

Ygalo® - Targeted Alkylator for the Treatment of Myeloma

DNB Nordic Healthcare Conference 2017

14th December 2017

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Investment Highlights

Oncopeptides is a late-stage clinical development company focused on new cancer therapies

 **Developing Ygalo®: a next-generation broad spectrum agent for late stage RRMM**

- Builds on best in class alkylator drug
- Overcomes resistance mechanisms that impact current therapies (IMiDs)
- Data so far supports superior efficacy over current standard of care

 **Significant and growing addressable patient population**

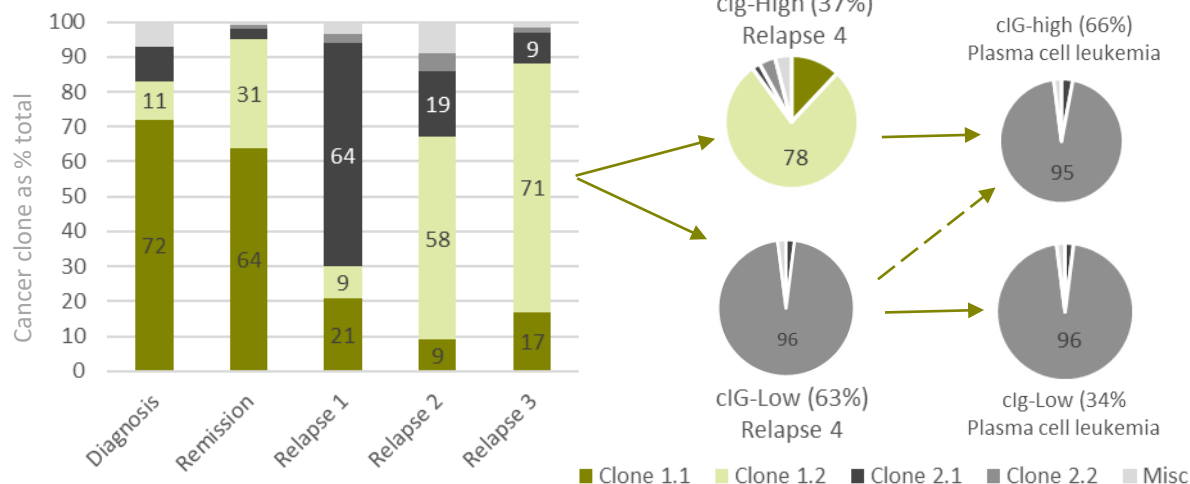
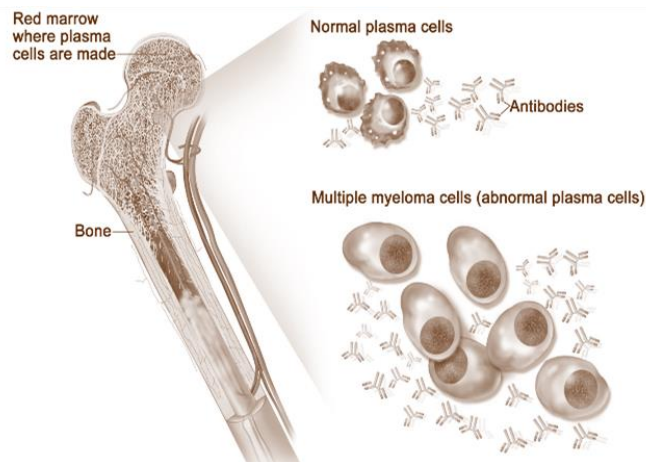
- Relapse is inevitable. New targeted therapies grow the market opportunity
- Prognosis is poor, with limited options available in late-stage disease
- Ygalo® addressing a \$1.6B¹ market with double digit % growth

 **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

Multiple Myeloma is a hematologic cancer with no cure

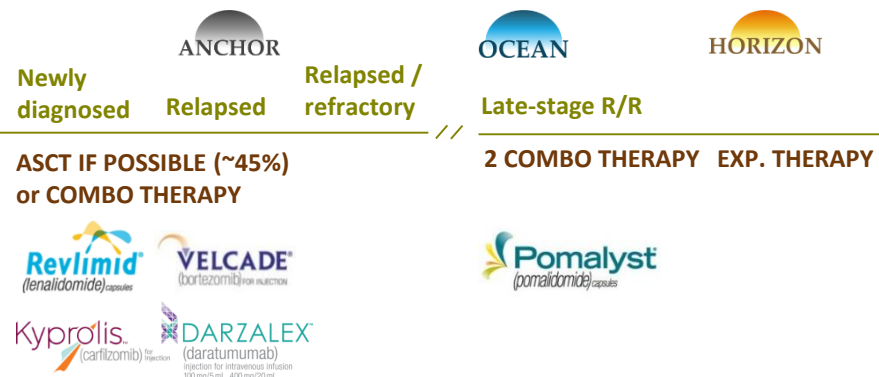
MM is a disease that is constantly evolving and becoming refractory / resistant to therapy is inevitable



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		

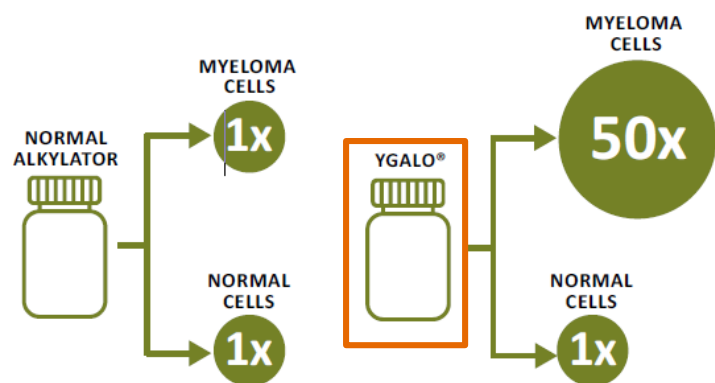
Late stage drugs limited: POM shares resistance with REV



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.

Strong Phase 2 data supports superiority over SoC

Targeted broad spectrum mechanism underpins efficacy



- >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

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

Phase 2 data: Comparison with data from patients that have not recently failed on lenalidomide

Strong Phase 2 Results Presented at ASH 2017

N	PD	SD	MR	PR	VGPR	ORR	CBR
ITT (N = 45)*	7	12	8	9	5	31%	49%
Efficacy evaluable (N = 34)	1	11	8	9	5	41%	65%

Multiple potential paths to market approval

Clinical development program fully characterizes Ygalo® in multiple myeloma

Addressable Patient population

Quad- and Penta-Refractory



TREATMENT	ORR	CBR	MEDIAN PFS	MEDIAN DOR	MEDIAN OS
Selinexor + dexamethasone	21%	32%	2.1 months	5.0 months	9.3 months

Note: Selinexor is not market approved.
Source: Blood 2016 128:491;

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
Carfilzomib	23%	37%	3.7 months	7.8 months	15.6 months
Daratumumab	29%	34%	3.7 months	7.4 months	17.5 months
Ygalo® + dexamethasone	31%	49%	5.1 months	8.8 months	20.7 months

Note: NR=Not Reported. Ygalo® is not market approved.
Source: FDA Label.

Relapsed and Relapsed Refractory

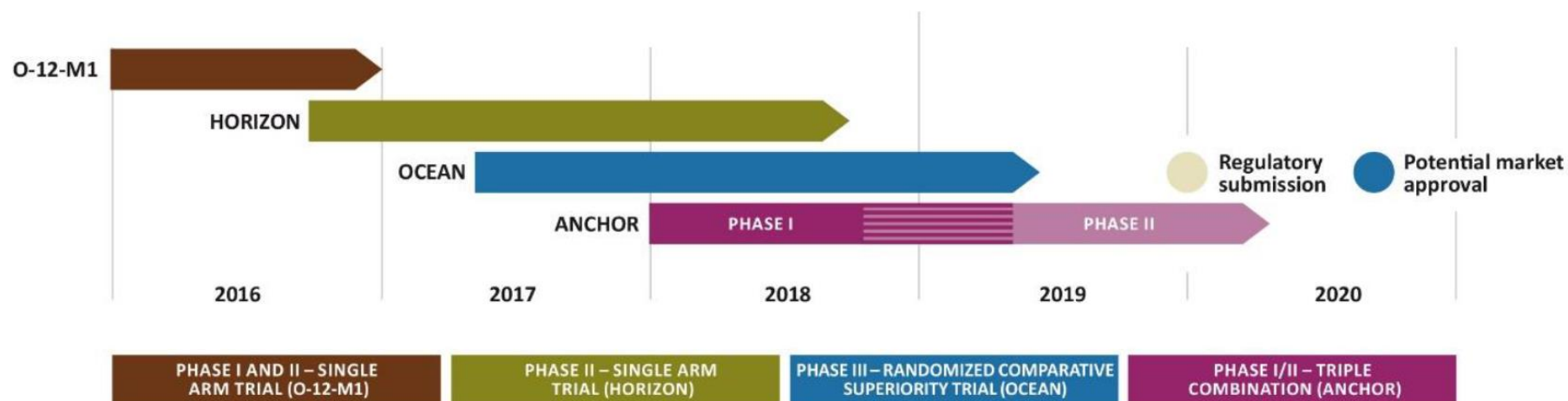


TREATMENT	ORR	MEDIAN PFS	MEDIAN DOR
Carfilzomib + lenalidomide + dexamethasone	87%	26.3 months	28.6 months
Lenalidomide + dexamethasone	67%	17.6 months	21.2 months

Note: Representative examples of recent clinical trials (triple and double combination therapy).
Source: FDA Label.

- Patients who have failed other therapies
- Single- arm Phase 2 trial ongoing, **data due mid 2018**
- Supports OCEAN to receive market approval
- If data exceptionally convincing, potential for conditional marketing authorization
- Patients refractory to lenalidomide
- Phase III trial ongoing, **topline data due Q3 2019**
- Superiority study vs. pomalidomide (though superiority is/may not be needed for approval)
- Evaluating potential for earlier line use in combination with other agents
- Phase 1/2 trial ongoing, **data due 2019**
- Could significantly expand market opportunity

Time-line for our Clinical Development Program in late-stage RRMM



Corporate Information

Management Team

Jakob Lindberg, Med Lic | CEO
Birgitta Ståhl, MSc, MBA | CFO
Elisabeth Augustsson, MSc | Head of Regulatory Affairs
Paula Boulton | Chief Commercial Officer
Johan Harmenberg, MD, PhD | Chief Medical Officer
Fredrik Lehmann, MSc PhD | Head of CMC
Eva Nordström, MSc | VP, Head of Clinical Dev.
Rein Piir, MSc | Head of IR
Bengt Gustavsson, MSc PhD | Head of Medical Relations

Board of Directors

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Jonas Brambeck, PhD
Luigi Costa, MBA
Cecilia Daun Wennborg, MSc
Jarl Ulf Jungnelius, MD, PhD
Per Samuelsson, MSc
Olof Tydén MD, PhD

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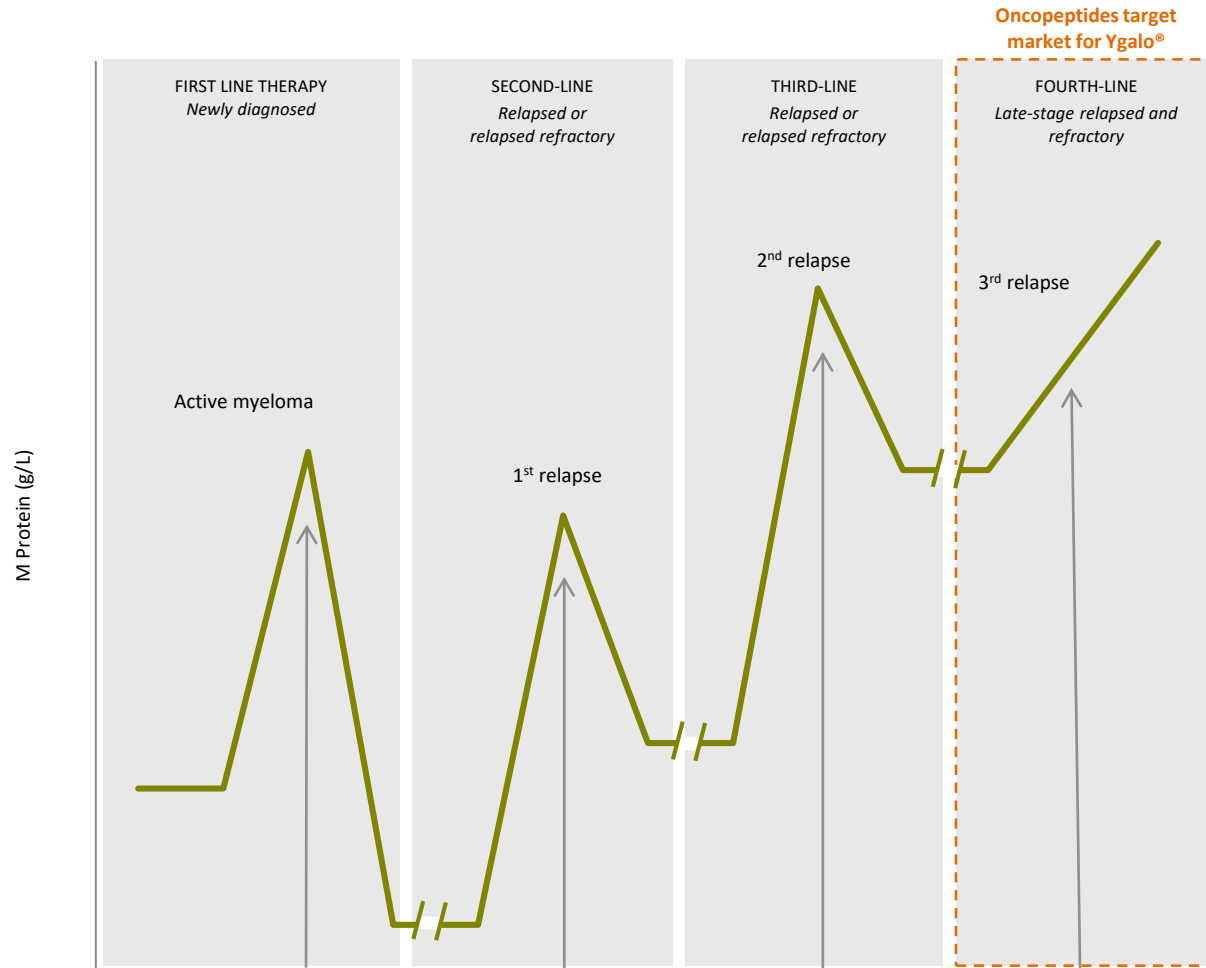
Stock

Ticker: ONCO (Stockholm)
ISIN: SE0009414576
Analysts: ABG Sundal Collier,
Carnegie Investment Bank, DNB
markets

Contact

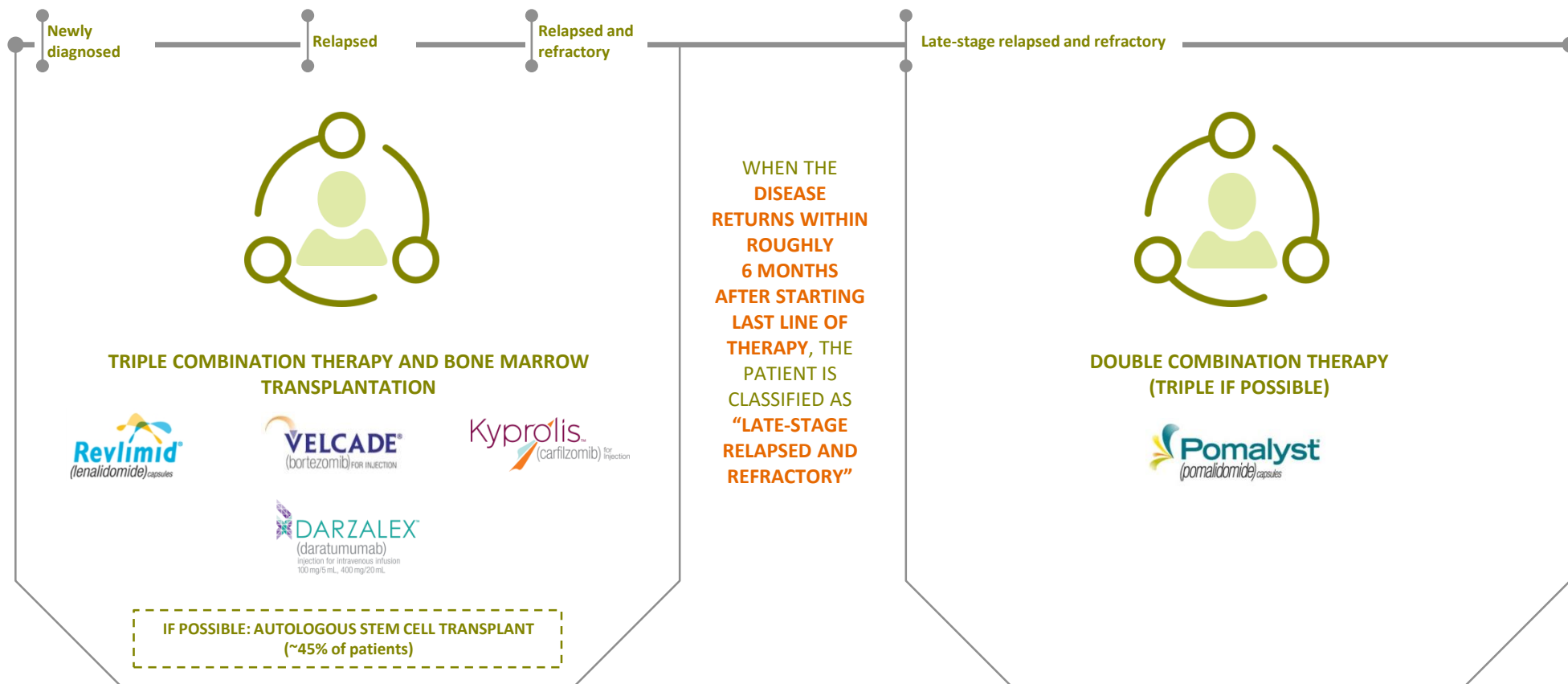
Rein Piir, Head IR
Rein.piir@oncopeptides.se

All patients become resistant to treatment and relapse into disease progression over time



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⁾

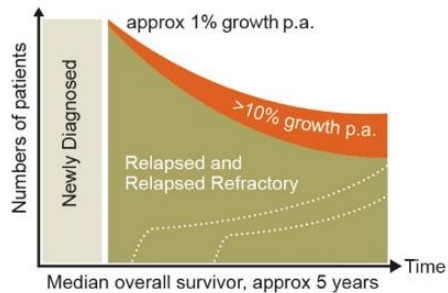


Limited number of treatment options for late-stage RRMM patients –
Novel treatment options are necessary and demanded by patients and regulatory bodies

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

The medical need in treatment resistant patients is significant and growing

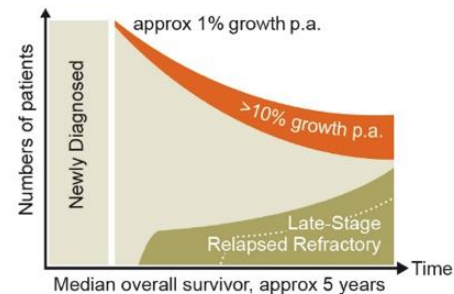


Relapsed and Relapsed Refractory

TREATMENT	ORR	MEDIAN PFS	MEDIAN DOR
Carfilzomib + lenalidomide + dexamethasone	87%	26.3 months	28.6 months
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Note: Representative examples of recent clinical trials (triple and double combination therapy).

Source: FDA Label.



Late-Stage Relapsed Refractory

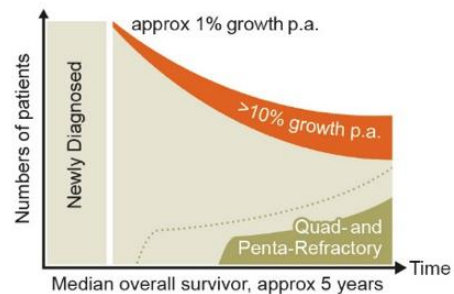
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Ygalo® + dexamethasone	31%	49%	5.1 months	8.3 months	20.7 months

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

Source: FDA Label.



Significant reduction in efficacy after resistance development



Quad- and Penta-Refractory

TREATMENT	ORR	CBR	MEDIAN PFS	MEDIAN DOR	MEDIAN OS
Selinexor + dexamethasone	21%	32%	2.1 months	5.0 months	9.3 months

Note: Selinexor is not market approved.

Source: Blood 2016 128:491;



Different treatment modalities complement each other in myeloma care

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

Our current Phase II data supports superiority over standard of care in late-stage RRMM

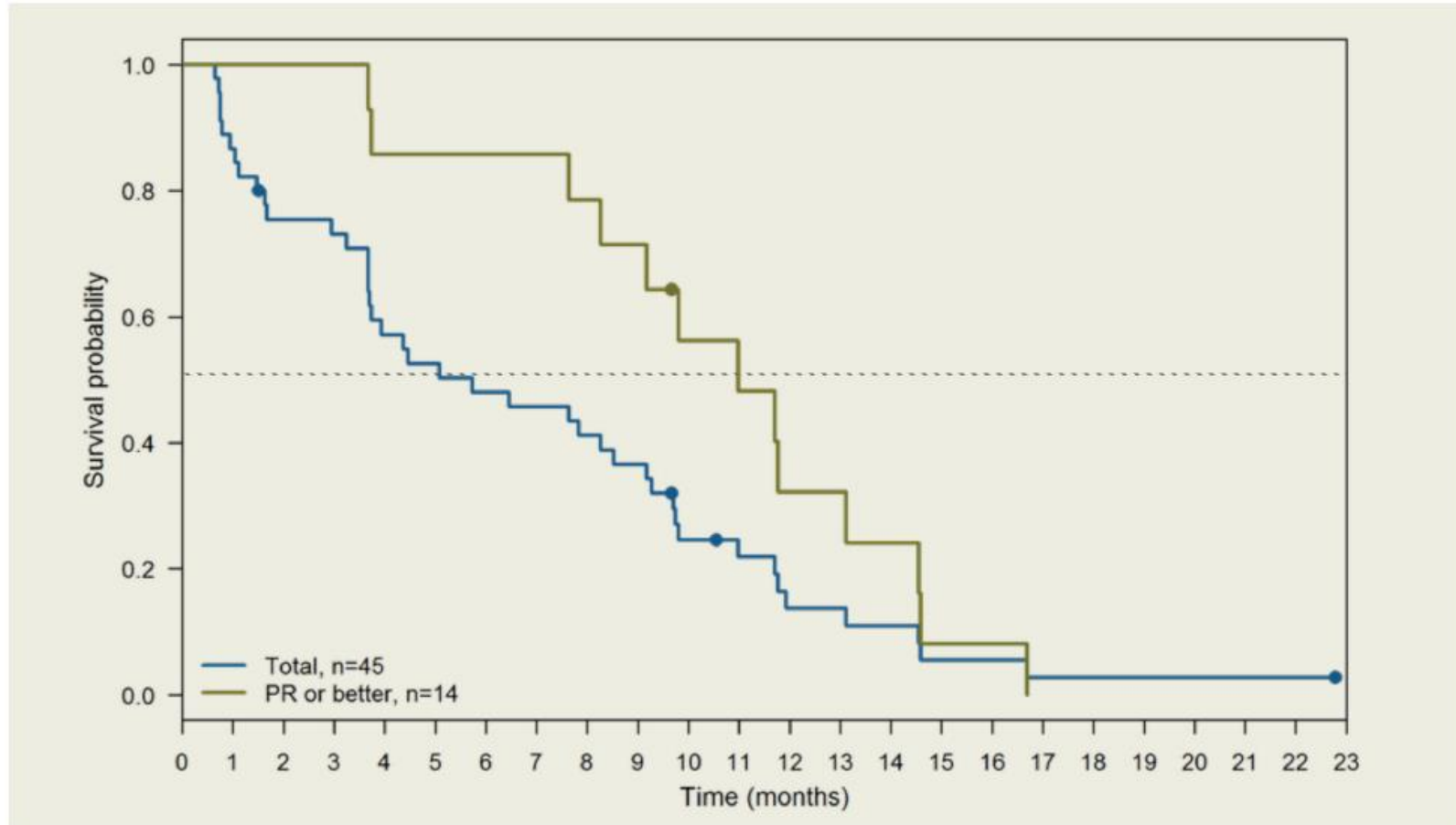
Comparison with data from patients that have not recently failed on lenalidomide

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- Better tolerated by the patients

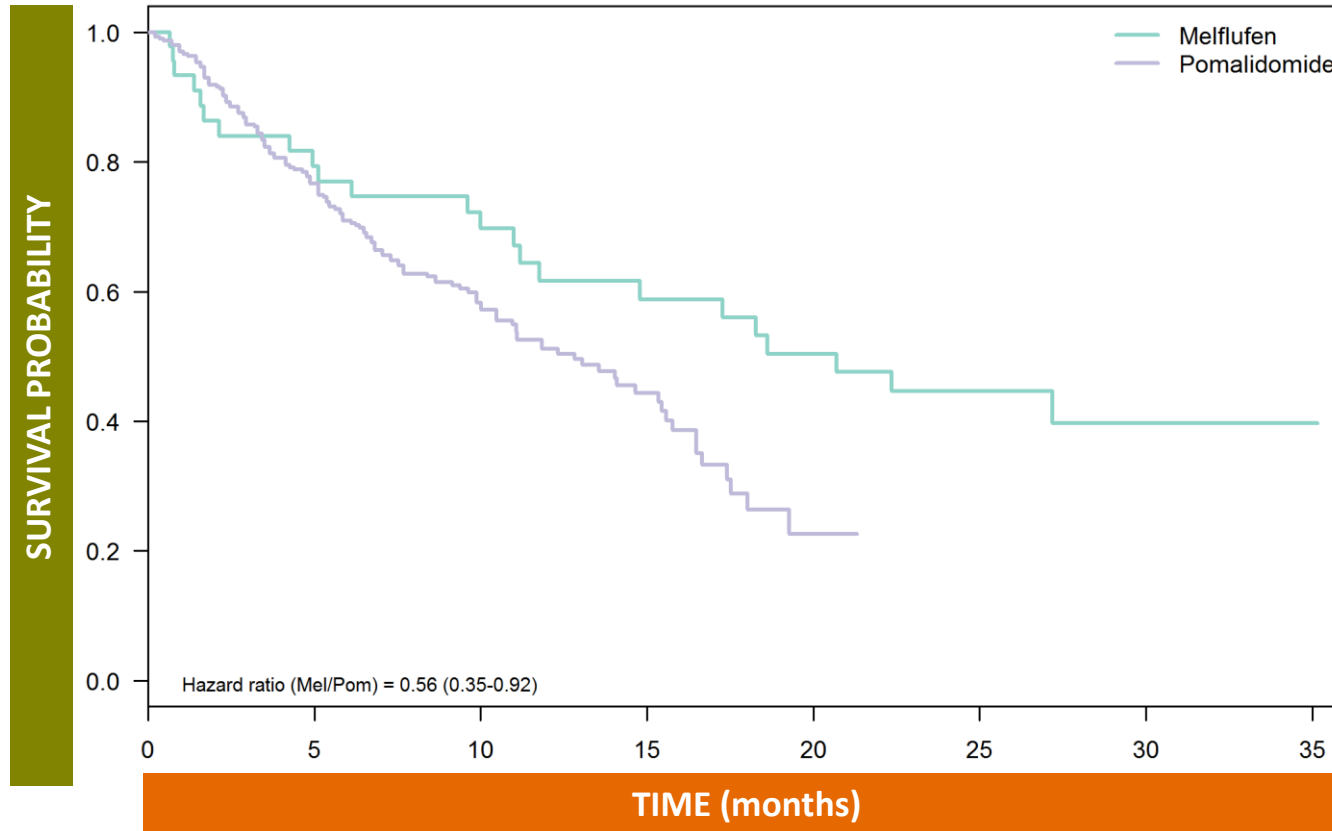


Strong foundation for Phase III program design where Ygalo® will be directly compared to current standard of care: pomalidomide

Best Progression Free Survival from any broad-spectrum agent in late-stage RRMM: Data from O-12-M1 (Ygalo® + dex)



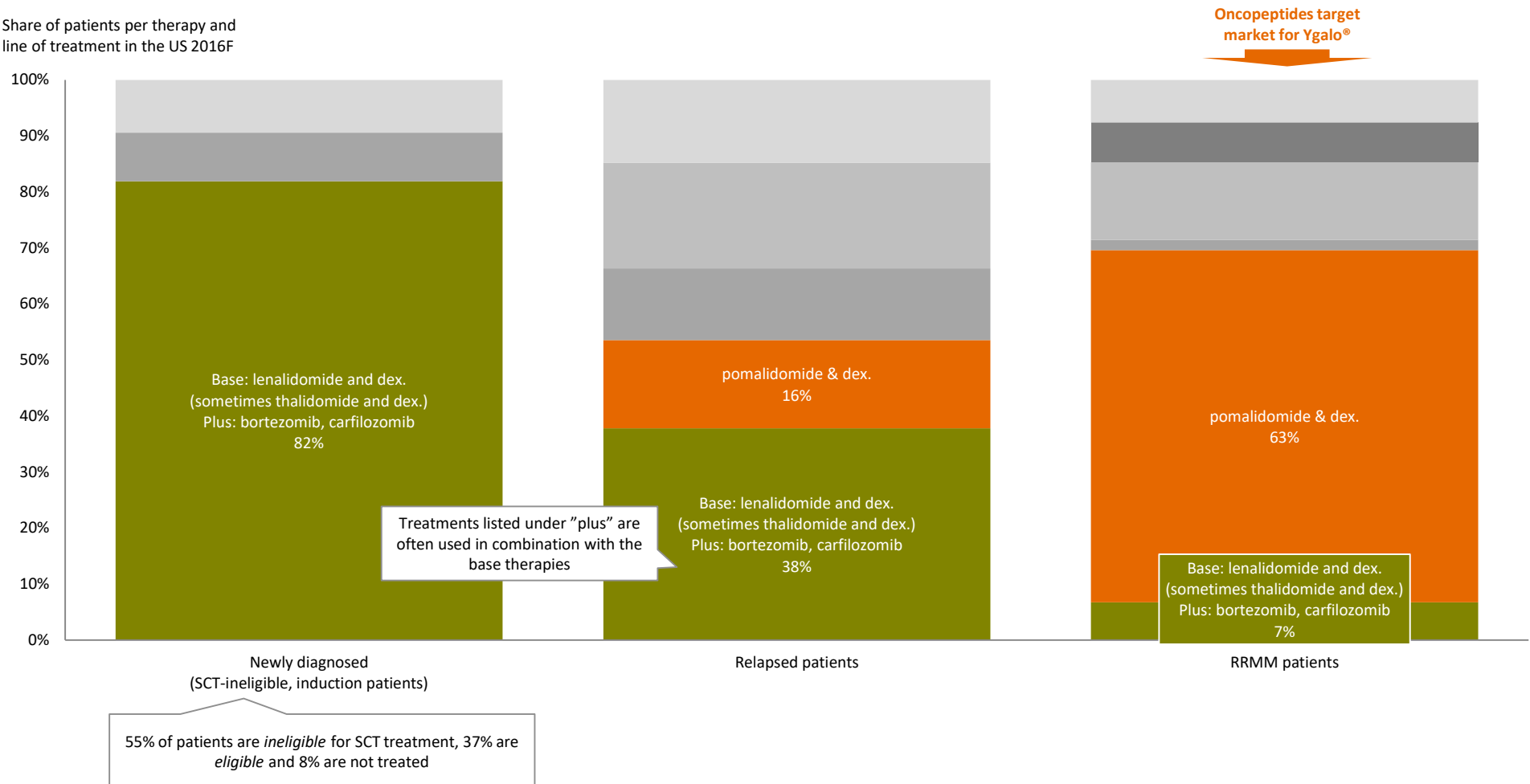
Efficacy comparison between O-12-M1 (Ygalo[®] + dex) and MM-003 (pomalidomide + dex) – Overall Survival



Continuous IMiD backbone is standard of care – lenalidomide in newly diagnosed patients and pomalidomide in late-stage patients

Simplified overview of treatments used in different phases of multiple myeloma excluding stem cell transplantation

Share of patients per therapy and line of treatment in the US 2016F

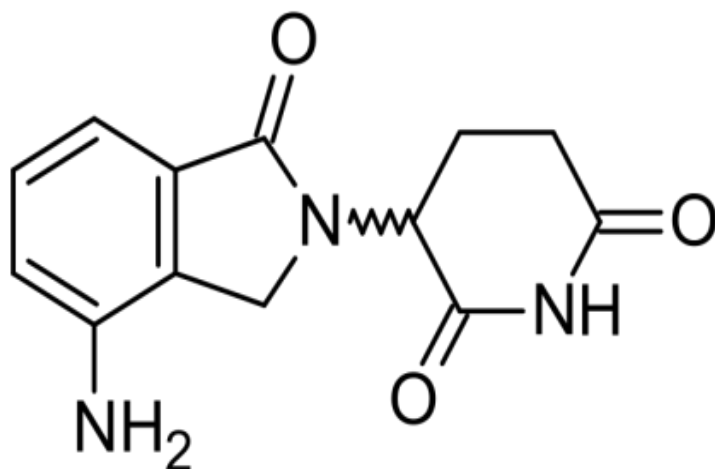


Source: GlobalData. Sources used by GlobalData in their estimation of patient shares per treatment: interviews with 10 KOLs and 90 prescribers across the 8 covered markets. Estimated shares of patients in the US 2016. Maintenance and consolidation treatment excluded (lenalidomide dominant).

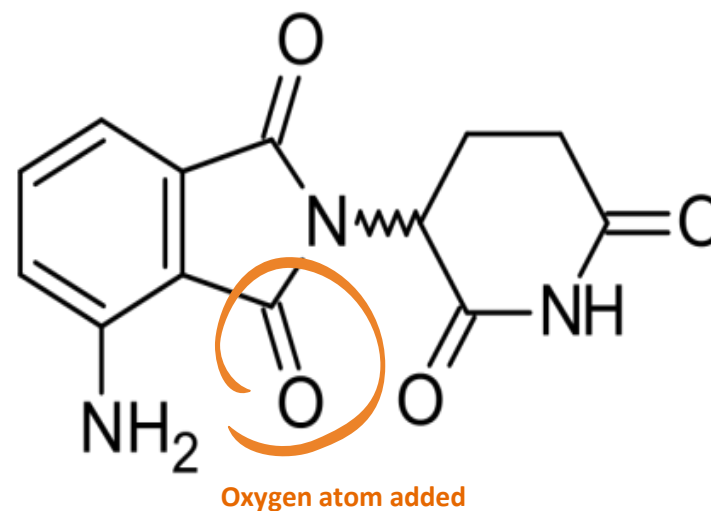
Lenalidomide and pomalidomide originate from the same drug library...

Similar molecular structure from same library

LENALIDOMIDE



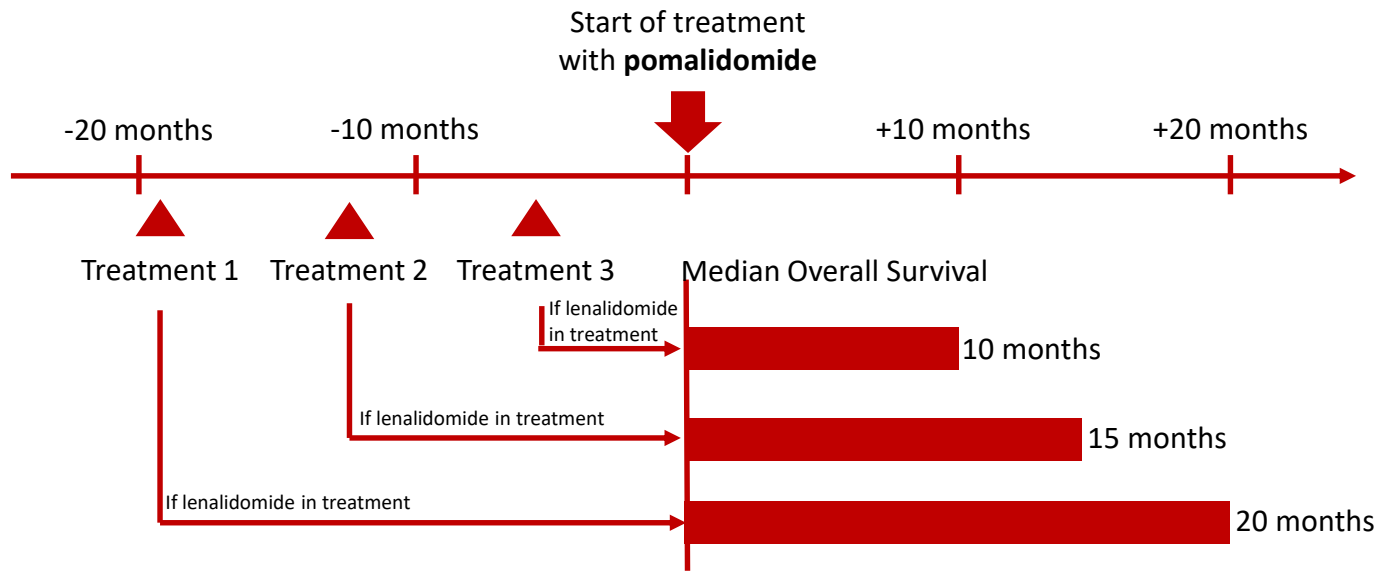
POMALIDOMIDE



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

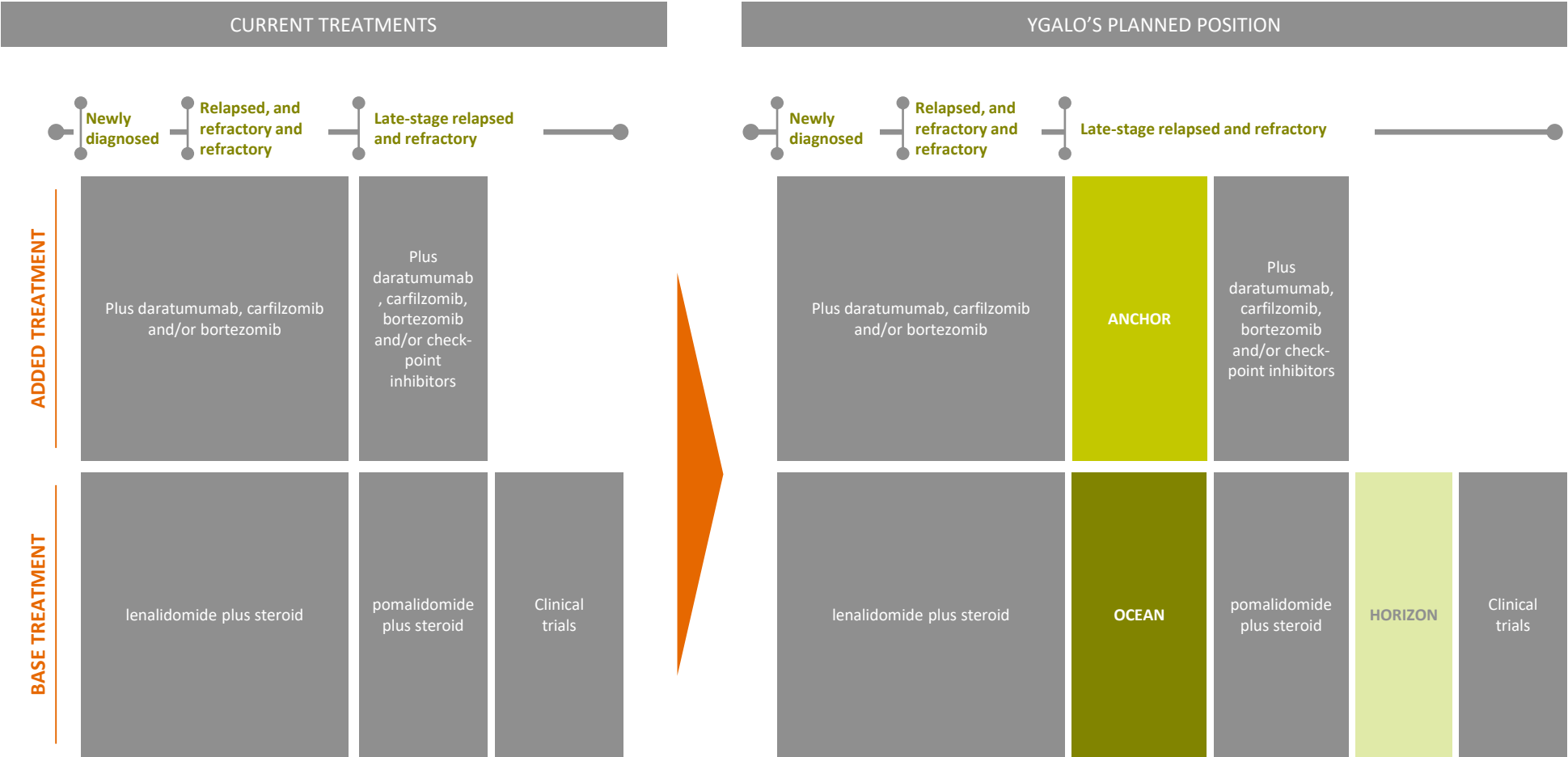
...and they seemingly share resistance mechanism to a significant extent (ASH 2016)

Dimopoulos research supporting an IMiD free period



Suggests significant resistance overlap between lenalidomide and pomalidomide

Clinical development program 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

Promising efficacy signal in HORIZON with excellent tolerability in patients with no or few remaining treatment options

Table 5. Overall response rate (N=30)

N	PD	SD	MR	PR	VGPR	ORR	CBR
Adjusted ITT, n (%)	11 (37)	9 (30)	2 (7)	6 (20)	2 (7)	26.7%	33.3%

Figure 1. Waterfall plot (N=30)

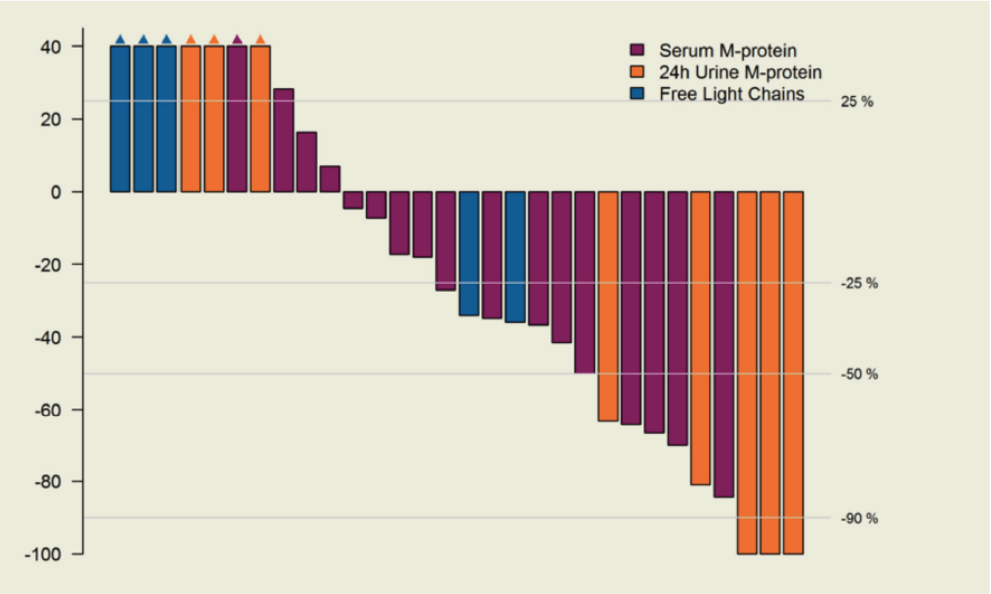
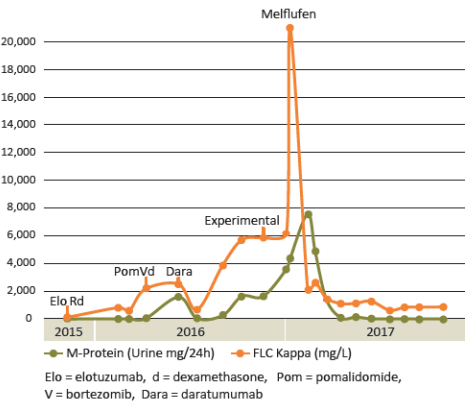


Table 6. Treatment-related G3/4 AEs occurring in ≥ 5% of the patients (N=38)

	GRADE 3 OR 4, n (%)	GRADE 4, n (%)
Any treatment-related AE	22 (58)	15 (39)
Blood and lymphatic system disorders	20 (53)	14 (37)
Thrombocytopenia	17 (45)	12 (32)
Neutropenia	15 (39)	9 (24)
Leukopenia	3 (8)	3 (8)
Anemia	8 (21)	0
Lymphopenia	3 (8)	0
Hemolytic anemia	2 (5)	0

Figure 2. Patient case study



42-year old man with ISS stage 3, MM diagnosed 2007. No detectable serum M-protein. Nine prior lines of therapy including ASCT X 2 and Allo-SCT. Refractory to R, Elo, V, Pom, Dara and an experimental drug. The patient only achieved PD to the last 4 lines of therapy.

Following 5 cycles of melflufen, the urinary M-protein was undetectable (Figure 2). The patient has received 9 cycles of melflufen, achieved VGPR and is ongoing as of Nov 2017.

Key Opinion Leaders and regulatory interactions provides strong foundation for planned pivotal development program

KOL network consisting of leading oncologists within the field of MM

SELECTION OF ONCOPEPTIDES CLINICAL ADVISORS AND INVESTIGATORS



Prof. Paul Richardson – Dana-Farber Cancer Institute, Harvard, USA

- Clinical program leader and Director of Clinical Research at Jerome Lipper Multiple Myeloma Center (Dana-Farber Cancer Institute)
- Lead clinical investigator for bortezomib
- Lead clinical investigator for pomalidomide



Prof. Pieter Sonneveld – Erasmus University, Netherlands

- Professor and Head of Hematology at Erasmus University
- President-elect European Hematology Association
- Founder European Hematology Network
- Scientific advisory member for International Myeloma Foundation, International Myeloma Working Group and International myeloma Society



KEY OPINION LEADERS WORKSHOPS

Jan-12: Boston, US

Dec-13: New Orleans, US

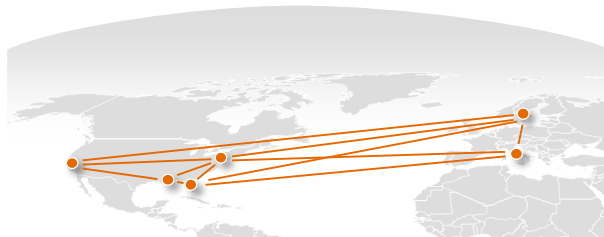
Jun-14: Stockholm, SE

Dec-14: San Francisco, US

Jan-15 to May-15: Individual Scientific Advice meetings with KOLs in EU and US

Sep-15: Rome, Italy

Dec-15: Orlando, US



Several regulatory interactions with meaningful authorities

FOOD AND DRUG ADMINISTRATION

Nov-12: Pre-IND type B meeting

Jan-13: IND application

Feb-13: IND approved

Mar-15: Orphan Drug Designation granted

Jun-15: Scientific Advice type C meeting

Dec-15: Scientific Advice type C meeting

Apr-16: Scientific Advice type C meeting

Jun-16: End of Phase II meeting

Jul-16: Application for exemption to conduct pediatric development under Pediatric Research Equity Act

Aug-16: Special Protocol Assessment Agreement Letter



NATIONAL AUTHORITIES (MHRA & SMPA)

May-04: Scientific Advice meeting with Swedish MPA

Feb-06: First phase I study application granted by Swedish MPA

Jan-13 to Dec-13: Permission granted to conduct clinical trials in DK, NL and IT

Apr-13: Phase I/II study application granted by Swedish MPA

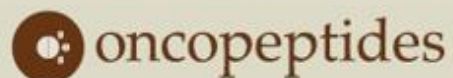
May-14: Scientific Advice meeting with Swedish MPA

Mar-15: EU Orphan Drug Designation granted by COMP / EMA

Apr-15 to Nov-15: Several Scientific Advice meetings with Swedish MPA

Mar-16: MHRA (British Medicines and Healthcare Products Regulatory Agency) gives positive feedback on design of phase III study





Melflufen is a targeted alkylator challenging the treatment paradigm in RRMM

Where: Omni Atlanta at CNN Center (Pecan Room/Foyer) 100 CNN Center, Atlanta, GA 30303

When: Sunday, December 10, 2017
Reception 8:00 – 8:30 PM and Scientific Program 8:30 – 10:00 PM

By Invitation Only

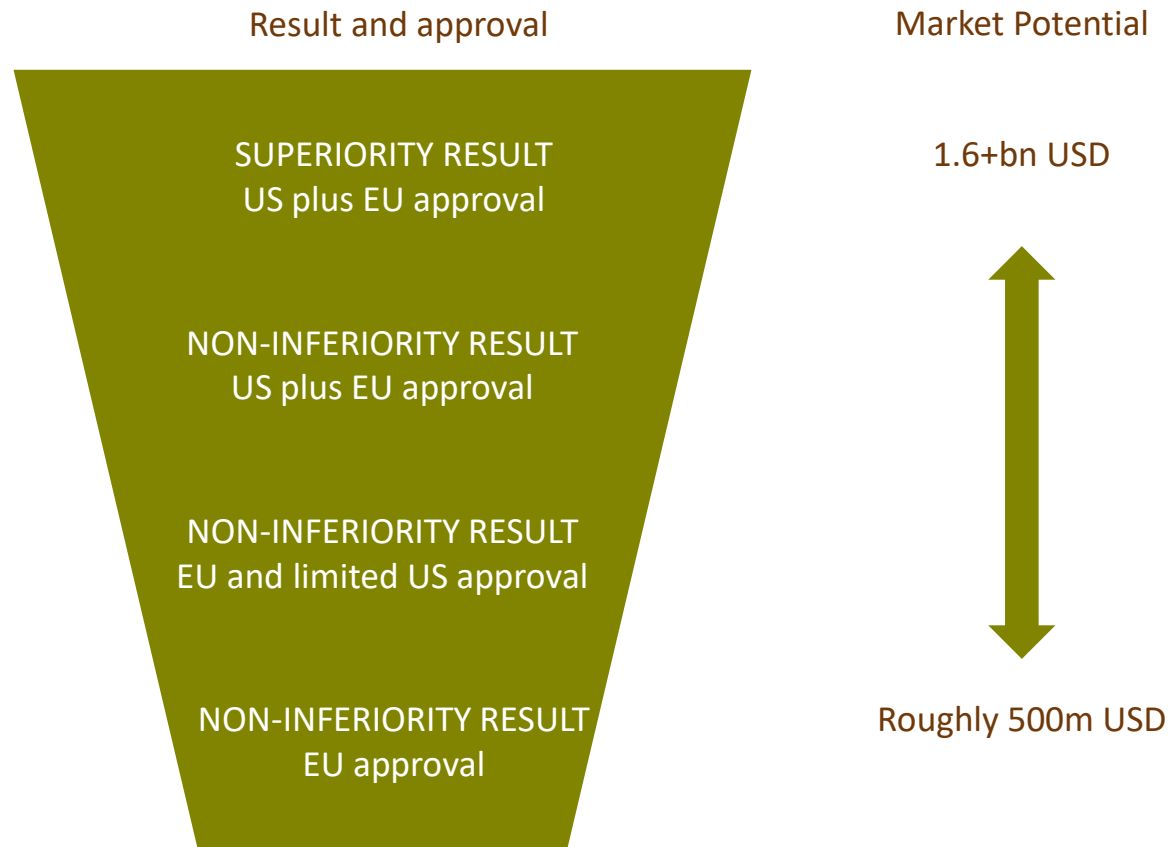
Speakers: **O-12-M1 - Long-term follow-up from phase-2 data and reflections around the role of melflufen in multiple myeloma**
Paul Richardson, MD
RJ Corman Professor of Medicine Harvard Medical School, Clinical Program Leader and Director of Clinical Research Jerome Lipper Multiple Myeloma Center Dana-Farber Cancer Institute Boston, Massachusetts

Horizon - Initial activity of melflufen after pomalidamide and daratumumab failure
Maria-Victoria Mateos, MD
Associate Professor of Medicine and Consultant Physician in the Hematology Department of the University Hospital of Salamanca, Salamanca, Spain

Host: **Bengt Gustavsson** Dr Med Sci, MSc Pharm,
Medical Relations, Oncopeptides AB, Stockholm, Sweden



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
- **H2 2017:** Patient enrollment rate OCEAN and ANCHOR
- **During 2018:** Patient enrollment rate OCEAN and ANCHOR
- **Q2/Q3 2018:** Last patient out HORIZON
- **H1 2019:** Last patient out OCEAN
- **Summer 2019:** Top-line data OCEAN
- **H1 2020:** Last patient out ANCHOR

COMPANY RELATED

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

CONFERENCES WHERE DATA COULD BE PRESENTED

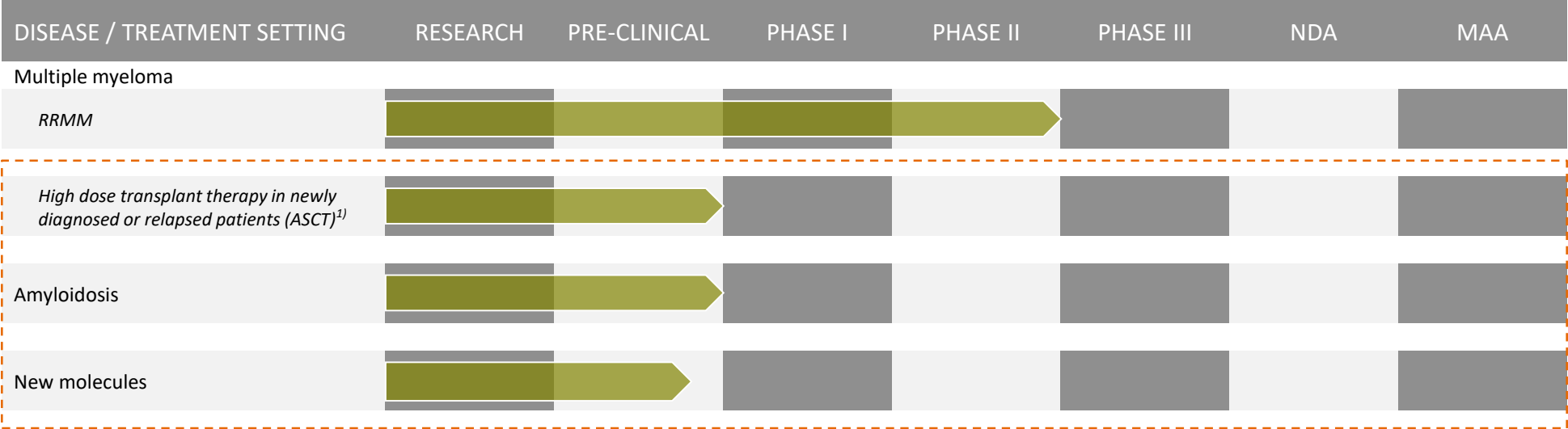
- **Dec 2017:** American Society of Hematology (ASH)
- **Jun 2018:** European Hematology Association (EHA)
- **Jun 2018:** American Society of Clinical Oncology (ASCO)
- **Dec 2018:** American Society of Hematology (ASH)
- **Jun 2019:** American Society of Clinical Oncology (ASCO)
- **Jun 2019:** European Hematology Association (EHA)



EUROPEAN
HEMATOLOGY
ASSOCIATION



Additional upside potential in pipeline – indication broadening as well as NMEs



Source: Company information
Note:
1) Allows broadening of transplant indication outside of MM

A microscopic image showing a dense cluster of cells. The central cell is in sharp focus, revealing a highly textured, bumpy surface. Other cells in the background are blurred, creating a sense of depth. The overall color palette is a warm, monochromatic brown.

Thank you for your time