

Oncopeptides Operational Update Q4 2019

“We have started the journey to become a commercial company by the end of 2020”

Jakob Lindberg, CEO

February 20, 2020



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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
- LIGHTHOUSE, phase 3 combination study to start in the coming months
- HORIZON, targeting submission during Q2-20

Promising clinical data presented at ASH in December

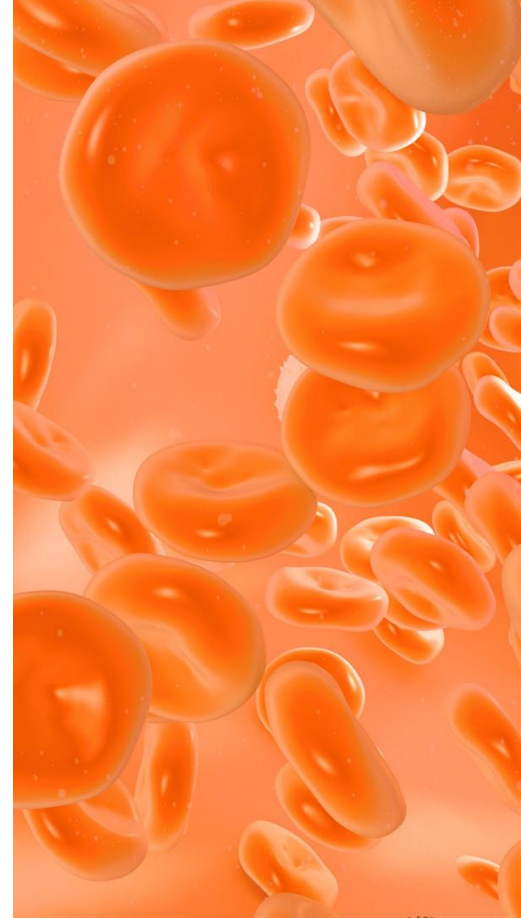
- ORR of 29% in HORIZON, 24% in triple-class refractory myeloma patients
- Progression-free survival of 14.3 months for melflufen in combination with daratumumab in RRMM (ANCHOR study) presented

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

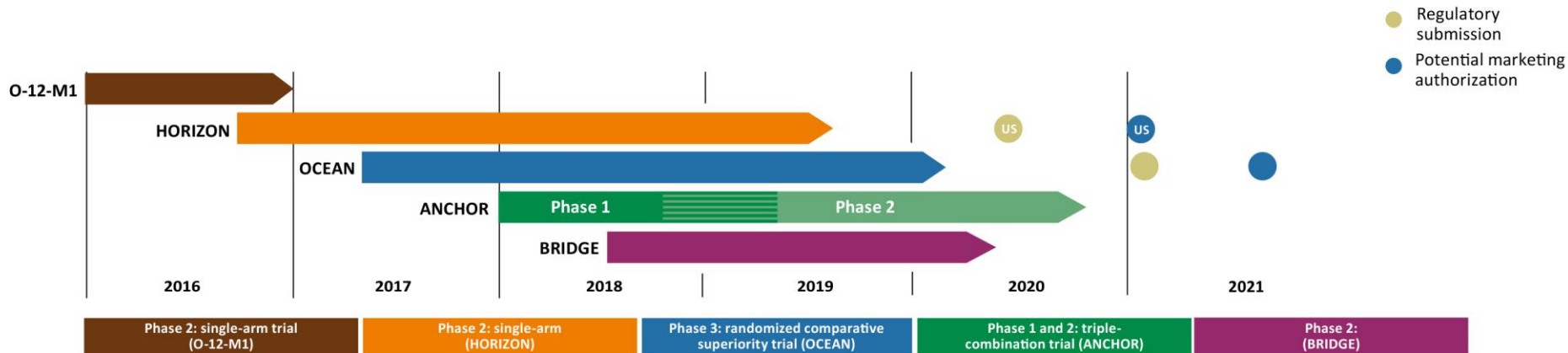
- Pre-NDA meeting held with the FDA in December confirming plans to submit on all 157 patient included in the study
- Application for accelerated approval in triple class refractory on track for Q2 2020

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



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)

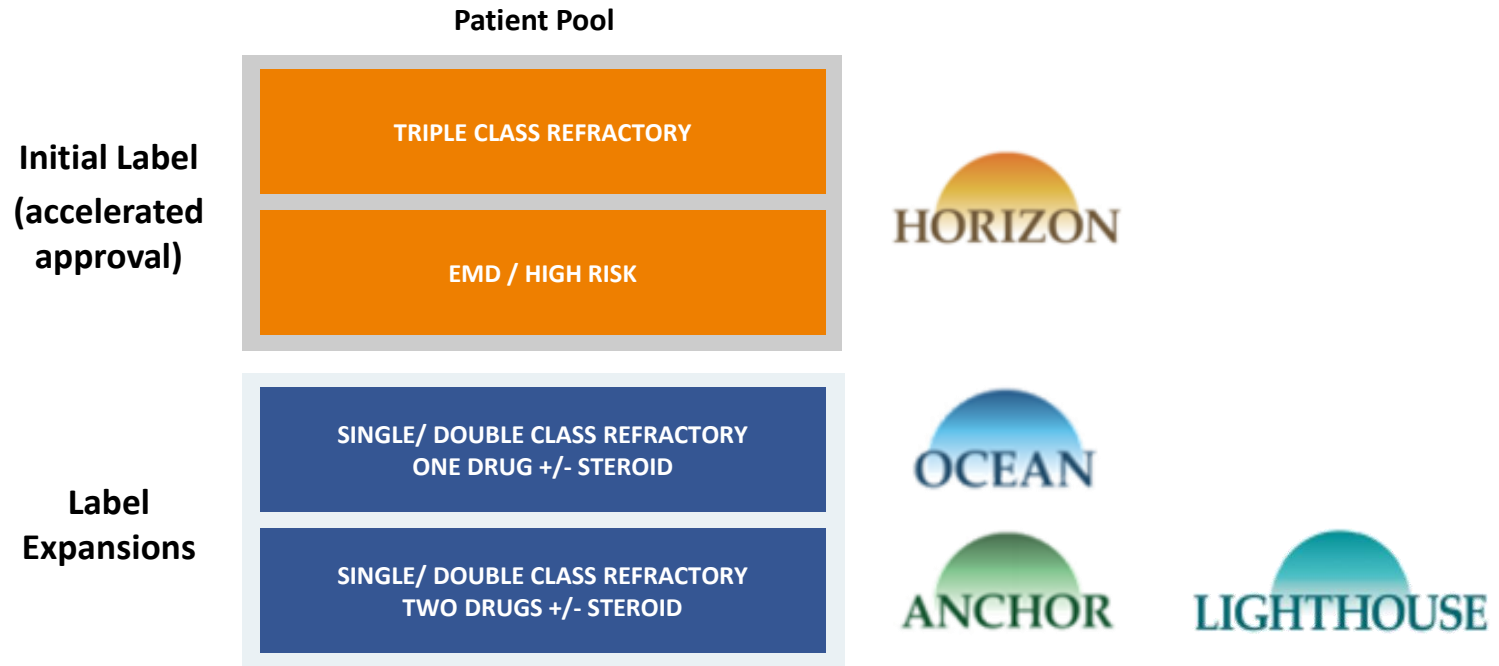
ANCHOR

Show combination synergy and tolerability with daratumumab and bortezomib

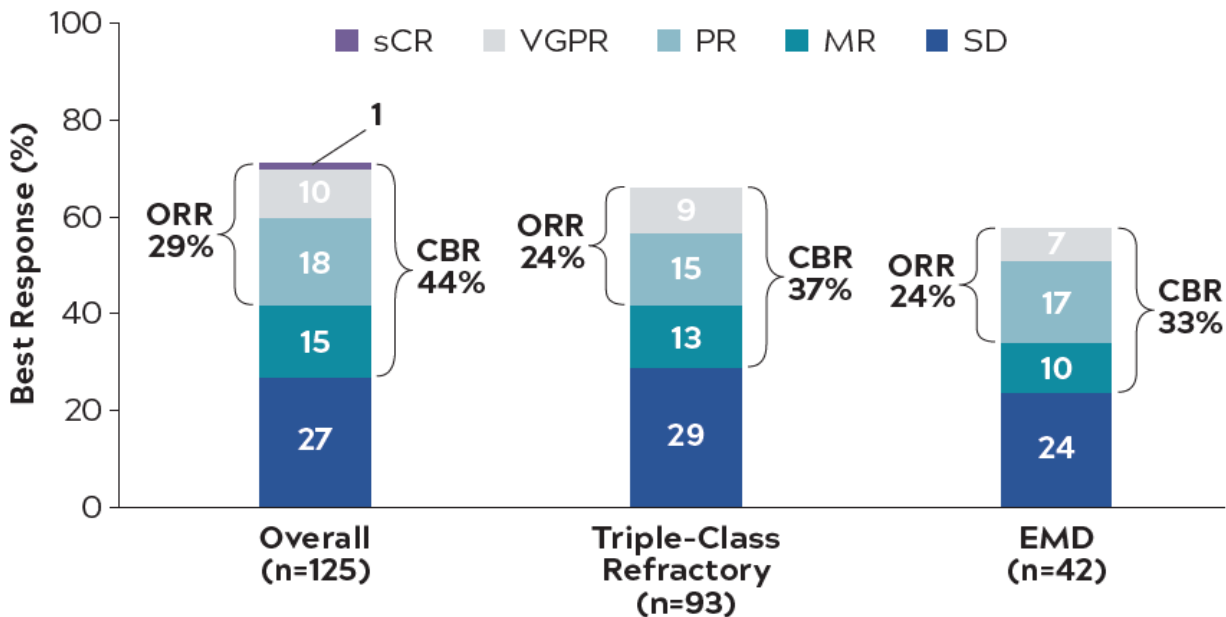
BRIDGE

Show that melflufen can be used in patients with renal impairment

Label journey with current development program in myeloma



Promising overall response rates in both triple-class refractory patients and patients with EMD at relapse



^aResponse was investigator assessed.

CBR, clinical benefit rate; EMD, extramedullary disease; IMWG, International Myeloma Working Group; MR, minimal response; ORR, overall response rate; PR, partial response; sCR, stringent complete response; SD, stable disease; VGPR, very good partial response.

Source: Mateos MV, et al. ASH 2019. #1883

Melflufen triple-class RRMM data highly competitive



	Melflufen (n=93)	Selinexor (n=122)	Belantamab (n=97)
ORR/CBR	24/37%	25%/39%	31%/34%
mDOR	7.5 months	4.4 months	NR (≈7-8months)
mPFS	4.0 months	3.7 months	2.9 months
mOS	11.3 months	8.0 months	NR (≈10months)
%EMD	34%	22%	23%
SAE 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

Combination study LIGHTHOUSE

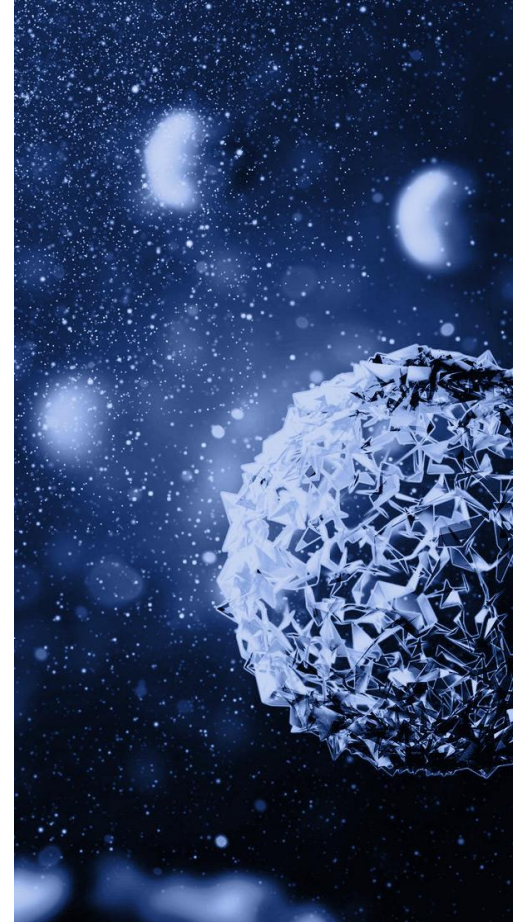
Our second confirmatory phase 3 study – final preparations ongoing

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



Study in AL amyloidosis initiated

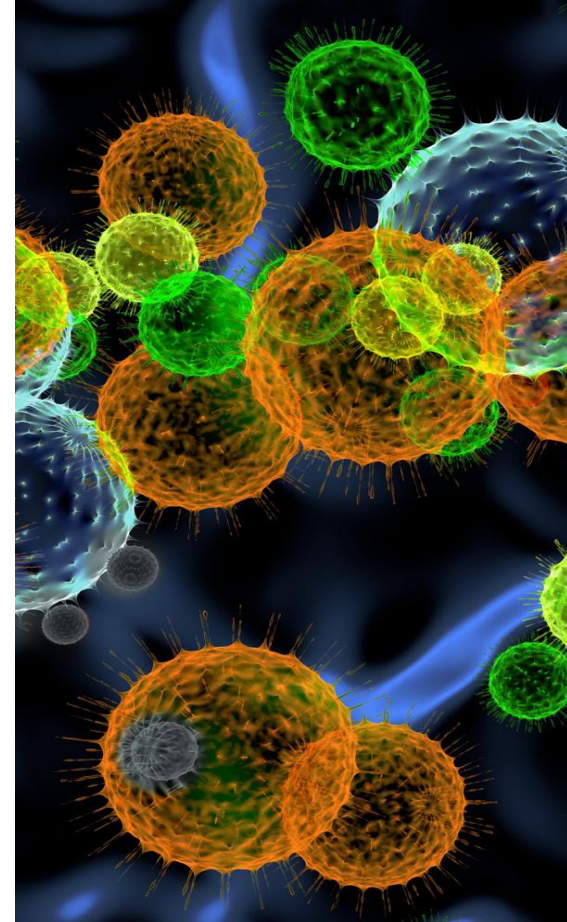
Similar to myeloma, AL amyloidosis is a disease of the B-cell system

- 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

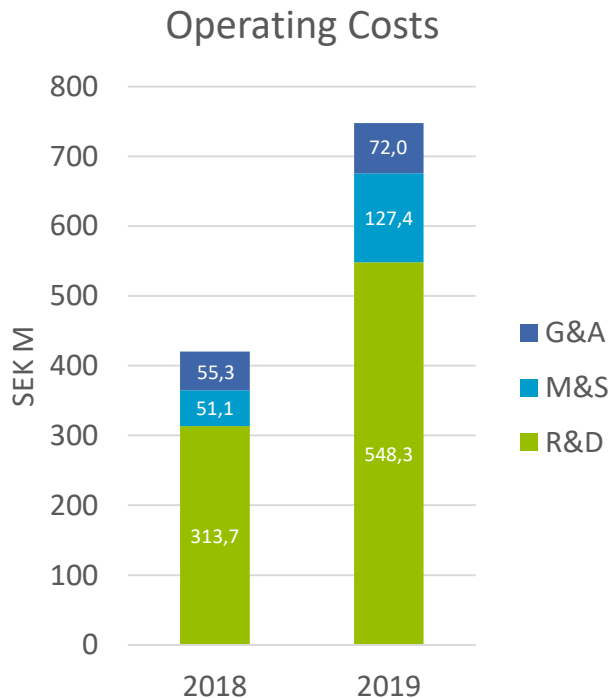
Similar drug use as for myeloma – drugs that are efficacious in myeloma are most of the time also used in AL amyloidosis

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 2010-2013)²

Phase I+II study – sites have been opened and patients are in screening - up to 40 patients will be recruited across both phases



Financial results for the period Jan – Dec 2019

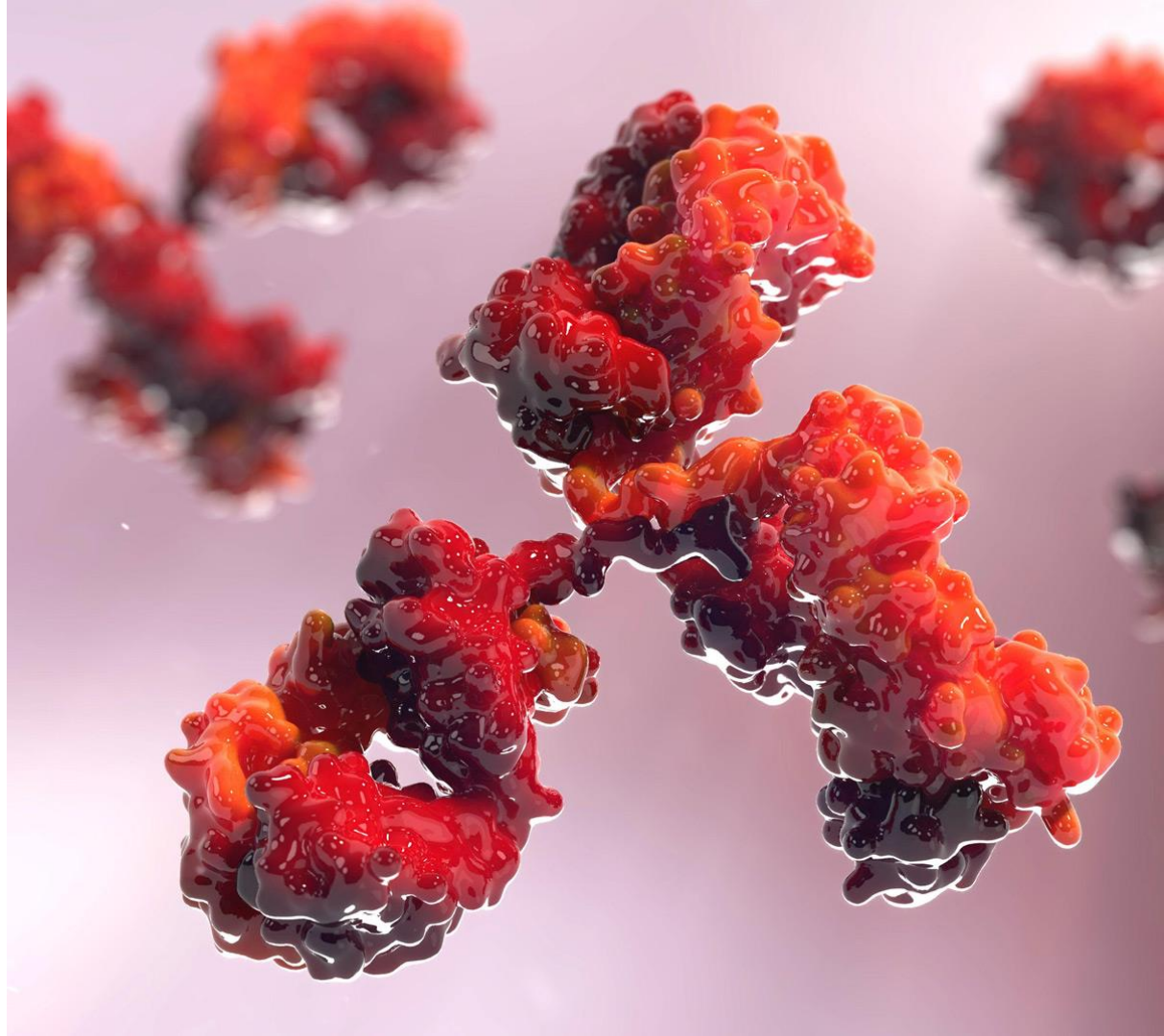


- Operating loss increased to SEK 739.4 M (loss:411.0)
 - R&D increase primarily due to increase in Clinical & drug supply: SEK 439.4 M (260.3)
 - OCEAN costs SEK 211.8 M (132.1)
 - HORIZON costs SEK 70.9 M (28.5)
 - ANCHOR costs SEK 44.6 M (25.9)
 - Build-up of commercial and medical relations explains increase in M&S costs
- Operating costs include non-cash costs related to incentive programs
 - SEK 37.8 M (54.1) for the year
- Cash flow from operating activities neg. SEK 690.6 M (neg. 333.7)
- Cash position was SEK 926.2 M (375.6) as of Dec 31, 2019
 - Directed share issue raised SEK 514.8 M after issue costs in January 2019
 - Second share issue raising SEK 682.9 M was completed in July

The coming quarters will be very information rich

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

Q&A



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

