

# Avanza Growth Day June 10, 2019

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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

## 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

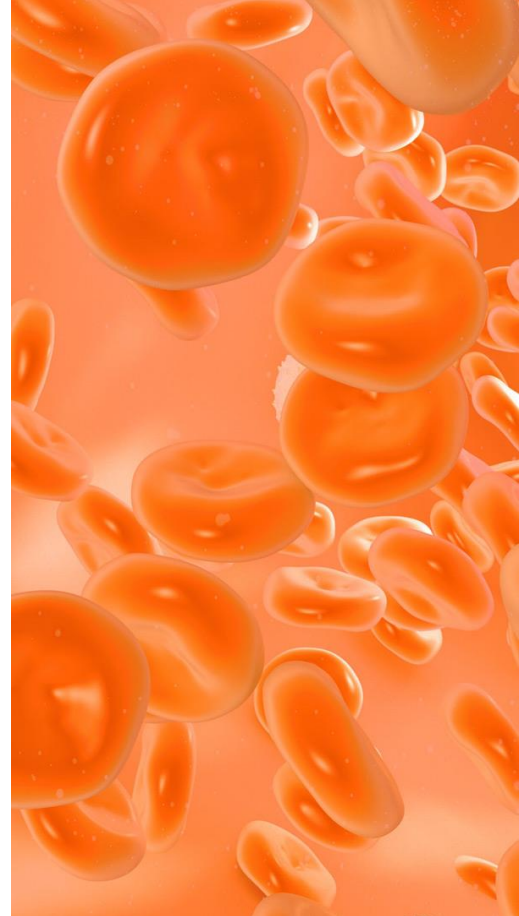
- Approximately 450 patients at 140 sites
- Two additional supporting trials ongoing, additional Phase 3 to be started 2019

## Listed on NASDAQ Stockholm, strong financial position

- Market cap: SEK 8 B
- Cash position was SEK 747.5 M as of March 31, 2019

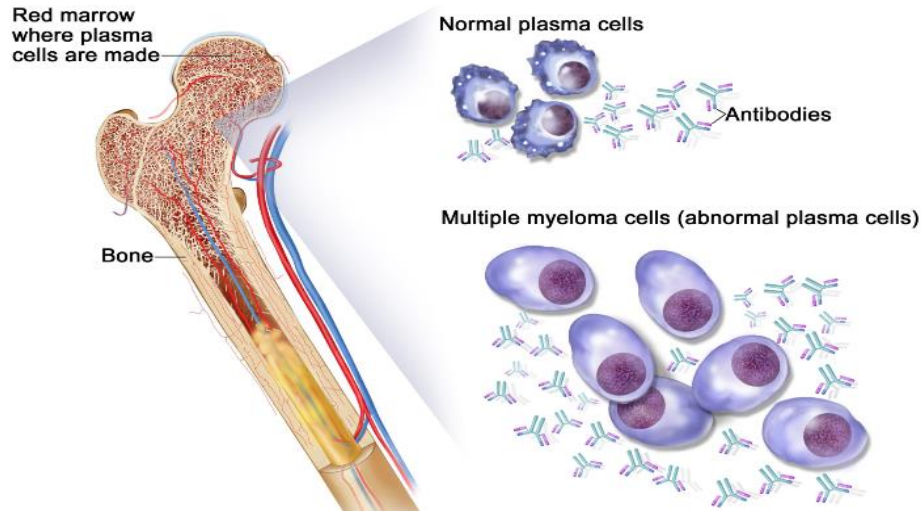
## New indications and NCEs in development

- Clinical trials expected to start in 2019

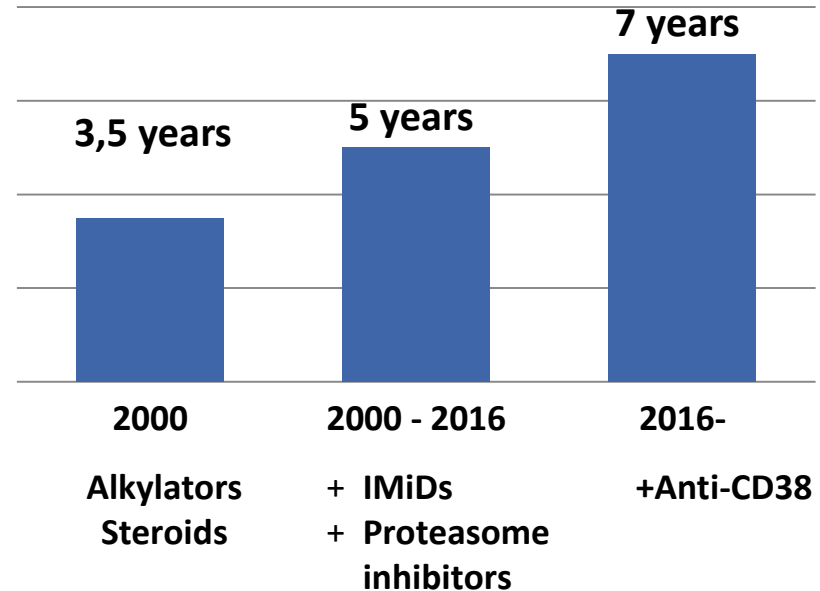


# Multiple Myeloma is a hematological cancer without cure

## Myeloma – Uncontrolled plasma cell proliferation

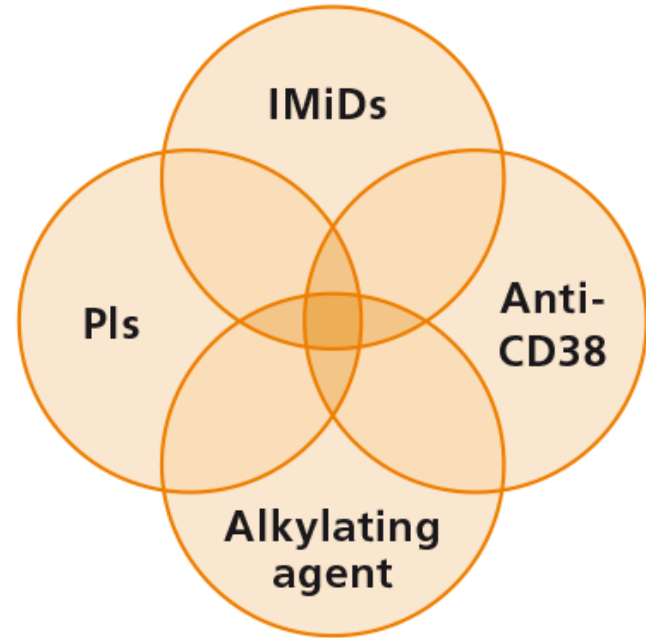


## Median Survival increasing with more available treatment options



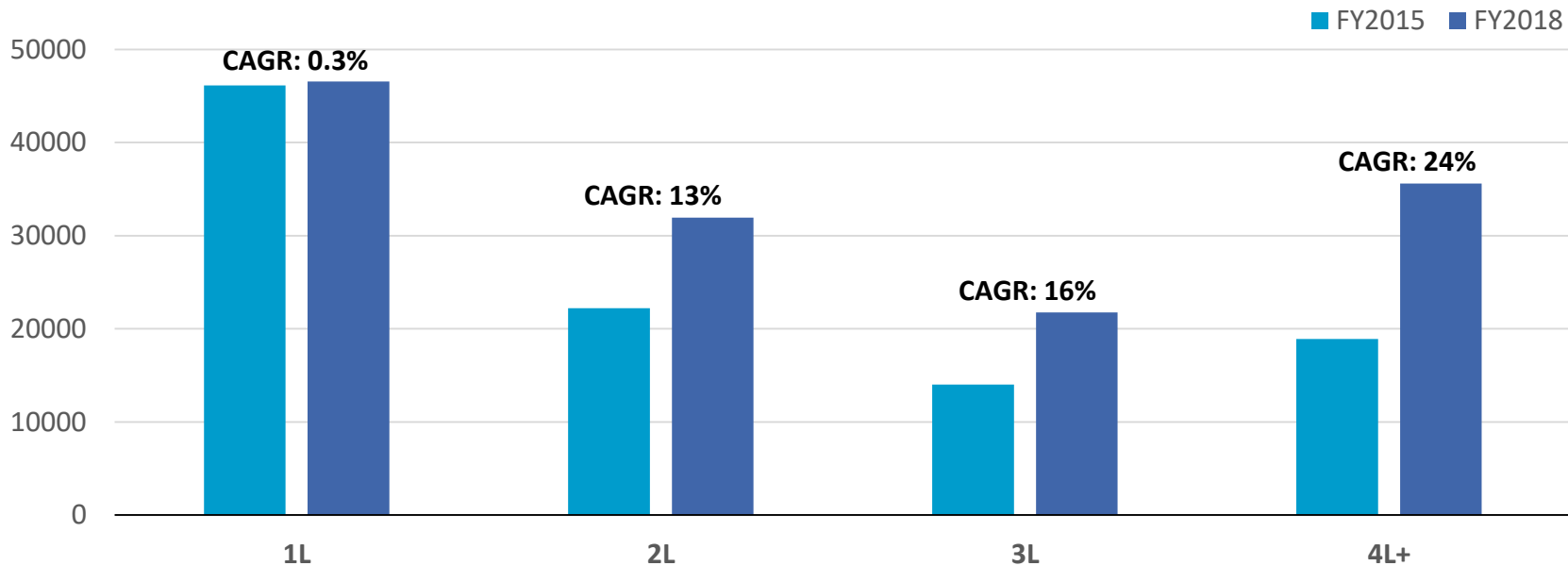
# Significant medical needs remain

- 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

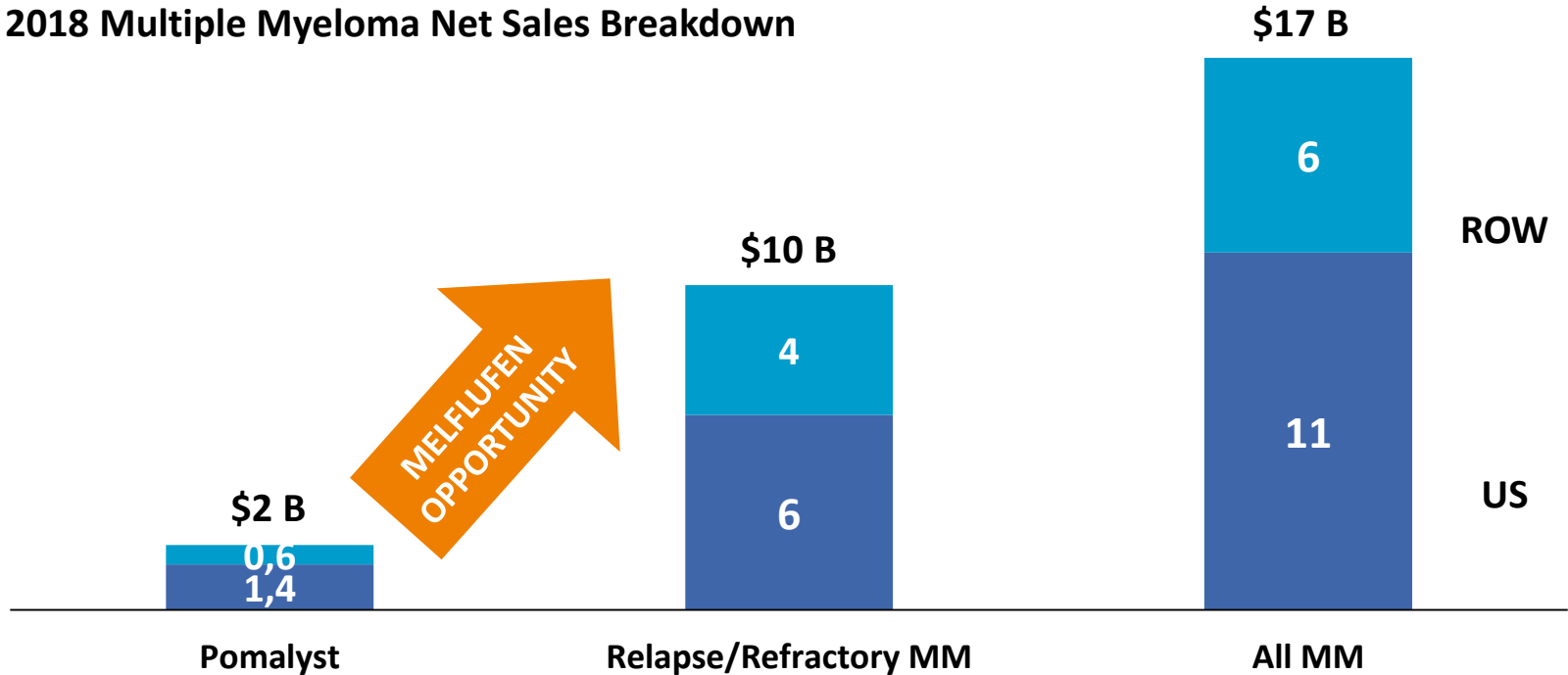


Source: Intrinsic Dec 2018, MAT

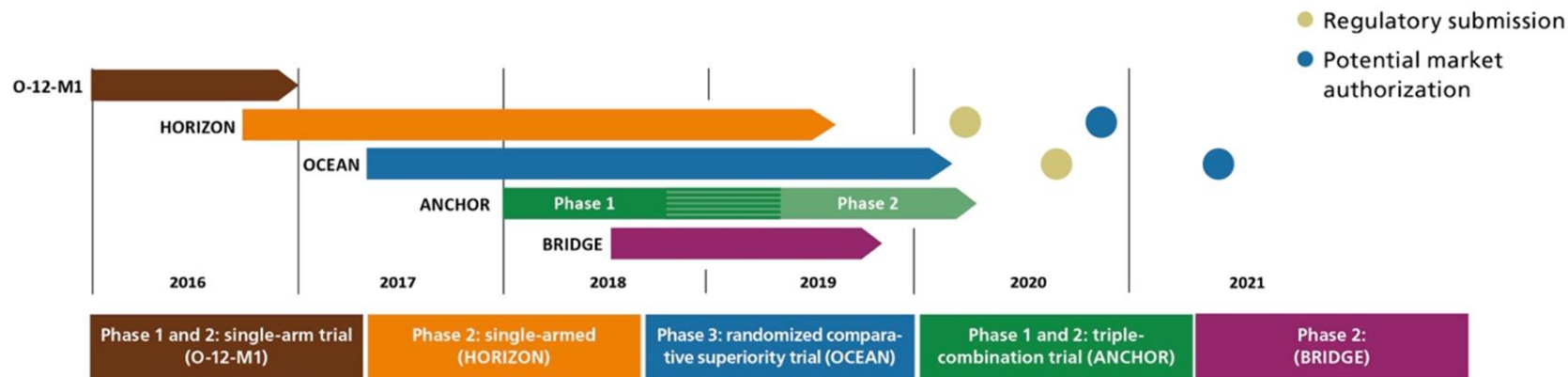
Note: 3-yr annual growth rate for 2015-2018

# Melflufen opportunity in Relapsed Refractory Multiple Myeloma

– 2018 Multiple Myeloma Net Sales Breakdown



# 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



# 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

## NICE TO HAVE CHARACTERISTICS

Easy administration schedule

## MELFLUFEN

O-12-M1 showed an ORR of 31% and HORIZON an ORR of 33% 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

One 30 minute infusion every 28 days

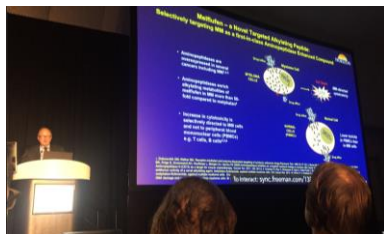
# Strong data presented at ASH 2018

## Interim HORIZON data in patients with no or limited treatment options

- Overall response rate of 33% with favorable safety profile

## Combination data with bortezomib or daratumumab from ANCHOR trial

- Overall response rate of 100% and 86% respectively

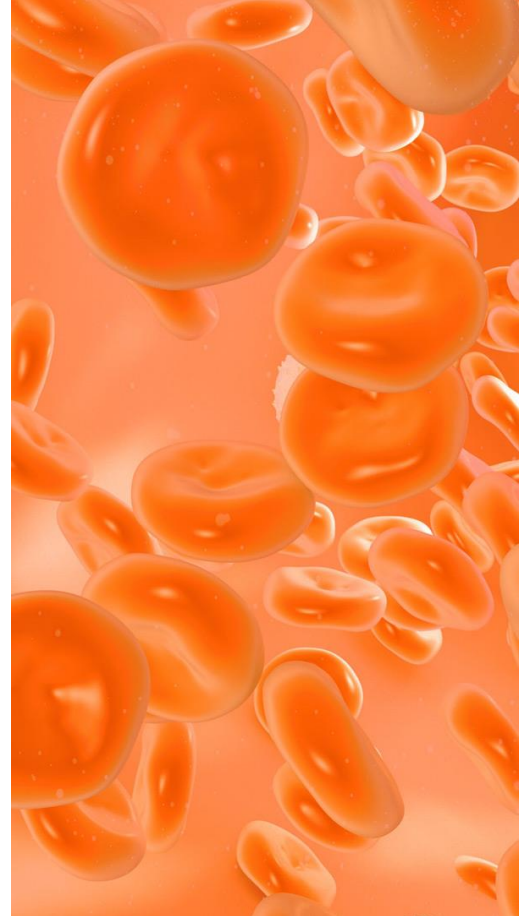


*"Good News on the HORIZON: Melflufen Induces Response in Heavily Refractory Myeloma"*

*"Safety And Efficacy of Melflufen for Relapsed Refractory Multiple Myeloma Patients"*

# Application process initiated for accelerated approval in the US

- Oncopeptides has been engaged in dialogue with the FDA during the Spring of 2019 about the HORIZON data
- FDA has had access to all data from our ongoing and completed trials (apart from OCEAN)
- Based on the dialogue, Oncopeptides has now initiated the submission process for accelerated approval in the US
  - Treatment of relapsed refractory multiple myeloma patients whose disease is triple-class refractory (i.e. refractory to one IMiD, one PI and one anti-CD38 Mab)
- Target filing date is Q1 2020



# Our new pivotal combination trial LIGHTHOUSE of high strategic importance

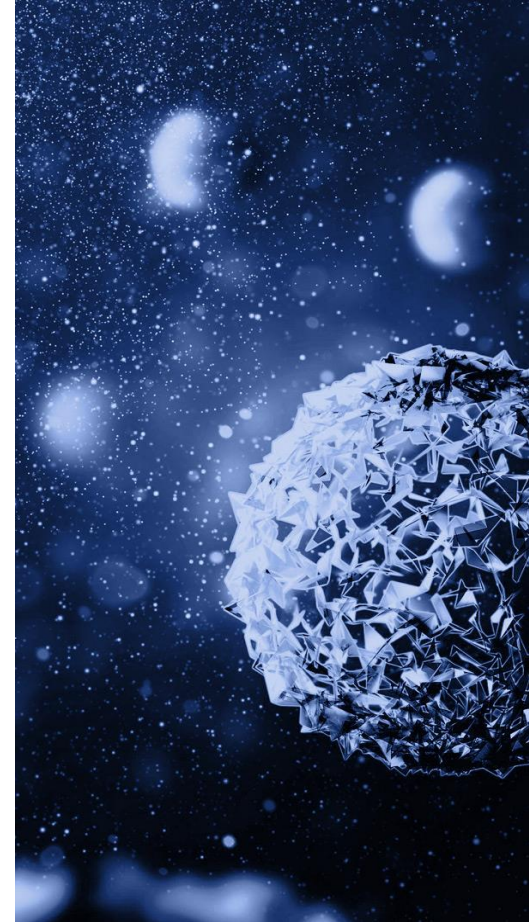
## Second pivotal phase III trial with melflufen in multiple myeloma

- 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 enrolling the first patient in H2 2019**



# Upcoming newsflow – highly exciting year ahead of us

H1 2019	H2 2019	H1 2020
Data from ANCHOR and HORIZON at AACR	FPI Amyloidosis Trial	NDA submission
O-12-M1 publication	FPI LIGHTHOUSE	LPI OCEAN
FDA meeting on HORIZON	LPI HORIZON	LPI ANCHOR
Updated data from ANCHOR and HORIZON at EHA	LPI BRIDGE	Top-line results OCEAN
	Updated Data from HORIZON, ANCHOR and BRIDGE at ASH	

# 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

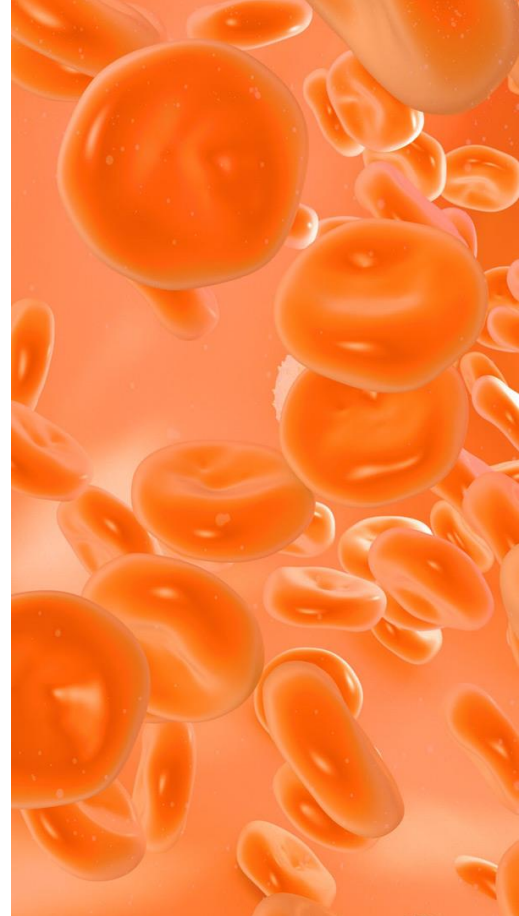
- Phase 2 showed very strong survival data
- Generally well tolerated giving patients good quality of life

## Broad development program with multiple ways to get approval

- Submission for accelerated approval for triple-class refractory patients in the US targeted in Q1-20
- Pivotal phase 3 expected to be fully enrolled Q1 2020
- Additional Phase 3 to be started 2019

## Strong financial position

- Cash position March 31, 2019: SEK 747.5 M



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

