Oncopeptides

Stockholm Corporate Finance Life Science Seminar

March 11, 2020



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Oncopeptides at a glance

Develops targeted cancer treatments

- Proprietary peptide-conjugated compounds
- Lead compound Melflufen a peptide-conjugated drug 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 H1-20 based on ongoing phase 2 study HORIZON
- Triple-class refractory MM

Phase 3 expected to be fully enrolled in Q1 2020

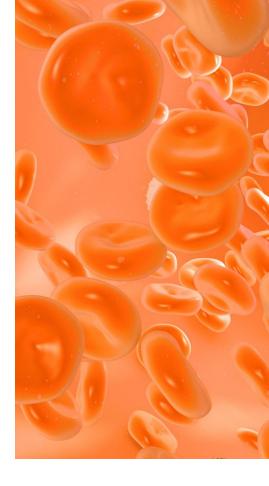
- Approximately 450 patients at 140 sites
- Two additional supporting studies ongoing. Additional phase 3 called LIGHTHOUSE will start early 2020

New indications and NCEs in development

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

Listed on NASDAQ Stockholm, strong financial position

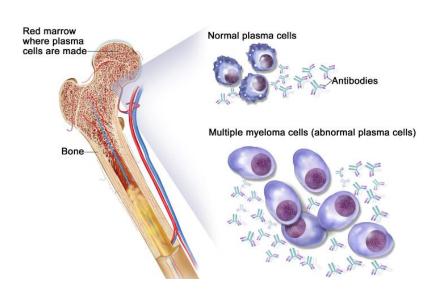
- Market cap: SEK 5.8 B
- Cash position: SEK 926 M as of December 31



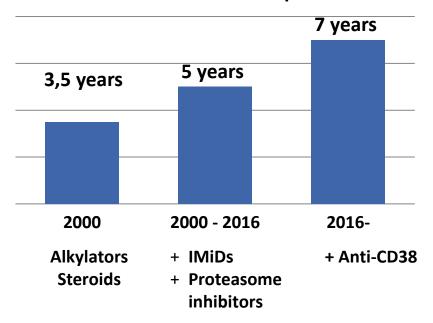


Multiple Myeloma is a hematological cancer without cure

Myeloma – Uncontrolled plasma cell proliferation

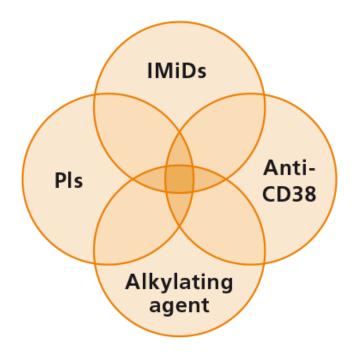


Median Survival increasing with more available treatment options



Significant medical needs remain

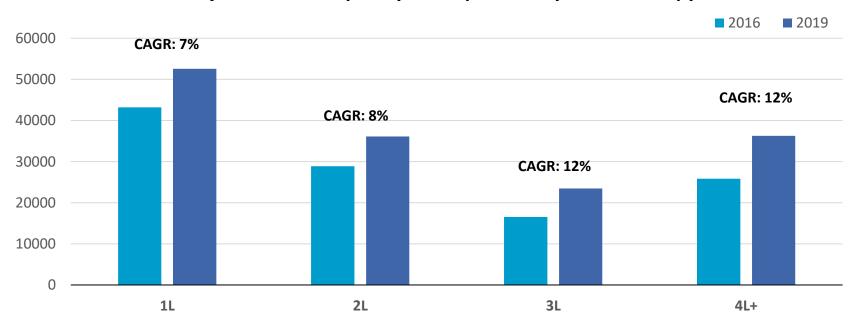
- Four treatment modalities used with inevitable resistance development
- Currently, the majority of patients have been treated with all four modalities after 2-3 lines of therapy with limited treatment options left
- Frequent co-morbidities further compounding the problem with limited treatment options





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

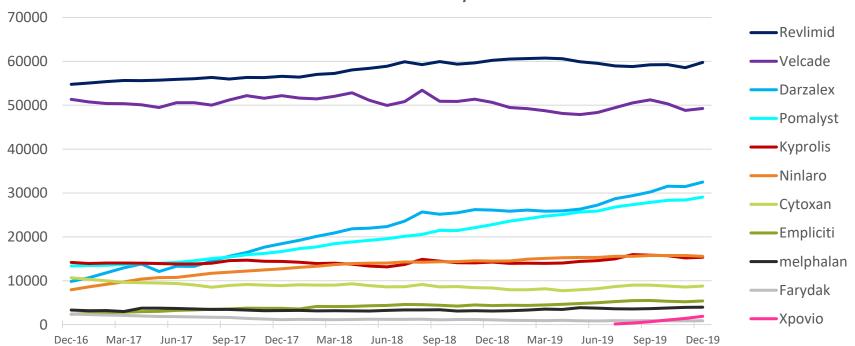




Note: 3-yr annual growth rate for 4Q2016-4Q2019

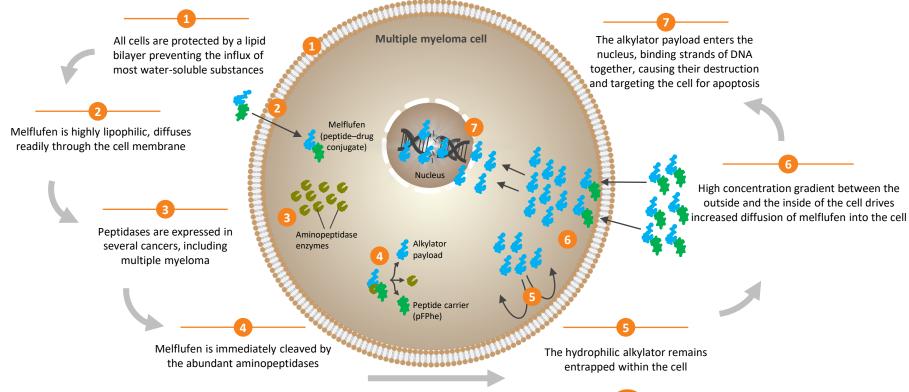
Newer products used in addition to older products as survival improves





Melflufen is a novel peptide-drug conjugate

- Uses high peptidase levels to target myeloma cells



Overview of our present clinical development program in multiple myeloma



O-12-M1

Show single-agent activity in RRMM



Show single-agent activity in RRMM



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



Show combination synergy and tolerability with daratumumab and bortezomib



Show that melflufen can be used in patients with renal impairment



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







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

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

MELFLUFEN

O-12-M1 showed an ORR of 31% and HORIZON an ORR of 29% 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

NICE TO HAVE CHARACTERISTICS

Easy administration schedule

One 30-minute infusion every 28 days

Label journey with current development program in myeloma

Patient Pool TRIPLE CLASS REFRACTORY **Initial Label** (accelerated **HORIZON** approval) **EMD / HIGH RISK** SINGLE / DOUBLE CLASS REFRACTORY ONE DRUG +/- STEROID **OCEAN** Label **Expansions** SINGLE / DOUBLE CLASS REFRACTORY TWO DRUGS +/- STEROID **ANCHOR** LIGHTHOUSE

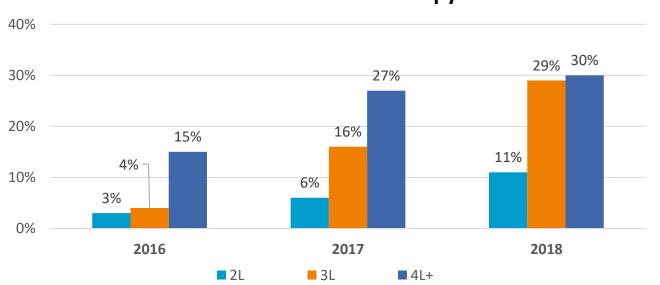
Melflufen triple-class RRMM data highly competitive HORIZON



	Melflufen	Xpovio Karyopharm US approval July 2019	Belantamab GSK In filing	
Number of patients studied	93	122	97	
Overall Response/Clinical Benefit Rate	24%/37%	25%/39% 31%/34%		
Duration of response	7.5 months	4.4 months	NR (≈7-8months)	
Progression-free Survival	4.0 months	3.7 months	2.9 months	
Overall survival	11.3 months	8.0 months	NR (≈10months)	
Share of patients with EMD	34%	22%	23%	
Serious Adverse Event Rate	51%	58%	36% (excl. ocular tox.)	
Non-hematologic toxicity (grade 3/4) reported in >5% of patients	Pneumonia 8.4%	Fatigue 25.2% Hyponatremia 20.3% Nausea 9.8% Pneumonia 8.9% Diarrhea 7.3% Sepsis 5.7% Hypokalemia 5.7% Mental status 5.7% General det. 5.7%	Keratopathy/ 27.4% Blurred vision Hypercalcaemia 7.4% Pneumonia/ 6.3% Lung infections	

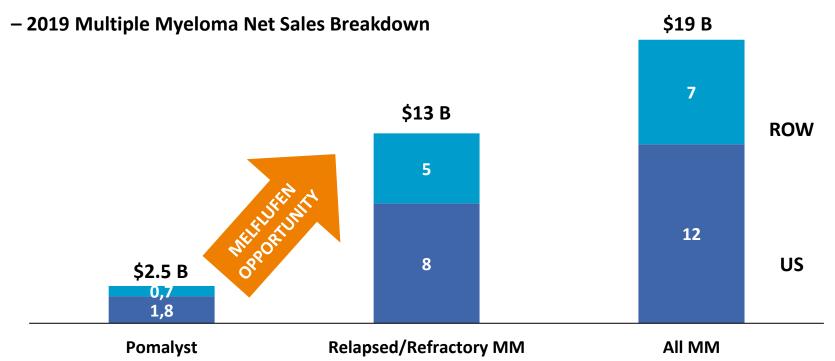
Initial indication of triple-class refractory disease is a significant and growing unmet medical need in myeloma

Triple-class refractory patient share after each Line of therapy



Estimated
>20,000
Triple-class
refractory
patients in the
US and
growing

Melflufen opportunity in Relapsed **Refractory Multiple Myeloma**



Recent highlights

Clinical programs progressing

- AL Amyloidosis study initiated, first patient to be dosed shortly
- The phase 3 study, OCEAN, on track to recruit last patient in Q1-20
- LIGTHOUSE, phase 3 combination study to start in the coming months
- HORIZON, targeting submission during Q2-20

Promising clinical data presented at ASH in December

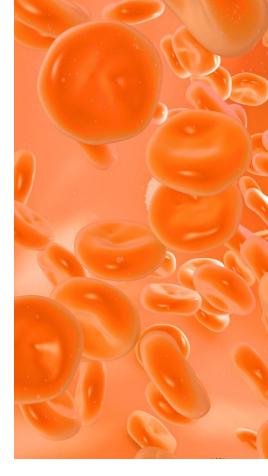
- ORR of 29% in HORIZON, 24% in triple-class refractory myeloma patients
- Progression-free survival of 14.3 months for melflufen in combination with daratumumab in RRMM (ANCHOR study) presented

NDA submission process on track with submission planned during first half of 2020

- Pre-NDA meeting held with the FDA in December confirming plans to submit on all 157 patient included in the study
- Application for accelerated approval in triple class refractory on track for Q2 2020

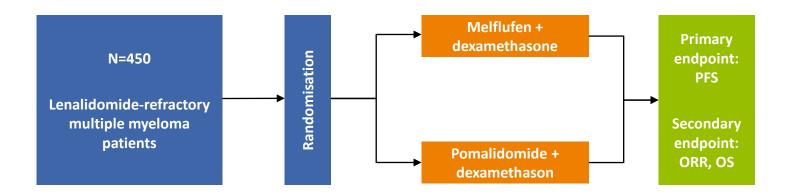
Key staff members recruited

In the process of preparing for a potential launch in the United States, Joseph Horvat was appointed as President North America



Data to date provide high conviction for success in our ongoing phase 3 study 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

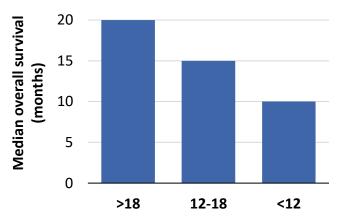
- Only 29% received lenalidomide as last treatment
 Lenalidomide used more aggressively today
- Median maintenance duration 24 months instead of 10 months

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

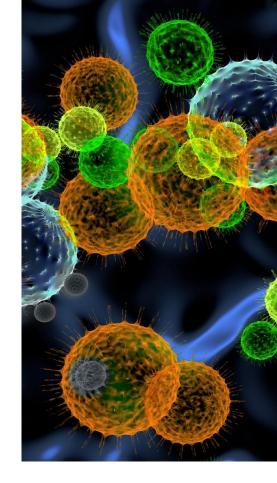


IMiD-free period before start of pomalidomide treatment (months)

Encouraging data for melflufen in combination with daratumumab

Summary of combination with daratumumab – n=33

- Median of 2 prior lines of therapy
- True RRMM population (not maintenance refractory) 39% had disease progression while on last line of therapy and 60% high-risk cytogenetics
- ORR of 76% with good tolerability and deepening responses - 22 patients ongoing
- Median PFS of 14.3 months





Combination study LIGHTHOUSE



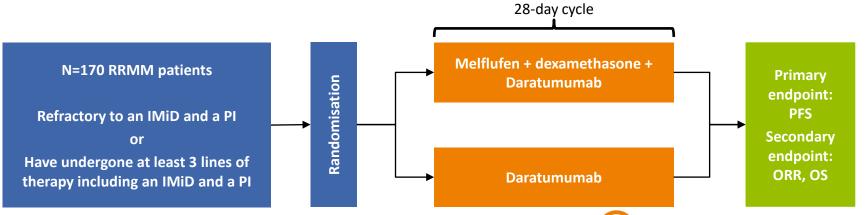
Our second confirmatory phase 3 study – final preparations ongoing

Second phase 3 study 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 development program add a third study that can result in market registration in the EU and US



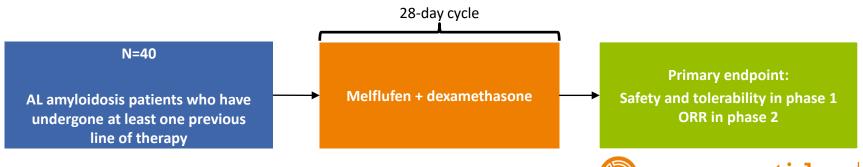
Phase 1/2 study in AL amyloidosis initiated - patients are in screening

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 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 2010-2013²⁾



The coming quarters will be very information rich

Q1 2020 Q2 2020 Q3 2020 Q4 2020 First patient in **Top-line results Potential accelerated** Last patient in **Amyloidosis study BRIDGE OCEAN** approval in US Last patient in New data and updates **Potential Launch in** Last patient in **OCEAN** at EHA **ANCHOR** US First patient in **NDA** submission LIGHTHOUSE

Summary

Significant unmet needs in Multiple Myeloma

• \$19 B orphan market

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

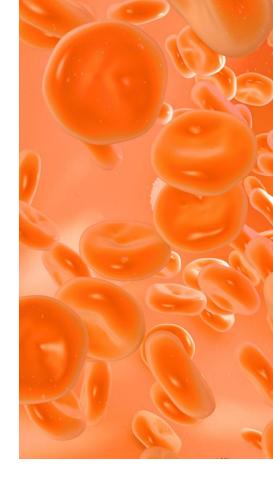
- Phase 2 study, O-12-M1, showed very strong survival data
- Both phase 2 studies, HORIZON and ANCHOR show strong overall response (ORR) data and competitive profile for progression-free survival (PFS)
- Generally well tolerated giving patients good quality of life

Late stage development program with multiple ways to get approval

- Submission for accelerated approval for triple-class refractory patients in the US targeted during Q2 2020 based on HORIZON data
- Phase 3 study OCEAN expected to be fully enrolled Q1 2020
- Additional Phase 3 study, LIGHTHOUSE will start in the coming months

Strong financial position

Cash position: SEK 926 M (\$ 95 M) as of December 31



Thank you for your attention!

