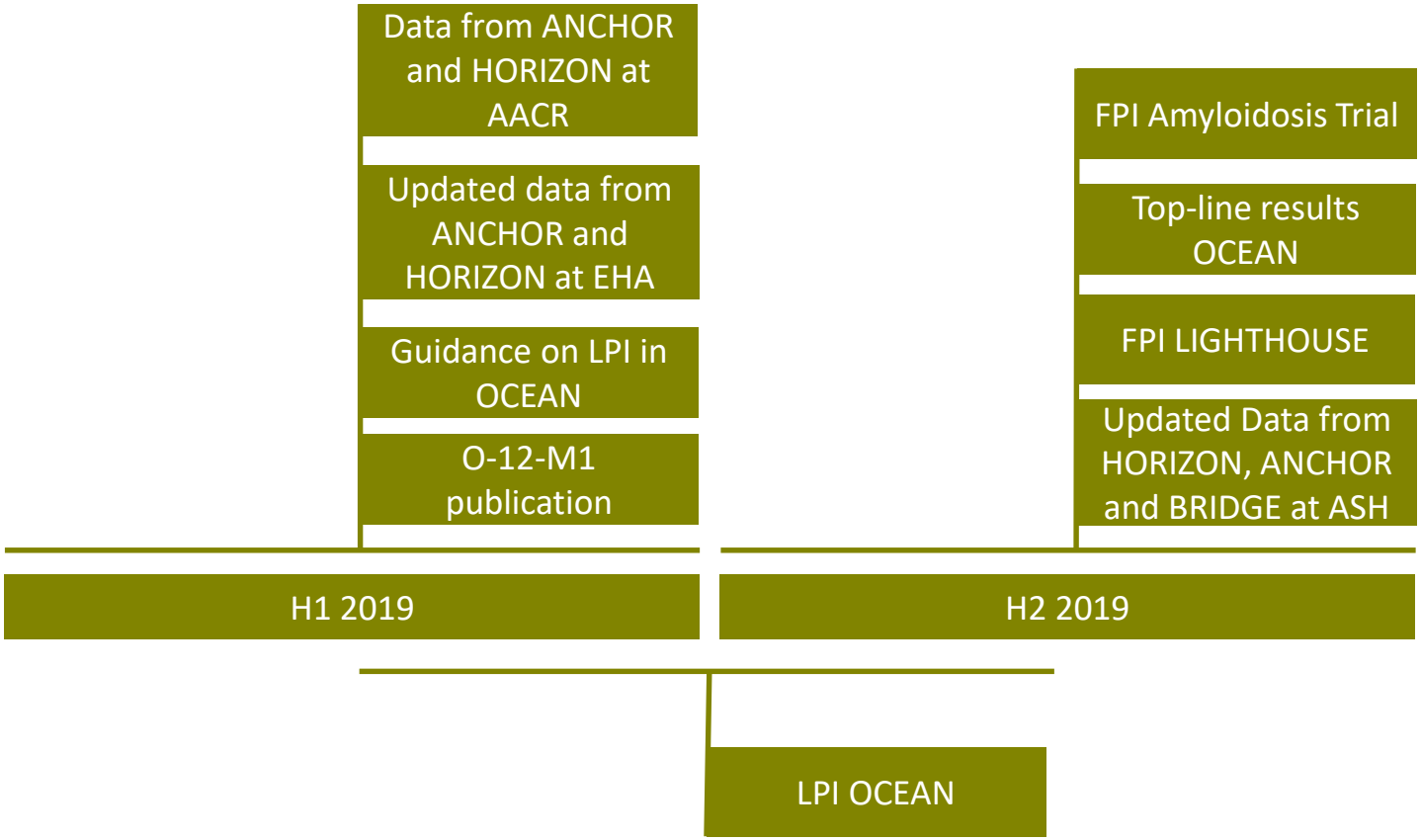


Our new indication AL AMYLOIDOSIS

- 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 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

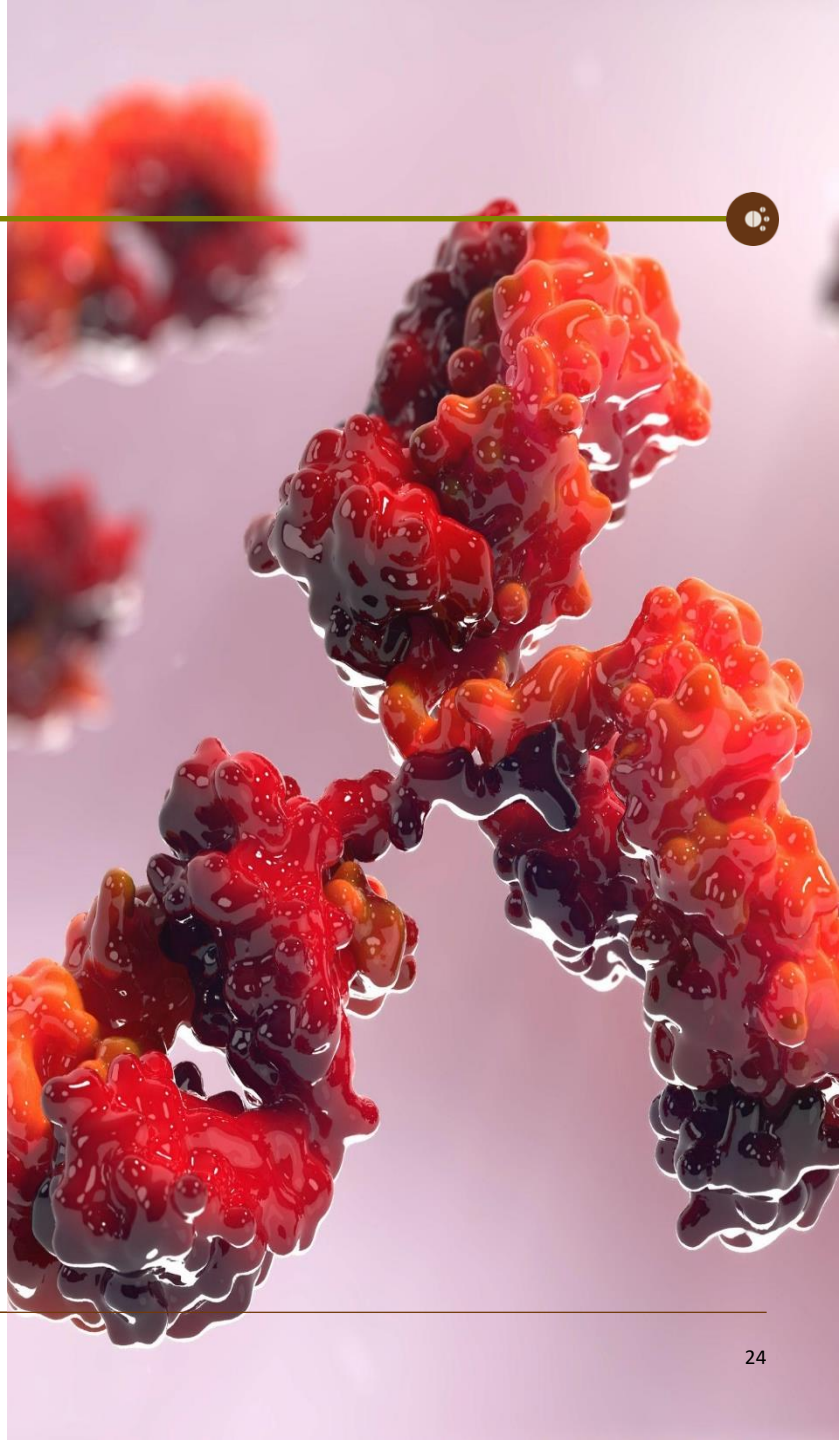
1) Quock et. al, Blood Advances, May 2018
2) Weiss et. al, Blood, 2016

Upcoming newsflow – highly exciting year ahead of us



Summary

- **Significant unmet needs in Multiple Myeloma**
  - 14 BUSD 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**
  - Pivotal phase 3 expected to be fully enrolled in the summer of 2019
  - Discussion the possibility to get accelerated approval with the FDA
  - Additional Phase 3 to be started 2019
- **Strong financial position**
  - Cash position Dec. 31, 2018: SEK 376 M, raised an additional 515 MSEK in January



oncopeptides

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Laboratory codes
Melflufen hydrochloride
J1
CK 1535

CAS No.
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380449-51-4 (free base)

Structure

Structural formula

Figure 1-1 Structural formula of melflufen hydrochloride

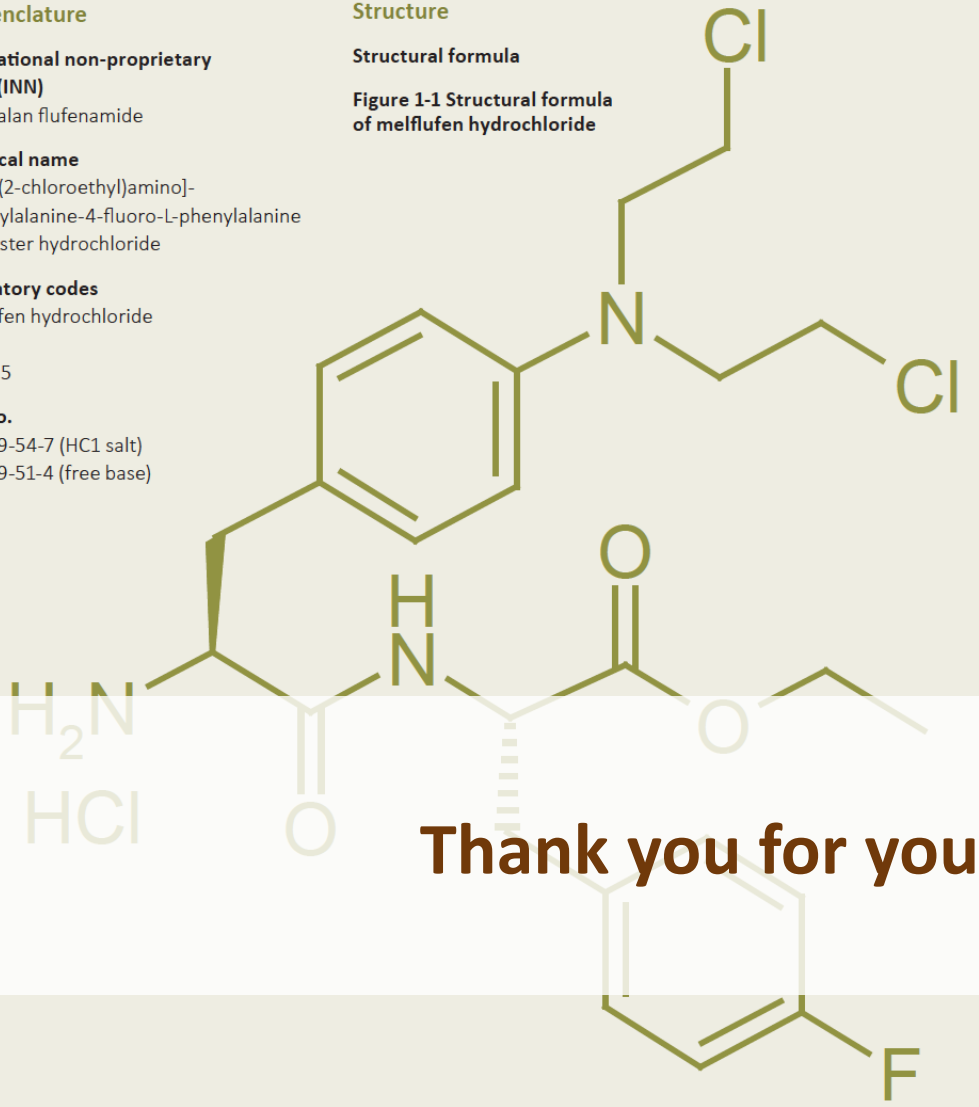

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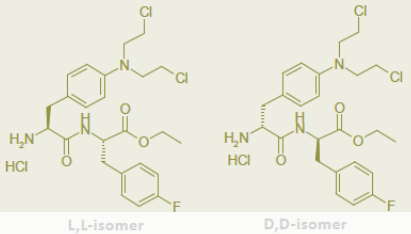
Figure 1-2 Structure of melflufen hydrochloride isomer



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Solubility
Melflufen hydrochloride is soluble in most organic solvents. The solubility in water and buffers is limited.

Partition coefficient
ClogP = 4.04 (tecken) 0.66, calculated using ACD logP DB, v.6.0 (from Advanced Chemistry Development)

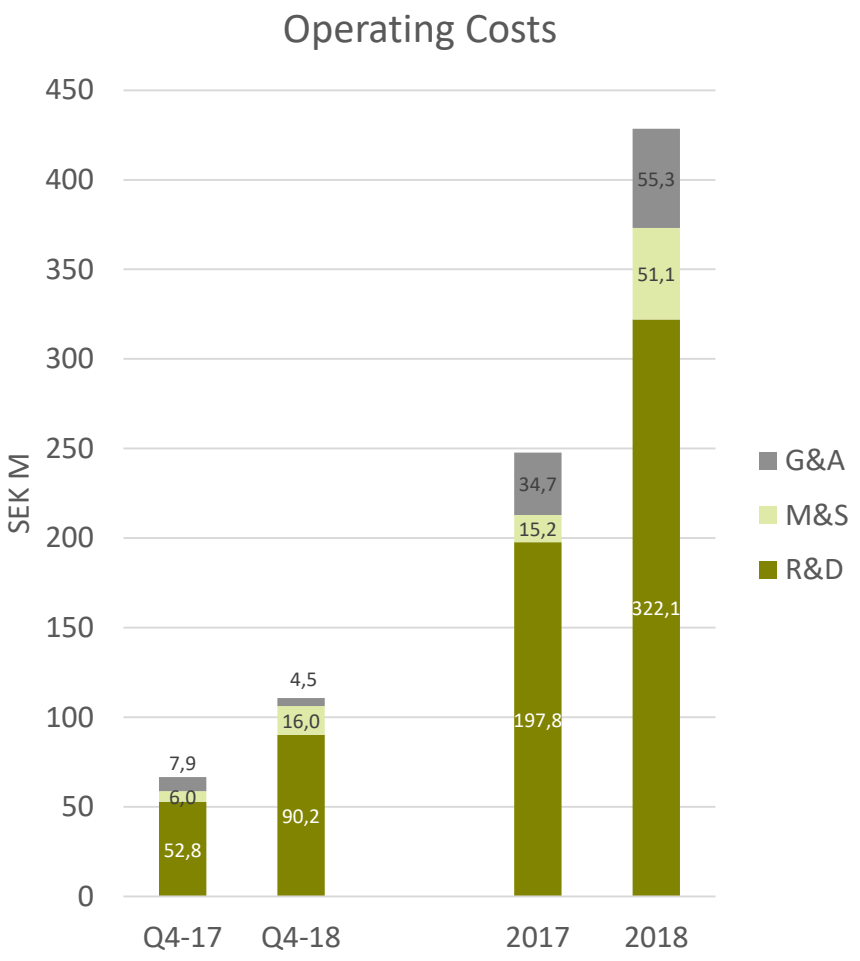
Dissociation constant
pKa 10.0 (determined in ethanol solution)

Optical rotation
[α]D 5.2° (c 1.9, CH3OH) at 20°C

Thermal behaviour
Differential scanning calorimetry (DSC) was performed using a Mettler Toledo DSC 822 instrument and a scanning rate of 2(tecken)C/minute. The melting temperature was measured using batch GF404528 and determined from the DSC thermogram to be 205.4°C, as shown in Figure 1-3.

Thank you for your attention

Financial results for the period Jan –Dec 2018



- Operating loss increased to SEK 419.3 M (loss:247.6)
  - R&D increased primarily due to increase in Clinical: SEK 260.3 M (146.2)
    - OCEAN costs SEK 132.1 M (79.8)
  - Build-up of commercial and medical relations
- Operating costs include non-cash costs related to incentive programs
  - SEK 45.7 M (30.5) for the year, -7.1 M (7.5) for q4
- Cash flow from operating activities neg. SEK 333.7 M (neg. 271.5)
  - Cash flow from financing activities SEK 304.9 M (636.8)
- Cash position was SEK 375.6 M (404.1) as of December 31, 2018
  - Directed share issue raised SEK 514.8 M after issue costs in January, 2019