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

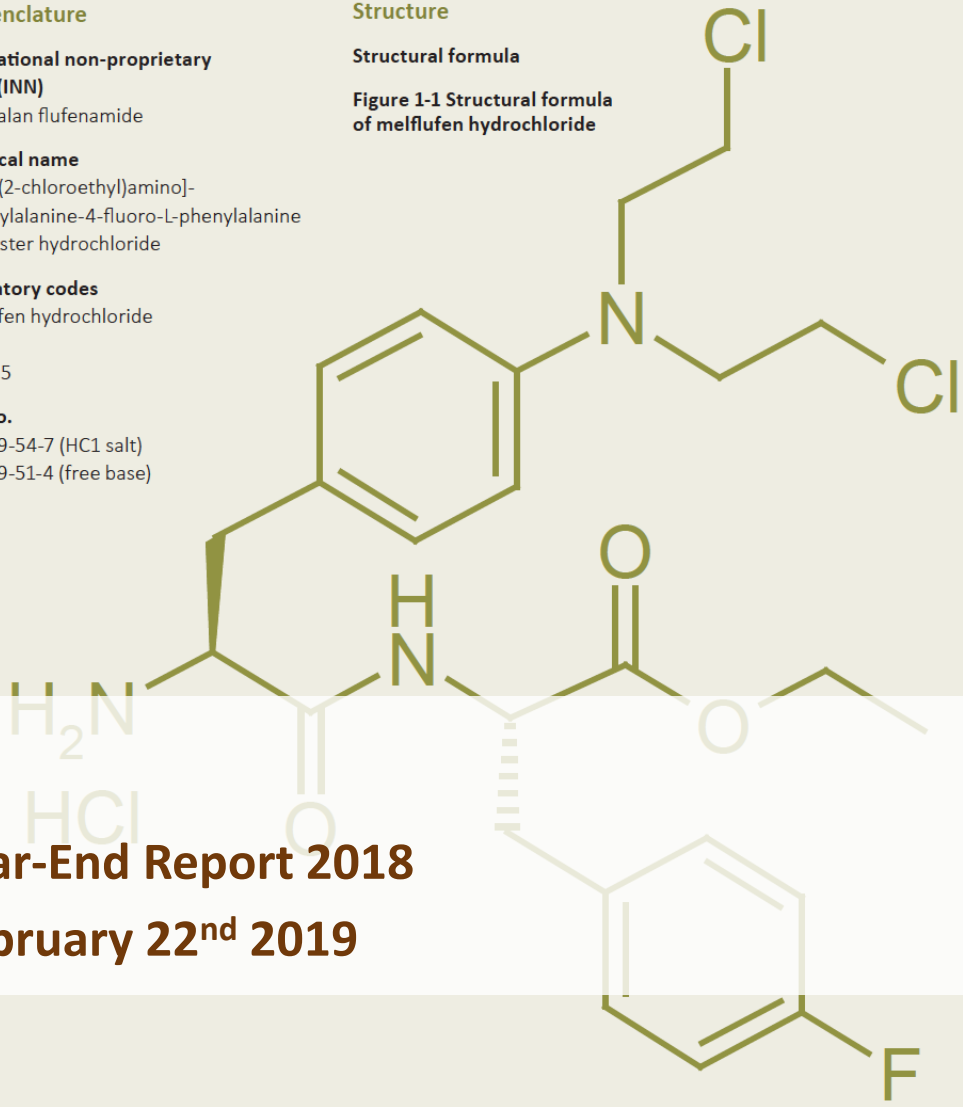
Laboratory codes
Melflufen hydrochloride
J1
CK 1535

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

Structure

Structural formula

Figure 1-1 Structural formula of melflufen hydrochloride

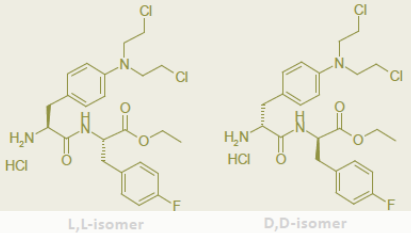


Molecular formula
C24 CH31C13FN3O3 (HC1 salt)

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.

Year-End Report 2018

February 22nd 2019

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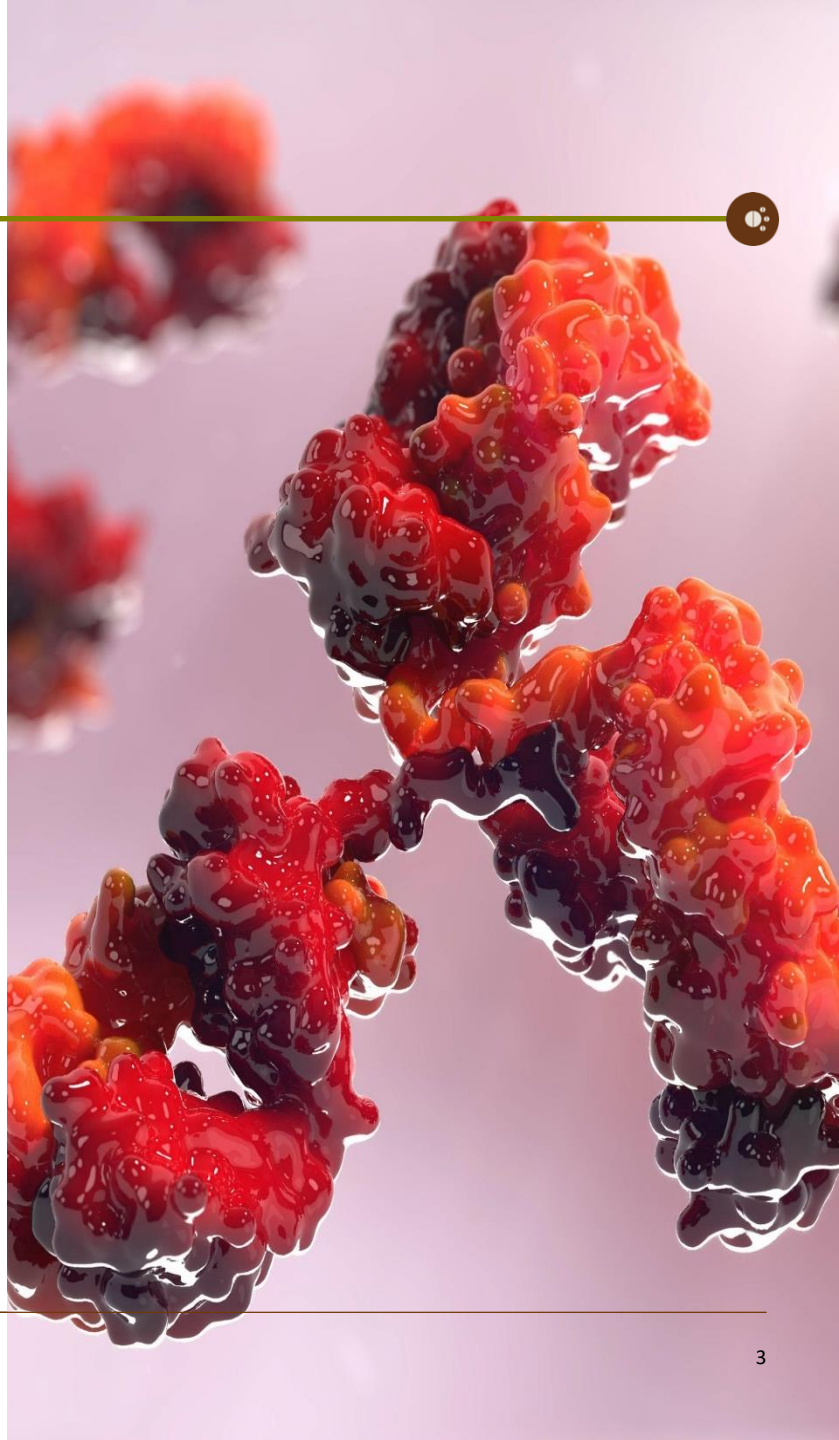
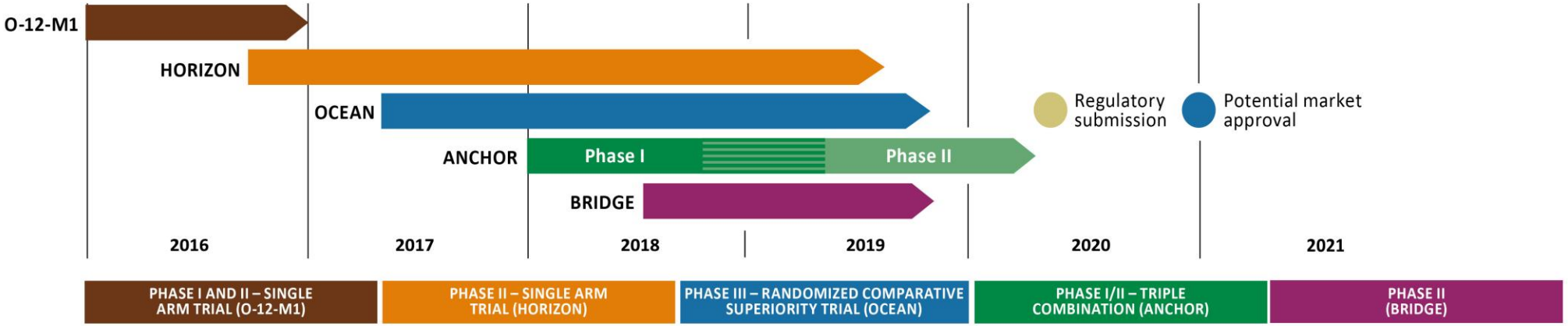
Oncopeptides at a glance

- Developing novel therapies for patients with cancer
- Initial focus on multiple myeloma – a significant market opportunity in an orphan indication
- First drug candidate – melflufen – currently in four clinical trials
- The phase 3 trial OCEAN is estimated to be fully enrolled (n=450) in the summer of 2019
- Well capitalized through phase 3 with SEK 376 M in cash or cash equivalents (as of Dec 31st 2018)
  - Capital raise of an additional SEK 546 M (USD 60M) in January 2019
- Listed on Nasdaq OMX since February 2017 with a market cap of SEK 5.6 B (around USD 600 M)



Overview of our clinical development program in multiple myeloma



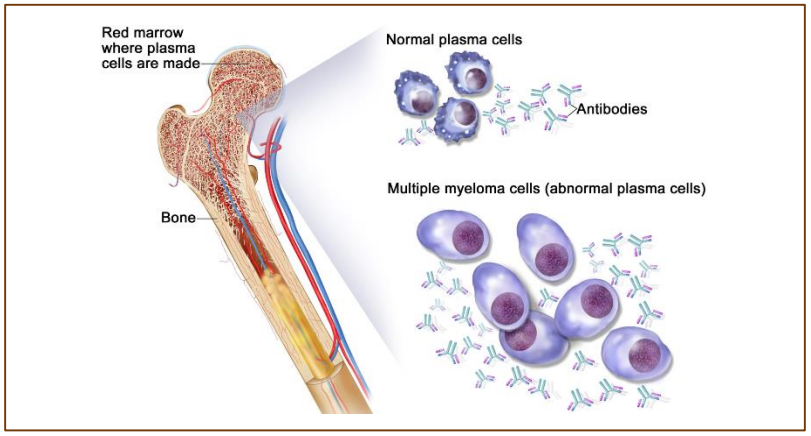
O-12-M1	HORIZON	OCEAN	ANCHOR	BRIDGE
Show single-agent activity in RRMM	Show single-agent activity in RRMM	Show single-agent superiority over SoC in RRMM (pomalidomide)	Show combination synergy and tolerability with daratumumab and bortezomib	Show that melflufen can be used in patients with renal impairment

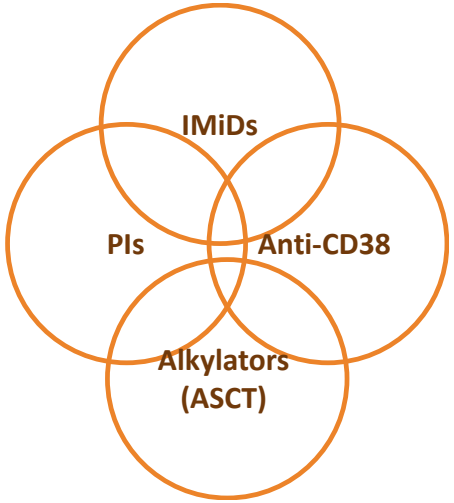
2018 was a year of significant progress for Oncopeptides

- Capital raise of SEK 314 M in March 2018 (around USD 38 M)
- Continued enrollment of patients in OCEAN
- Continued enrollment in HORIZON
- Initiated the combination study ANCHOR
- Initiated the positioning study BRIDGE
- Presented strong interim results from the ongoing trial HORIZON at EHA and later at ASH
- Strong interim results from the ongoing study ANCHOR presented for the first time at ASH

Multiple Myeloma is a hematological cancer without cure and significant medical need

Myeloma – Uncontrolled plasma cell proliferation





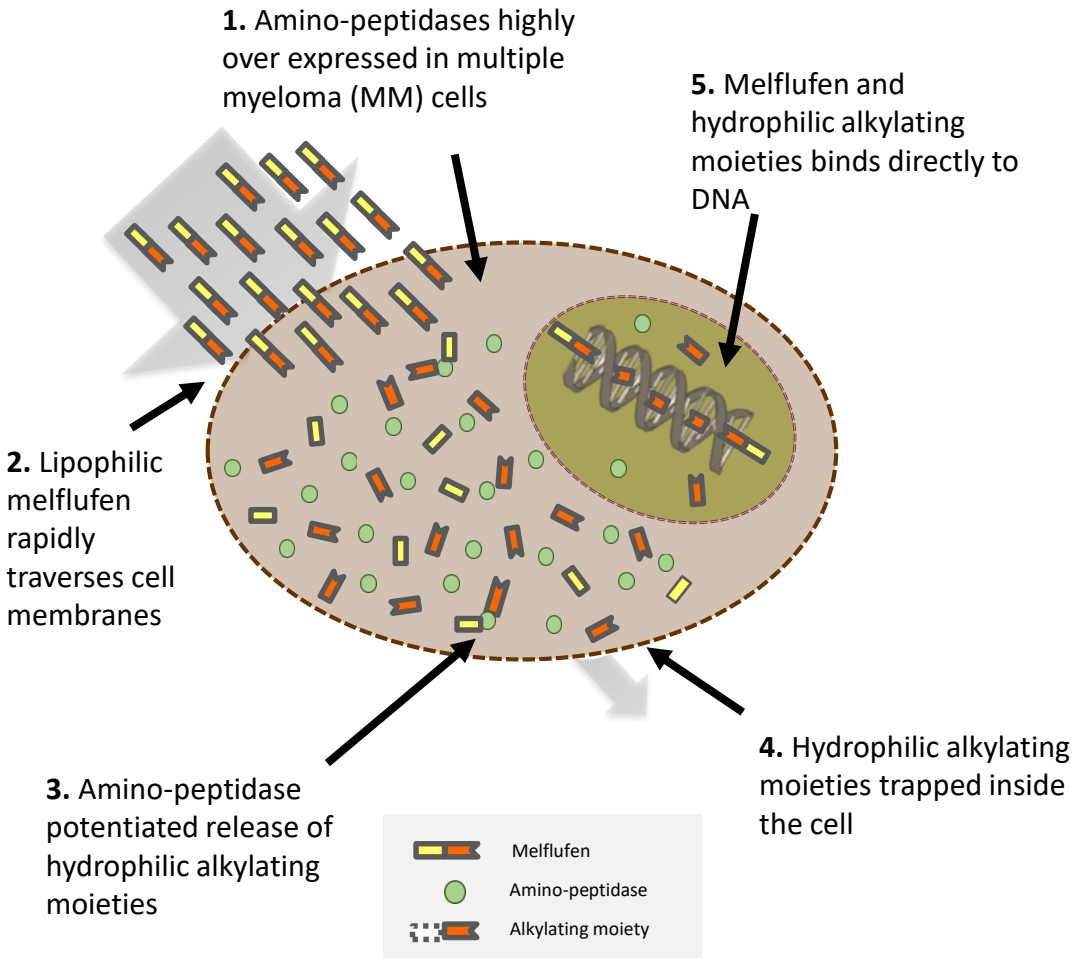
- Overall survival of around 5 years
- Four treatment modalities used with inevitable resistance development
- Currently, the majority of patients have been treated with all four modalities after 2-3 lines of therapy with limited treatment options left
- Frequent co-morbidities further compounding the problem with limited treatment options
- Growing USD 14B market
- Strong underlying growth beyond 1st line with 2-4th line patients growing with 12-25% CAGR (2015-2018)

Source: IntrinsiQ and Kantar Health.

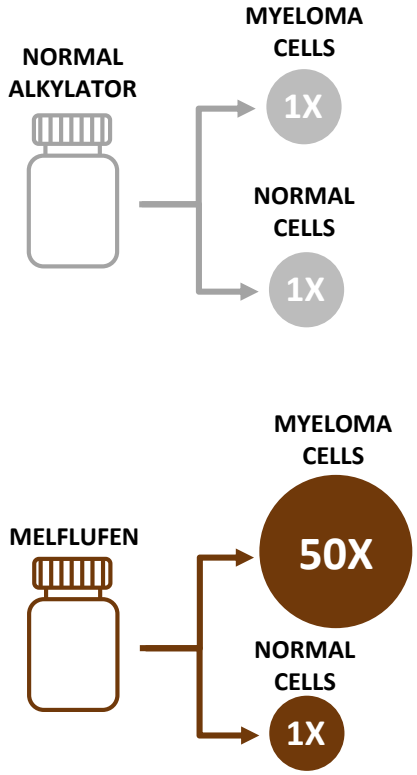
Melflufen is a first in class peptide conjugated alkylator

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% ORR	• 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

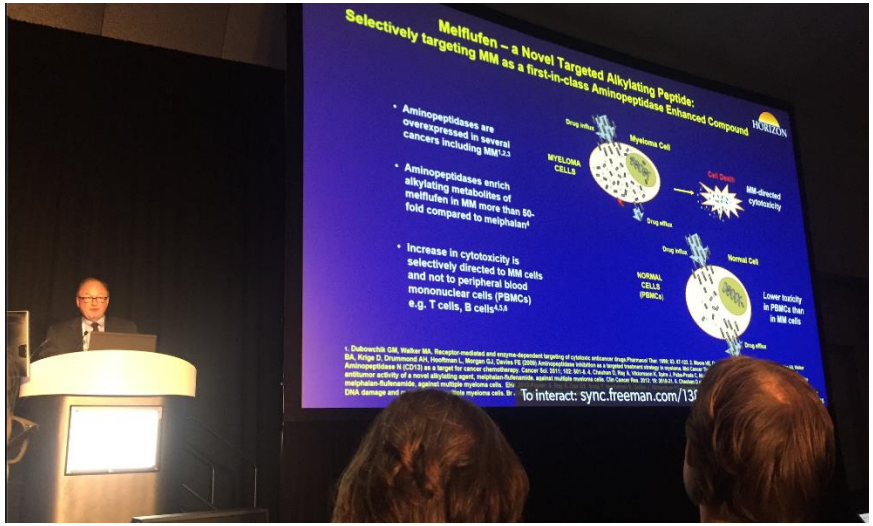
Strong data presented at ASH 2018

- Very good ASH for Oncopeptides
- Interim HORIZON data 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



Our new pivotal combination trial LIGHTHOUSE

- Second pivotal phase III trial with melflufen in multiple myeloma
- 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
- Melflufen+daratumumab+dexamethasone vs daratumumab+dexamethasone randomized 2:1
- We are preparing the study and aiming for having 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 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

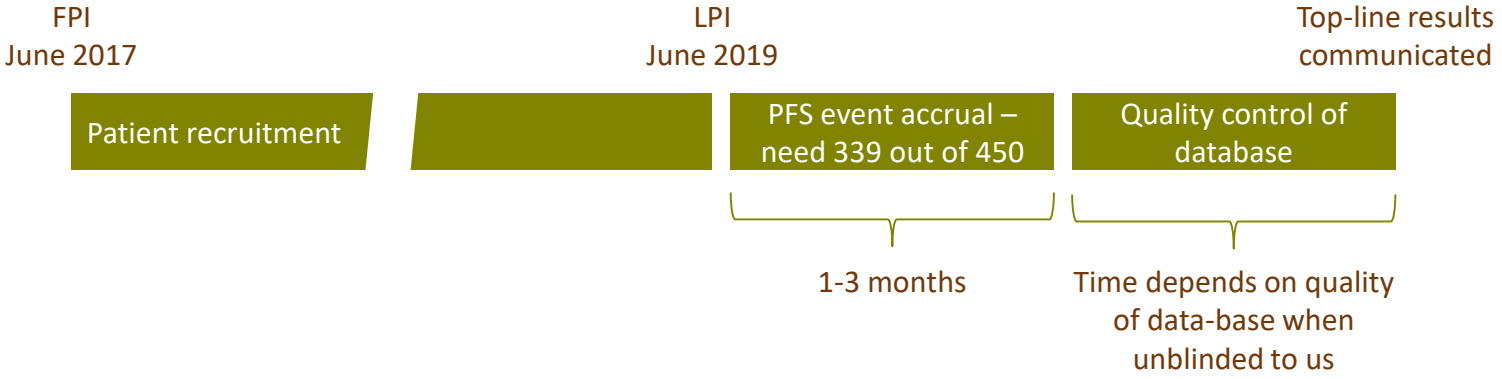
1) Quock et. al, Blood Advances, May 2018
2) Weiss et. al, Blood, 2016

Upcoming discussion with the FDA with regard to HORIZON data

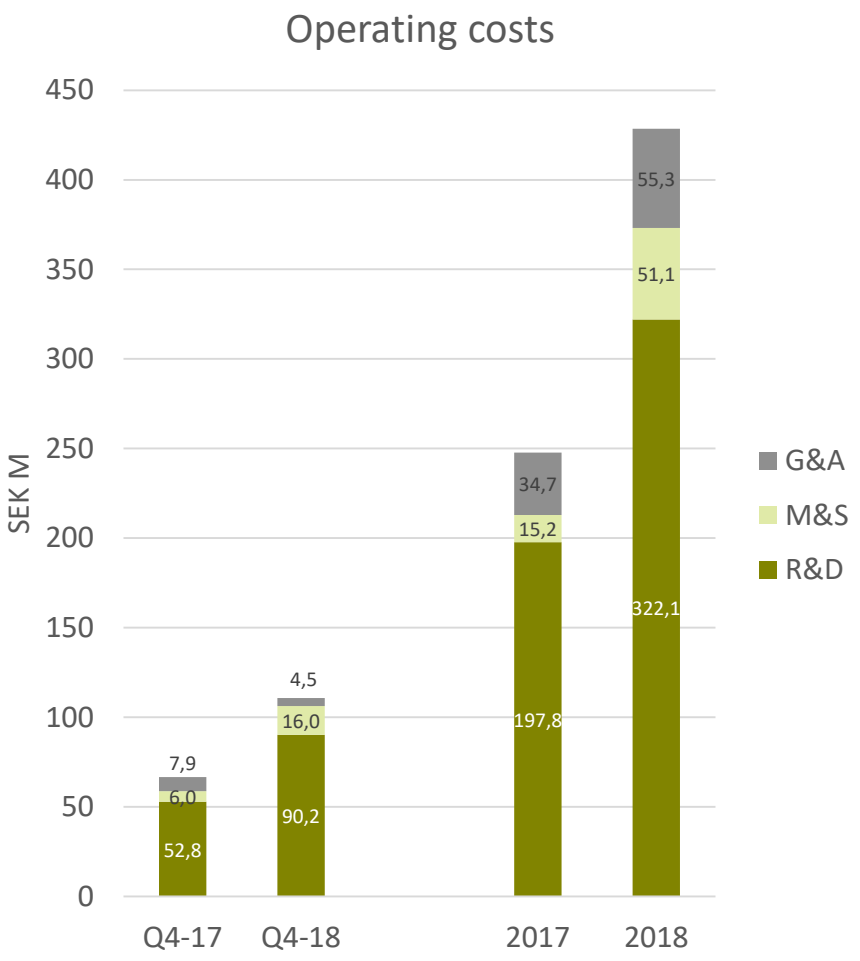
- HORIZON is a study in myeloma patients with no or limited treatment options
- Potential for accelerated approval path in the USA – but not certain
- ODAC meeting regarding selinexor (a competitor) on February 26th regarding accelerated approval in myeloma that will be very informative for Oncopeptides
- FDA meeting before the summer regarding HORIZON with input from the ODAC as well as updated HORIZON data will guide Oncopeptides for the possibility to apply for accelerated approval.

Our first pivotal trial OCEAN – what happens when a pivotal trial is fully recruited

- 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:

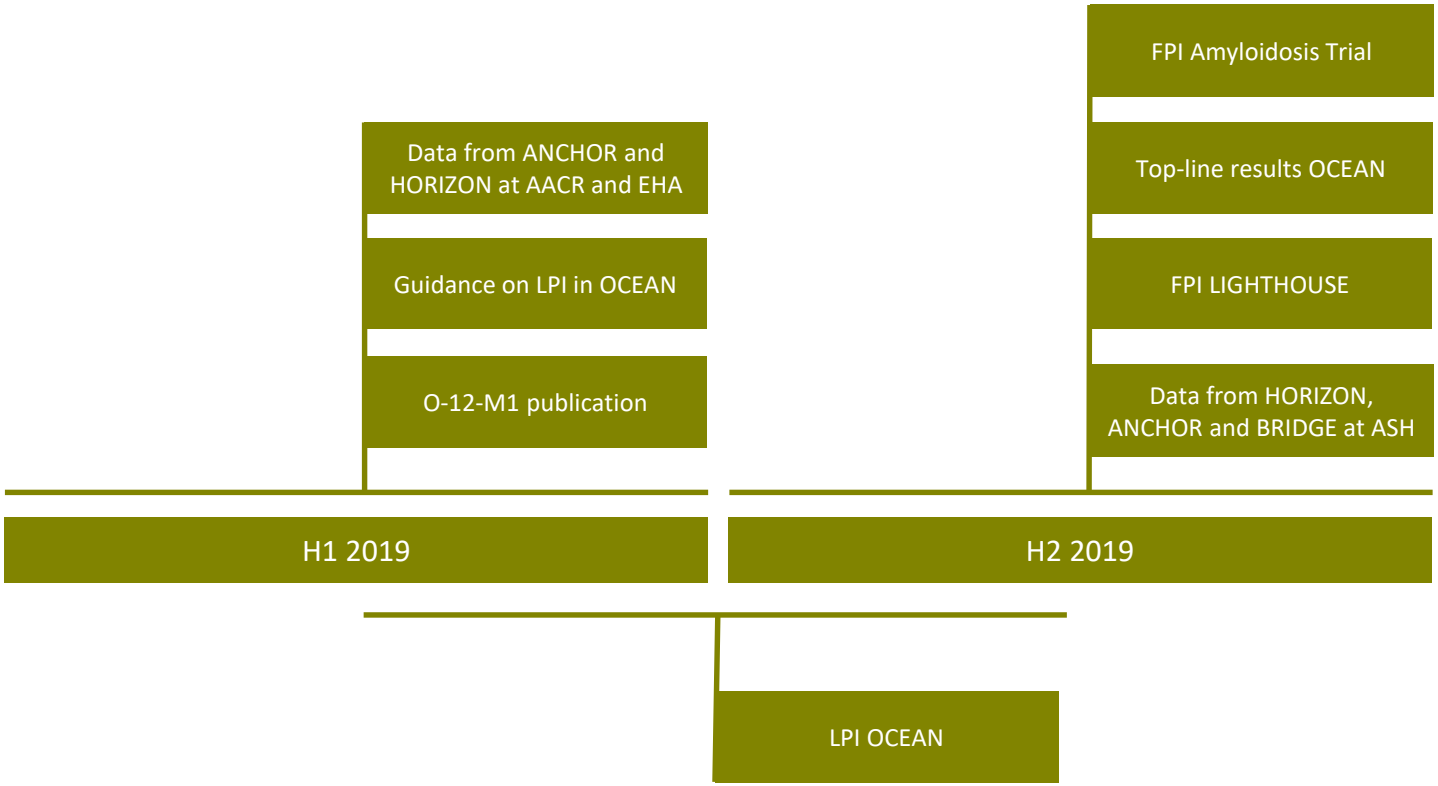


Financial results for the period Jan –Dec 2018



- 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 in January, 2019

Upcoming newsflow – highly exciting year ahead of us



Q/A

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