

Ygalo[®] - a Phase III asset addressing a \$2bn+ market in myeloma

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Ygalo[®] is a Targeted Alkylator for the Treatment of Myeloma

Phase III read-out mid 2019

Ygalo[®]: a next-generation broad spectrum agent for late stage RRMM

- Data so far supports superior efficacy over current standard of care in late-stage myeloma with improved tolerability profile (non-haematological toxicity is rare)
- First drug candidate is a PEnC class compound with an alkylating payload
- Overcomes resistance mechanisms that impact current therapies (IMiDs)

Significant unmet need and growing patient population

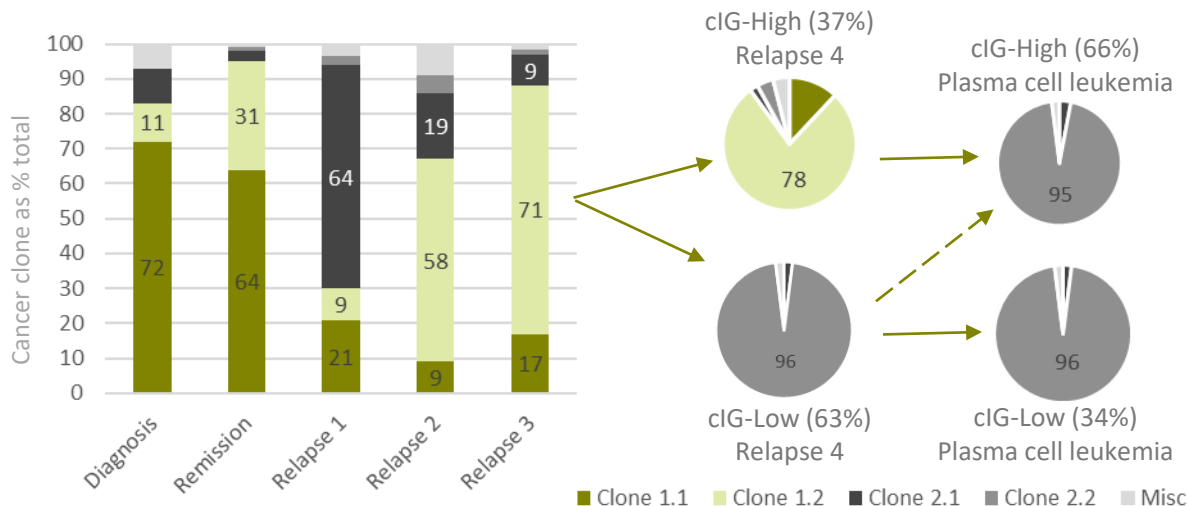
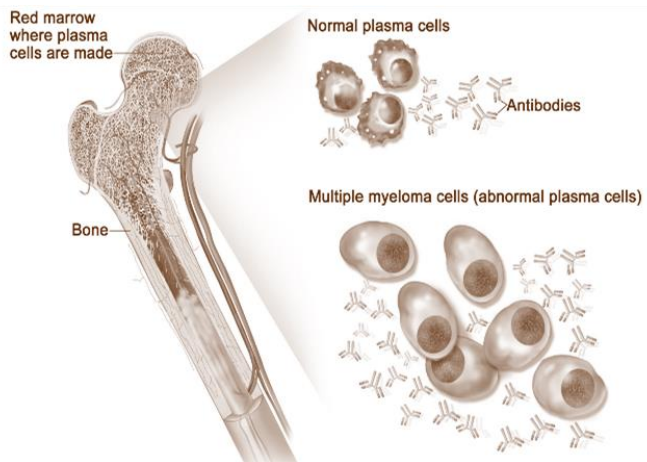
- Relapse is inevitable. New targeted therapies grow the market opportunity
- Prognosis is poor, with limited options available in late-stage disease
- Ygalo[®] addressing a \$2bn+ ¹⁾ late-stage disease market with double digit % growth

Fully funded pivotal Phase 3 trial underway; broad development program

- Agreement with FDA (SPA) and EMA on clinical trial design
- Orphan drug designation in EU and US
- Multiple paths to approval de-risk the development pathway
- New indications

Multiple Myeloma is a hematologic cancer with no cure

MM is a disease that is constantly evolving and becoming refractory / resistant to therapy is inevitable



Broad Spectrum agents are the bedrock of therapy

Modality	Pharmaceutical drugs	Myeloma Sales 2016	% US pts treated 2016
Broad Spectrum Agents			
Alylating agents	Bendamustine, cyclophosphamide, melphalan	} >10bn USD	93.9%
IMiDs	Revlimid, Pomalyst, thalidomide		
Proteasome inhibitors	Velcade, Kyprolis, Ninlaro		
Steroids	Dexamethasone, prednisone		
Targeted Agents			
Anti-CD38	Darzalex	} >0.7bn USD	9.2%
Anti-SLAMF7	Empliciti		

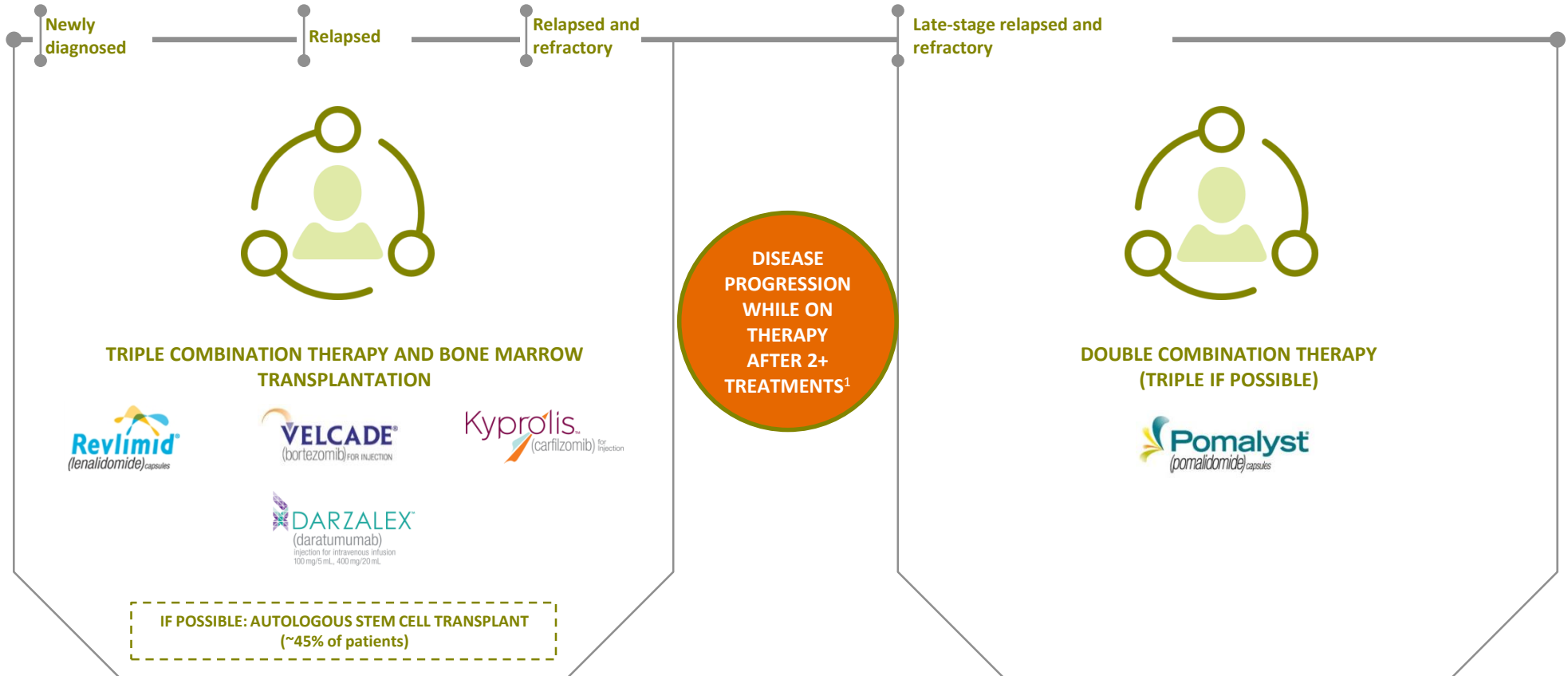
Late stage drugs limited: POM shares resistance with REV

Newly diagnosed	Relapsed	Relapsed / Refractory	Late-stage R/R
ASCT IF POSSIBLE (~45%) or COMBO THERAPY			2 COMBO THERAPY EXP. THERAPY

RRMM: relapsed refractory multiple myeloma, ASCT: autologous stem cell transplant; Sources: Blood 2012 120:1067-1076; GlobalData; steroids excluded (almost 100% patient share); Lines of therapy includes those with an estimated market share above 5% in respective stages in the US during 2016.

There are limited number of treatment options for late-stage RRMM patients despite advances in treatment of early-stage MM

Lines of therapy throughout the disease stages¹⁾



Limited number of treatment options for late-stage RRMM patients –
Novel treatment options are necessary and demanded by patients and regulatory bodies

Source: GlobalData. Steroids excluded (almost 100% patient share)

1) Including those with an estimated market share above 5% in respective stages in the US during 2016

Different treatment modalities complement each other in myeloma care – but there is no cure

Broad-spectrum Agents (alkylators, PIs, IMiDs and HDAC inh.)

- Back-bone in myeloma treatment
- Necessary treatment modality given heterogeneity of disease
- Resistance development is not on/off

Targeted Agents (CD38, BCMA, SLAMF7)

- No (or limited) resistance pattern overlap with broad-spectrum agents
- Single mutation resistance development
- Lack of good antigens in myeloma
- Best results together with broad-spectrum agents

CAR-Ts

- Lack of good antigens create limitations
- Good data in heavily pre-selected patients, but not better than antibody based therapies

Myeloma is primarily treated with single agents; lenalidomide and bortezomib are dominant (USA 2017)

Pomalidomide is the primary choice after lenalidomide and proteasome-inhibition failure

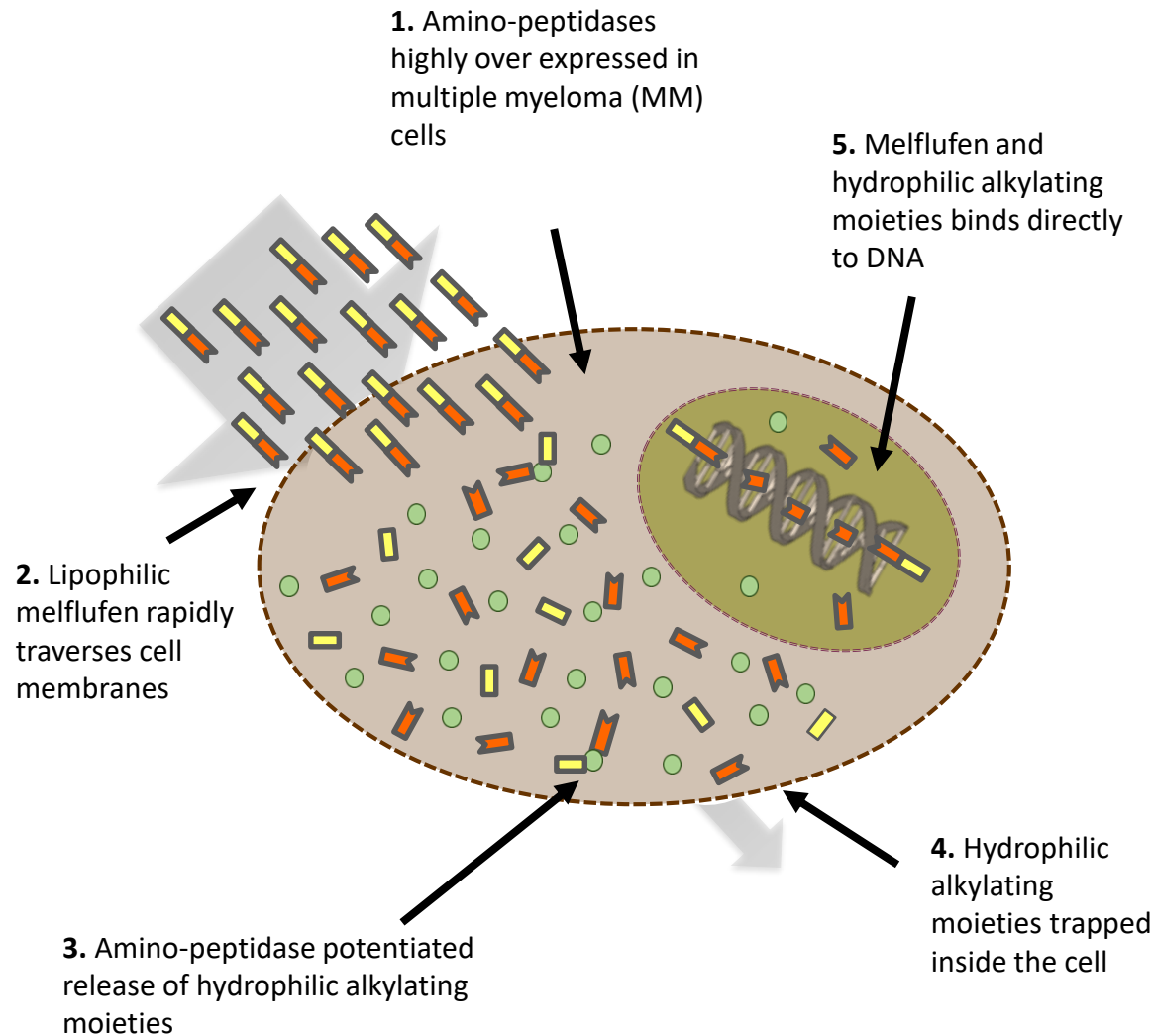
Number of patients treated per 12m¹⁾

Lenalidomide	55,565
Bortezomib	52,289
Daratumumab	17,068
Carfilzomib	15,133
Pomalidomide	13,459
Ixazomib	10,843
Other	22,305
<hr/>	
Total # of patients treated	132,829

- Single agent treatment is by far the most common (combination treatment is only significant in the 1st line)
- Lenalidomide and proteasome inhibitors (PIs) are used in early in the treatment algorithm. Daratumumab is moving from last-line to 1st line/ 2nd line rapidly
- Pomalidomide is the primary choice after lenalidomide and PI failure (disease progression while on therapy)

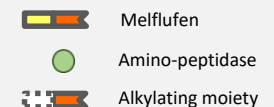
YGALO®

Ygalo[®] is a peptidase enhanced cytotoxic (PEnC) with an alkylating payload

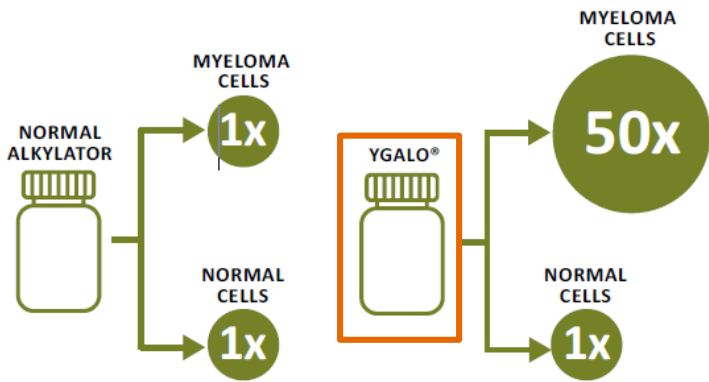


Peptidase enhanced activity in MM cells results in:

- Approx. 50-fold higher intra-cellular exposure in MM cells^{1,5}
- Approx. 50-fold higher anti-MM potency^{1,2,5}
- Alkylation of DNA with limited or no induction of DNA repair^{3,5}
- Strong anti-angiogenic properties^{1,4,5}
- Increase in therapeutic index of 20x – 40x (MM cells compared with peripheral blood mononuclear cells)^{1,5}



Phase II data supports superiority of Ygalo[®] over standard-of-care in late-stage myeloma - a \$2bn+ market opportunity



- >75% better Overall Survival (best survival data to date in late-stage myeloma)
- 30% better Progression Free Survival (by Hazard Ratio)
- 25%-35% better objective tumour Response Rates (ORR and CBR)
- Better tolerated by the patients – non-haematological toxicity is rare

Strong foundation for Phase III program design where Ygalo[®] will be directly compared to current standard of care

Phase II data: Comparison with data from patients that have not recently failed on lenalidomide

Late-Stage Relapsed Refractory



TREATMENT	ORR	CBR	MEDIAN PFS	MEDIAN DOR	MEDIAN OS
Pomalidomide + dexamethasone	24%	NR	3.6 months	7.0 months	12.4 months
Ygalo[®] + dexamethasone	31%	49%	5.7 months	8.8 months	20.7 months

Note: NR=Not Reported. Ygalo[®] is not market approved.

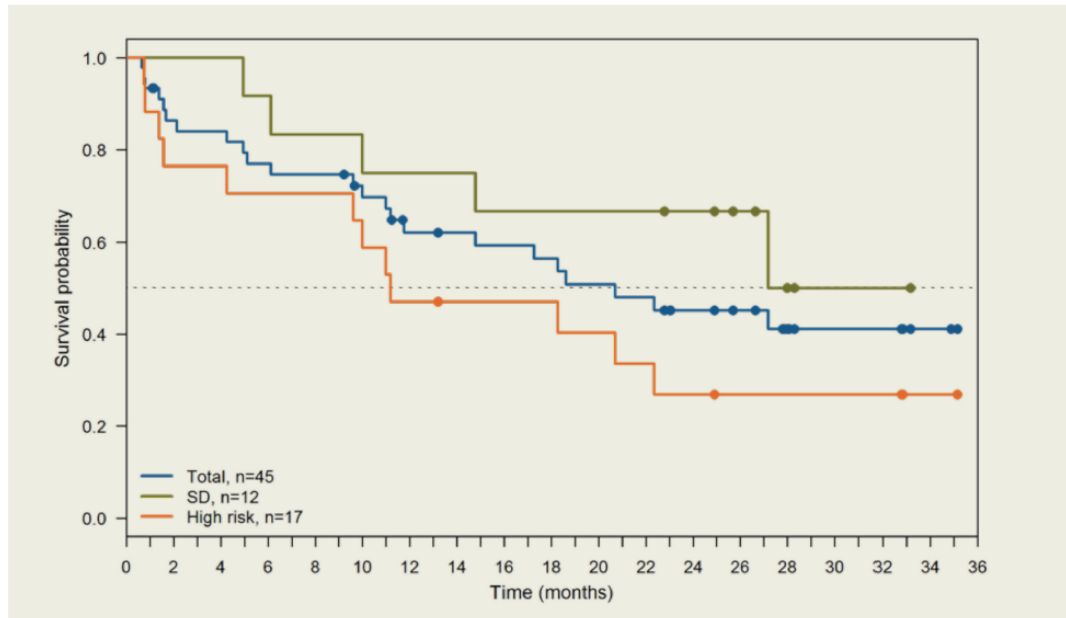
Source: FDA Label.

However, the cross-resistance between pomalidomide and lenalidomide puts pomalidomide at a disadvantage in the real-world setting (see OCEAN trial design)

Best-in-class survival data from Ygalo[®] in phase II in late-stage RRMM

Ygalo[®] has pronounced efficacy of its own and facilitates for further treatment following progression

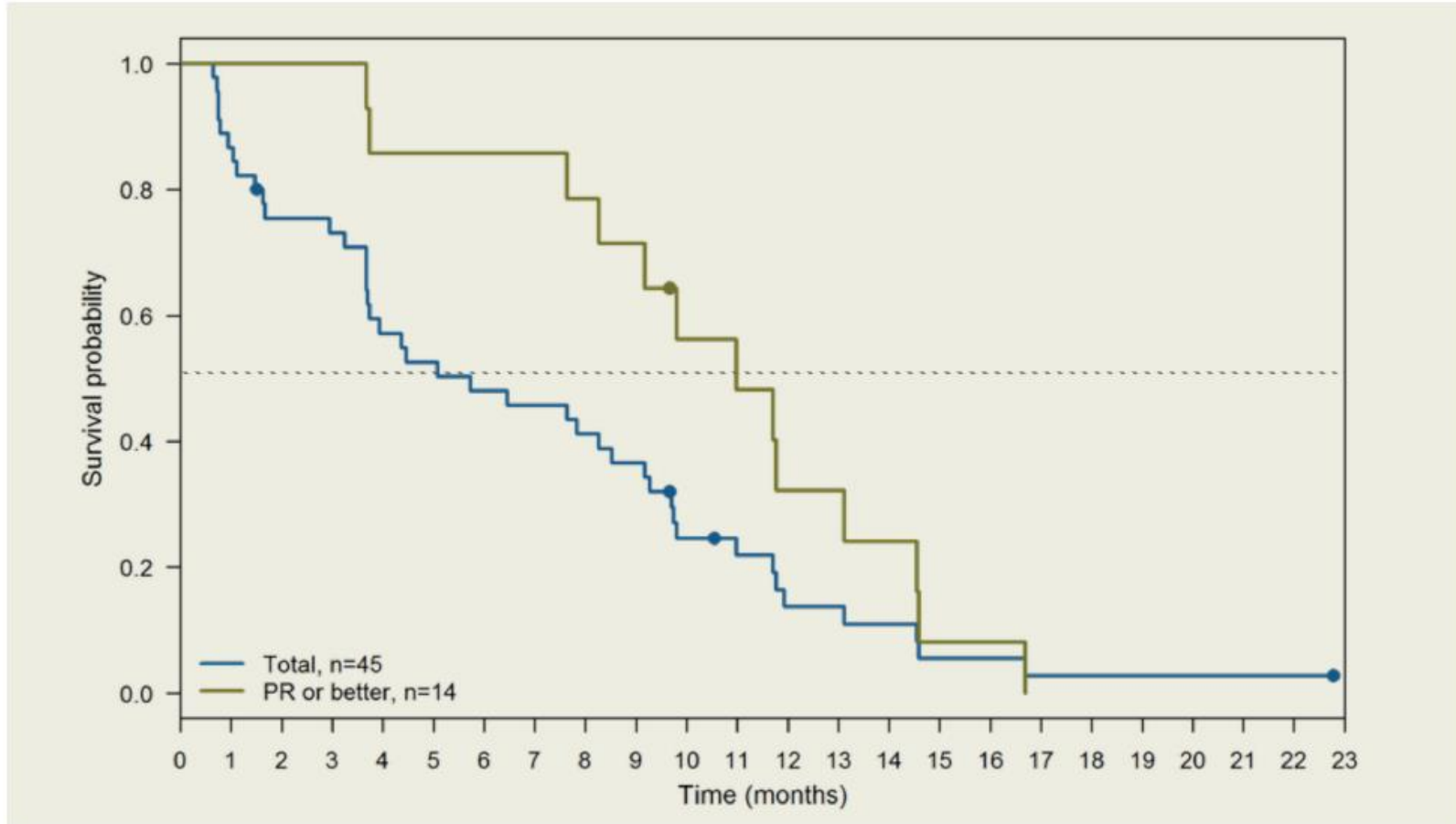
Figure 2. Overall survival



- Best-in-class survival data in late-stage RRMM
- Best PFS to date for a broad-spectrum agent in late-stage RRMM
- Tolerability profile very favorable with patients experiencing comparatively few side-effects that are detrimental to QoL (which in a palliative care setting with elderly patients is key)

Best Progression Free Survival data from any broad-spectrum agent in late-stage RRMM

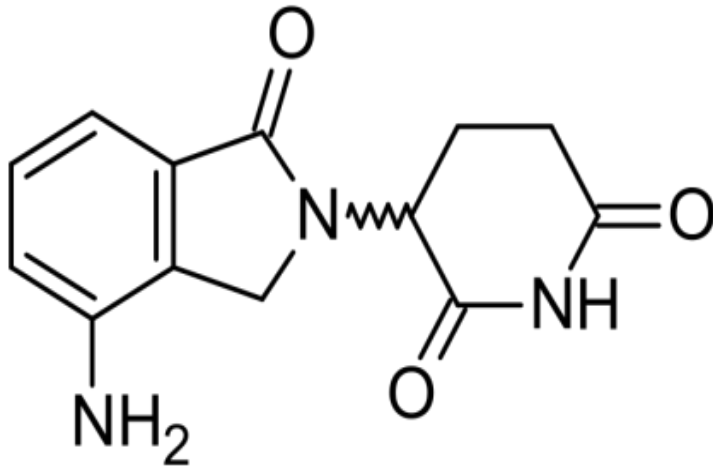
Data from O-12-M1 (Ygalo[®] + dex)



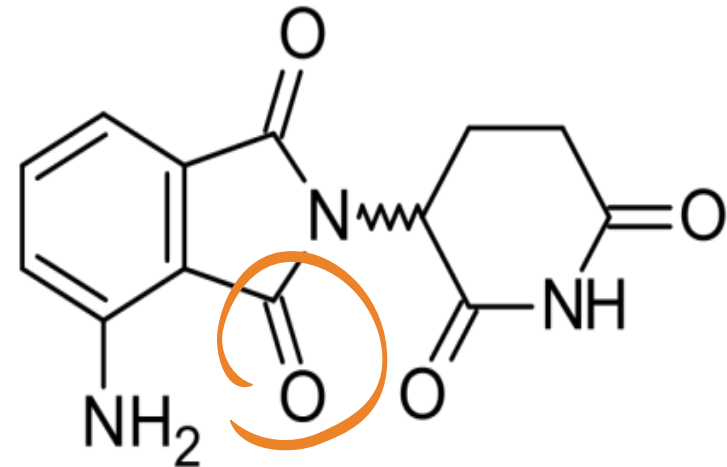
However, lenalidomide and pomalidomide originate from the same drug library...

Similar molecular structure from same library

LENALIDOMIDE



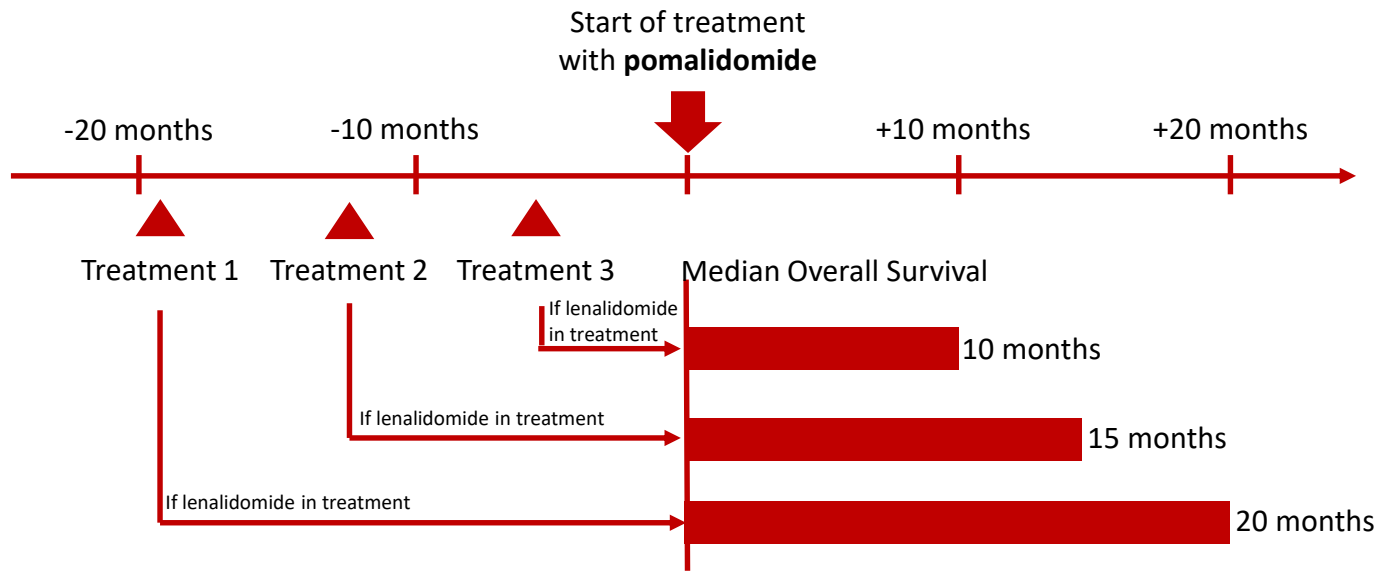
POMALIDOMIDE



Cross-resistance between lenalidomide and pomalidomide up for discussion based on pre-clinical data as well as FDA and EMA scrutiny of investigator reported clinical data

...and they seemingly share resistance mechanism to a significant extent (ASH 2016)

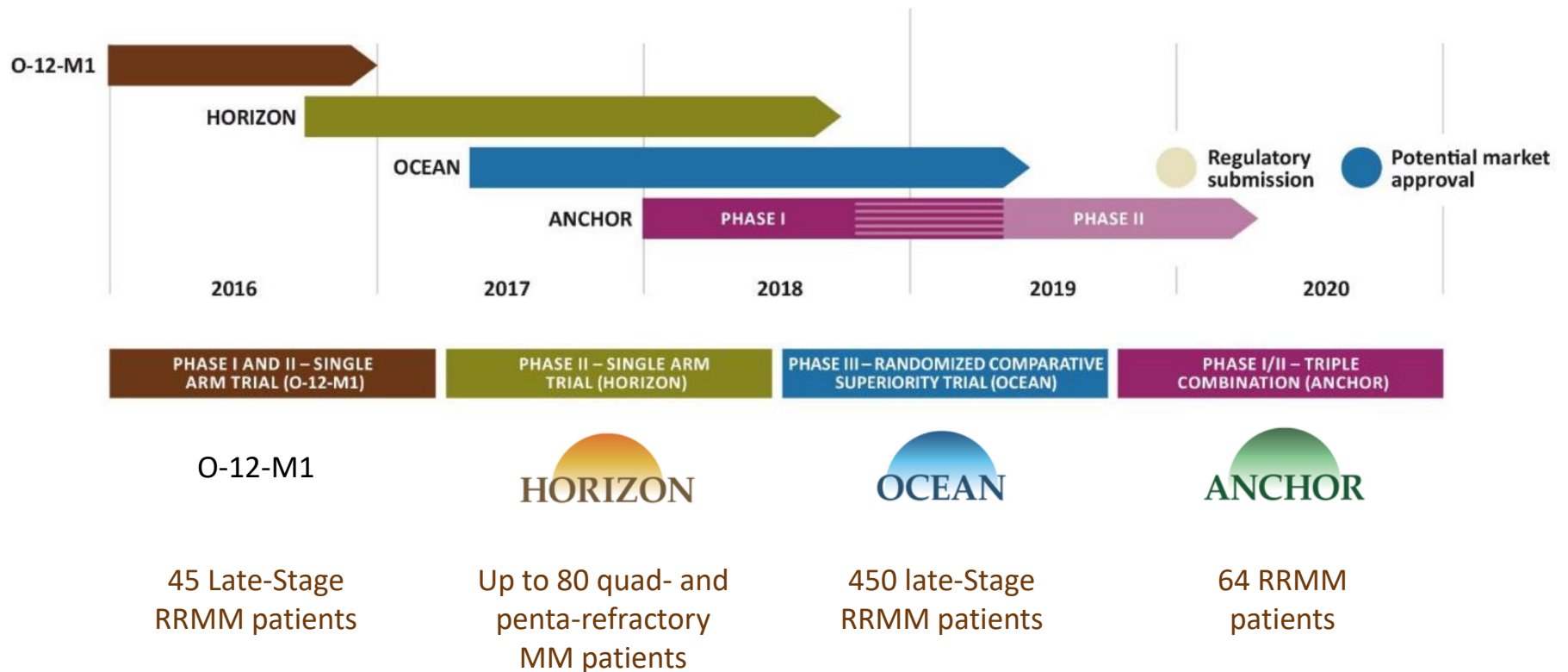
Dimopoulos research supporting an IMiD free period



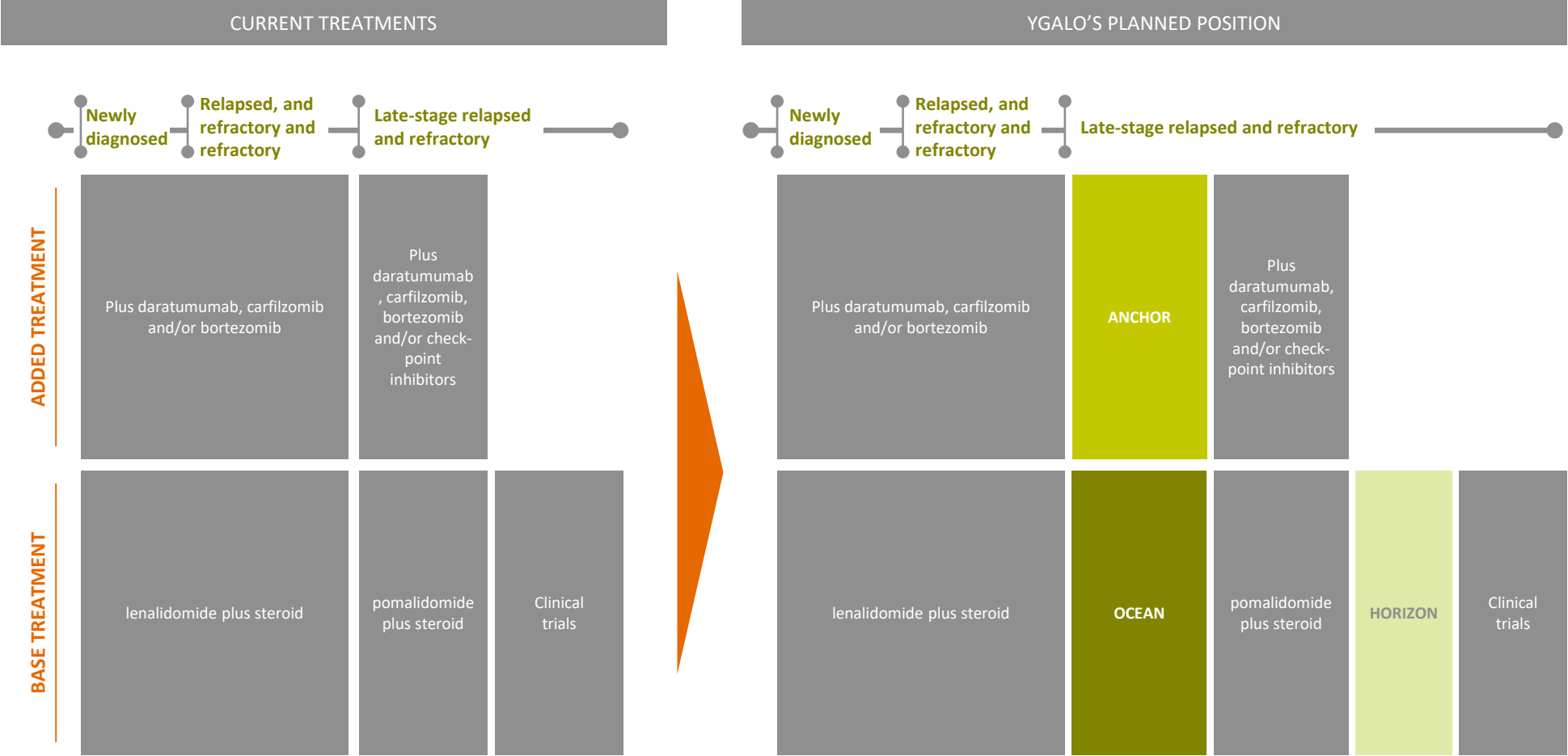
Suggests significant resistance overlap between lenalidomide and pomalidomide

CLINICAL DEVELOPMENT PROGRAM

Overview of Clinical Development Program in late-stage multiple myeloma



Clinical development program provides a complete data set to show how to use Ygalo[®] in late-stage RRMM



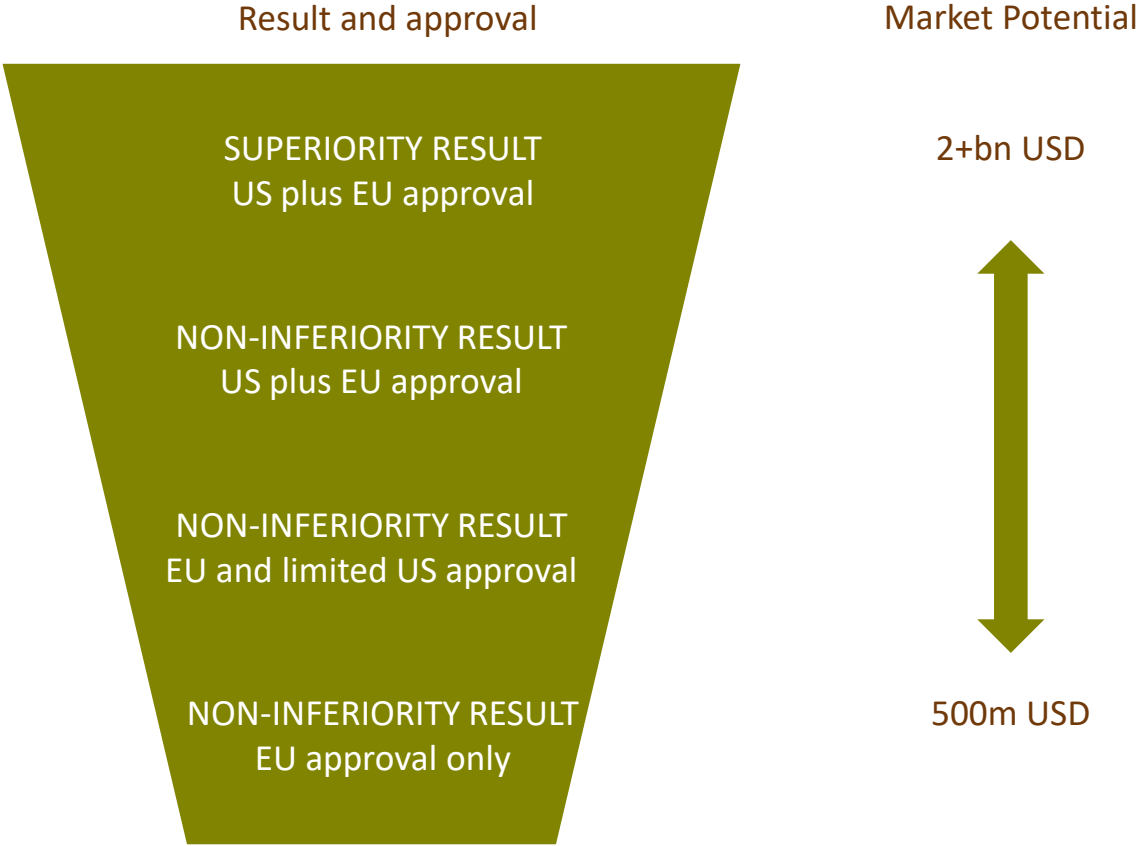
Full characterization of Ygalo[®] as a complement in late-stage RRMM will help increase physicians willingness to prescribe

Source: Company information
 Note: Excludes bone marrow transplants

Summary rationale for Phase III program

- Ygalo has showed best-in-class efficacy with excellent tolerability in late-stage RRMM patients
- Phase III study is 90% powered to show superiority of Ygalo in late-stage RRMM comparing the phase II data of Ygalo with pomalidomides phase III data (MM-003)
- However, patients have been pre-treated with close to 10x as much lenalidomide today compared to when MM-003 was conducted
- Studies show that pomalidomide loses as much as 50% efficacy in patients that have received lenalidomide recently (i.e. when the tumour has recently learned how to grow in a lenalidomide rich environment)
- In OCEAN, all patients have been treated with, and progressed on, lenalidomide in their last line of therapy prior to study inclusion

Clinical development program design enables multiple paths to approval with different labels



Expected news flow until regulatory submission

CLINICAL DEVELOPMENT PROGRAM

- **Q1 2018:** First patient in ANCHOR
- **Mid 2018:** Top line HORIZON
- **H2 2018:** Last patient out HORIZON
- **During 2018:** Patient enrollment rate OCEAN and ANCHOR
- **Q4 2018:** Full data set HORIZON
- **H1 2019:** Last patient out OCEAN
- **Summer 2019:** Top-line data OCEAN
- **Q4 2018:** Data from phase I study ANCHOR
- **Q4 2019:** Top line data phase II study ANCHOR

COMPANY RELATED

- **H1 2018:** Presentation of commercialization strategy

CONFERENCES WHERE DATA COULD BE PRESENTED

- **Jun 2018:** European Hematology Association (EHA)
- **Jun 2018:** American Society of Clinical Oncology (ASCO)
- **Dec 2018:** American Society of Hematology (ASH)
- **Jun 2019:** American Society of Clinical Oncology (ASCO)
- **Jun 2019:** European Hematology Association (EHA)



EUROPEAN
HEMATOLOGY
ASSOCIATION



A microscopic view of a cluster of cells, with one cell in the center being more prominent and showing detailed surface texture. The overall color is a warm, brownish-orange.

Thank you for your time