oncopeptides

Nomenclature

International non-proprietary name (INN)
Melphalan flufenamide

Chemical name
4-[Bis-(2-chloroethyl)amino]-L-Phenylalanine-4-fluoro-L-phenylalanine ethyl ester hydrochloride

Laboratory codes
Melflufen hydrochloride
J1
CK 1535

CAS No.
380449-54-7 (HC1 salt)
380449-51-4 (free base)

Structure

Structural formula

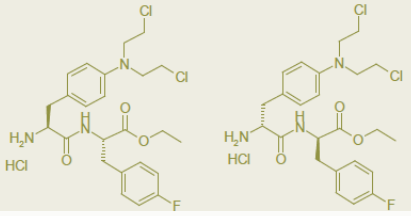
Figure 1-1 Structural formula of melflufen hydrochloride

Molecular formula
C24 CH31C13FN3O3 (HC1 salt)

Molecular weight
534.9 (HC1 Salt)

Stereochemistry
Melflufen hydrochloride contains two stereogenic centers giving rise to four possible stereoisomers. Melflufen hydrochloride drug substance is the L,L-isomer. The structures are outlined in Figure 1-2.

Figure 1-2 Structure of melflufen hydrochloride isomer



General properties

Appearance
White to slightly yellowish powder

Solubility
Melflufen hydrochloride is soluble in most organic solvents. The solubility in water and buffers is limited.

Partition coefficient
ClogP = 4.04 (tecken) 0.66, calculated using ACD logP DB, v.6.0 (from Advanced Chemistry Development)

Dissociation constant
pKa 10.0 (determined in ethanol solution)

Optical rotation
[α]D 5.2° (c 1.9, CH3OH) at 20°C

Thermal behaviour
Differential scanning calorimetry (DSC) was performed using a Mettler Toledo DSC 822 instrument and a scanning rate of 2(tecken)C/minute. The melting temperature was measured using batch GF404528 and determined from the DSC thermogram to be 205.4°C, as shown in

Ygalo® - A first in class potential new backbone for multiple myeloma

Jefferies London Healthcare Conference November 14th

Jakob Lindberg CEO

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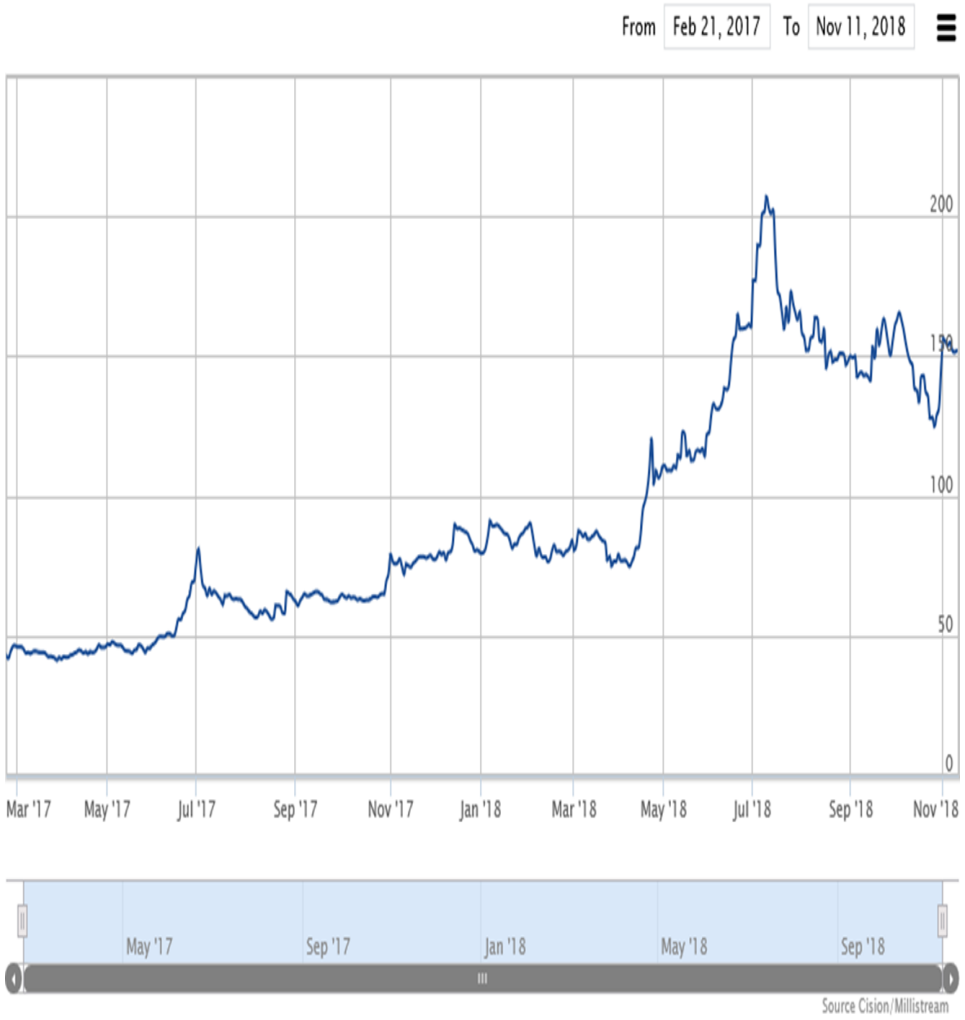
Oncopeptides overview

Ongoing Phase 3 program addressing a $2bn+ market opportunity in myeloma

- Located in Sweden (Stockholm) and US (Bay Area)
- IPO in February 2017 on Nasdaq OMX in Stockholm
- Market cap: approximately 750 MUSD
- Cash position end of Q3 2018: 54 MUSD
- Burn rate Q3 2018: 9.2 MUSD
- Experienced management team
- Most advanced indication is myeloma. Programs currently running at more than 100 hospitals in the US, EU, Israel, South Korea and Taiwan
- Phase 3 read-out Q3 2019
- New indications and NCEs in development with clinical trials expected to start in 2019



Melflufen (Ygalo®) - Potential new backbone agent in multiple myeloma

Phase III read-out Q3 2019

Significant unmet need for novel backbone agent

- Relapse in multiple myeloma inevitable despite approval of novel agents
- Treatment paradigm evolving rapidly – resistance and tolerability remain key challenges
- 9 out of 10 patients receive broad spectrum ("backbone") agents (IMiDs/PIs/Alkylators)
- Majority of patients receive single agent (+/- steroid) treatments after 1L
- Once refractory, prognosis is poor, with limited options (pomalidomide de facto SoC)

Melflufen (Ygalo®): With a novel mechanism of action

- Melflufen is an alkylating peptide developed with Oncopeptides proprietary Peptidase Enhanced Compound (PEnC) platform
- Highly selective for transformed cells, with significant increase in therapeutic index
- 50+x activity increase in transformed cells with no increase against PBMCs
- Does not share resistance mechanisms with other classes of agents including alkylators

Best-in-class efficacy seen in Phase 2

- Phase 2 demonstrated the best overall survival data to date in late-stage myeloma
- Well tolerated with limited adverse events negatively impacting patient quality of life
- Bone pain improvement seen in first-cycle of treatment
- Data provides high level conviction for success in Phase 3 OCEAN head-to-head comparison with polamidomide

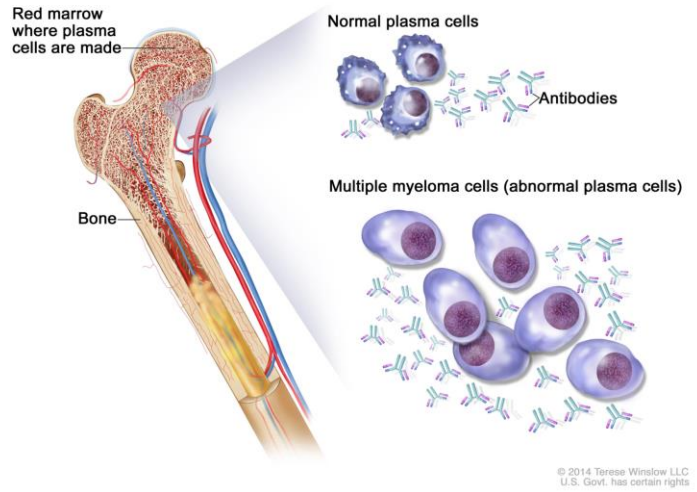
Ygalo well positioned to address $8bn+ market opportunity

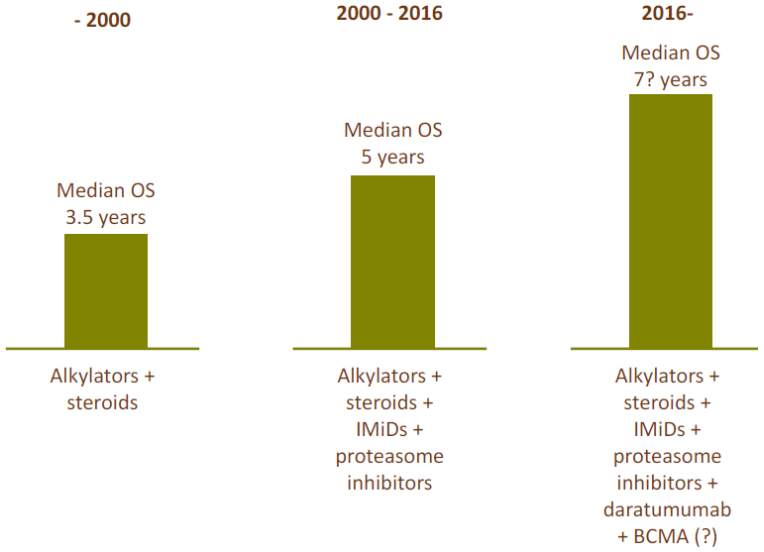
- Melflufen (Ygalo®) addresses $8bn+ market opportunity with double digit % growth
- Agreement with FDA (SPA) and EMA on P3 clinical trial design
- Orphan drug designation in EU and US
- Multiple paths to approval de-risk the development pathway
- Good activity signal in a broad range of oncology indications

RRMM: Relapsed Refractory Multiple Myeloma. PEnC: Peptidase Enhanced Compound.

Almost all multiple myeloma patients receive broad spectrum agents

Treatment paradigm rapidly evolving with increased use of backbone agents



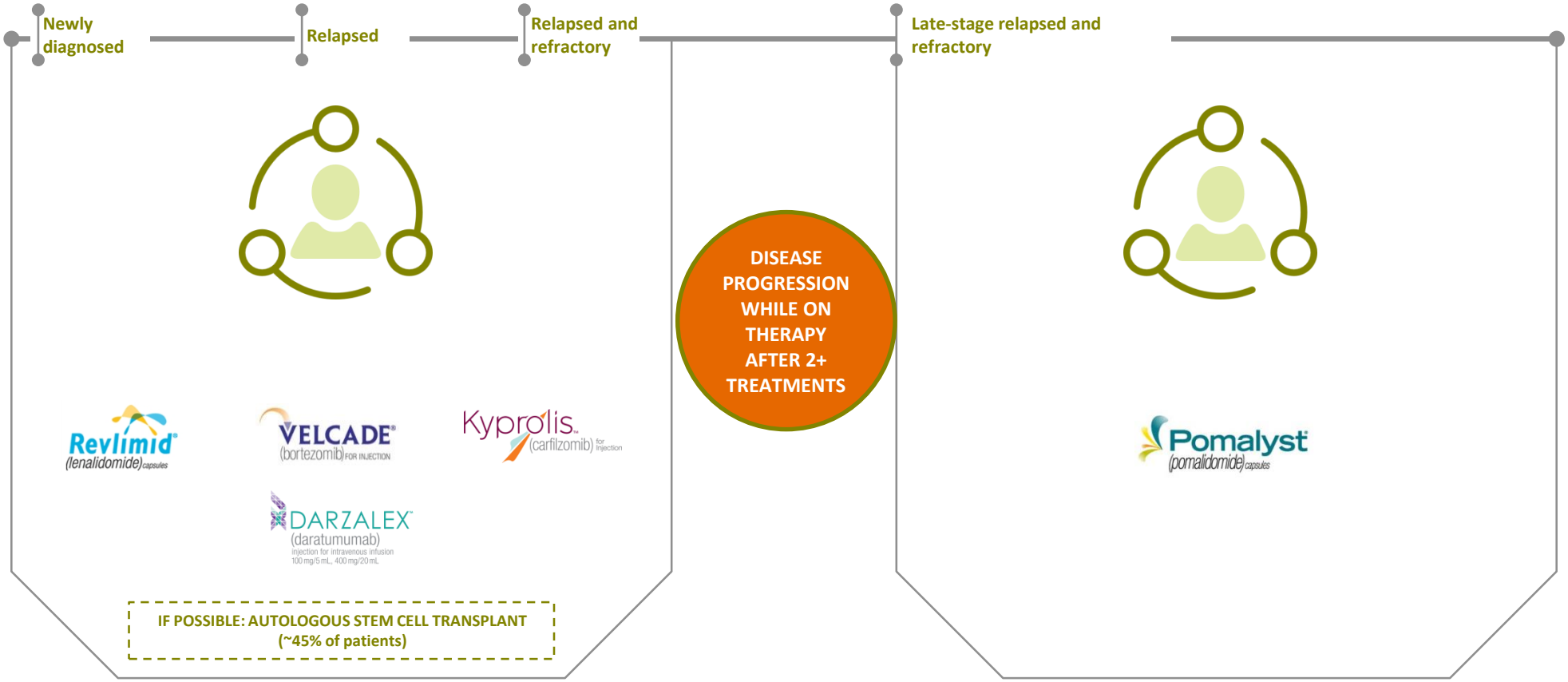


- Median OS in myeloma just over 5 years & increasing
- Clonal selection results in inevitable relapse and development of resistance to treatment
- 9 out of 10 patients receive broad spectrum agents (IMiDs, PIs and/or alkylators)
- Lack of ubiquitously expressed antigens in myeloma means that antibody-based therapies are used in combination with IMiDs, PIs and alkylators outside of rescue treatment setting (to ensure that all clones get some level of treatment)
- New targeted agents are growing the patient population
  - 4^{th}+ line patients receiving treatment in the US grew by >40% in 2017
- Lenalidomide and proteasome inhibitors are used early in the treatment algorithm. Daratumumab is moving from last-line to 1^{st} line/ 2^{nd} line rapidly

Source: IntrinsiQ and Kantar Health.

Late-stage myeloma patients are well defined from both a regulatory and clinical point of view

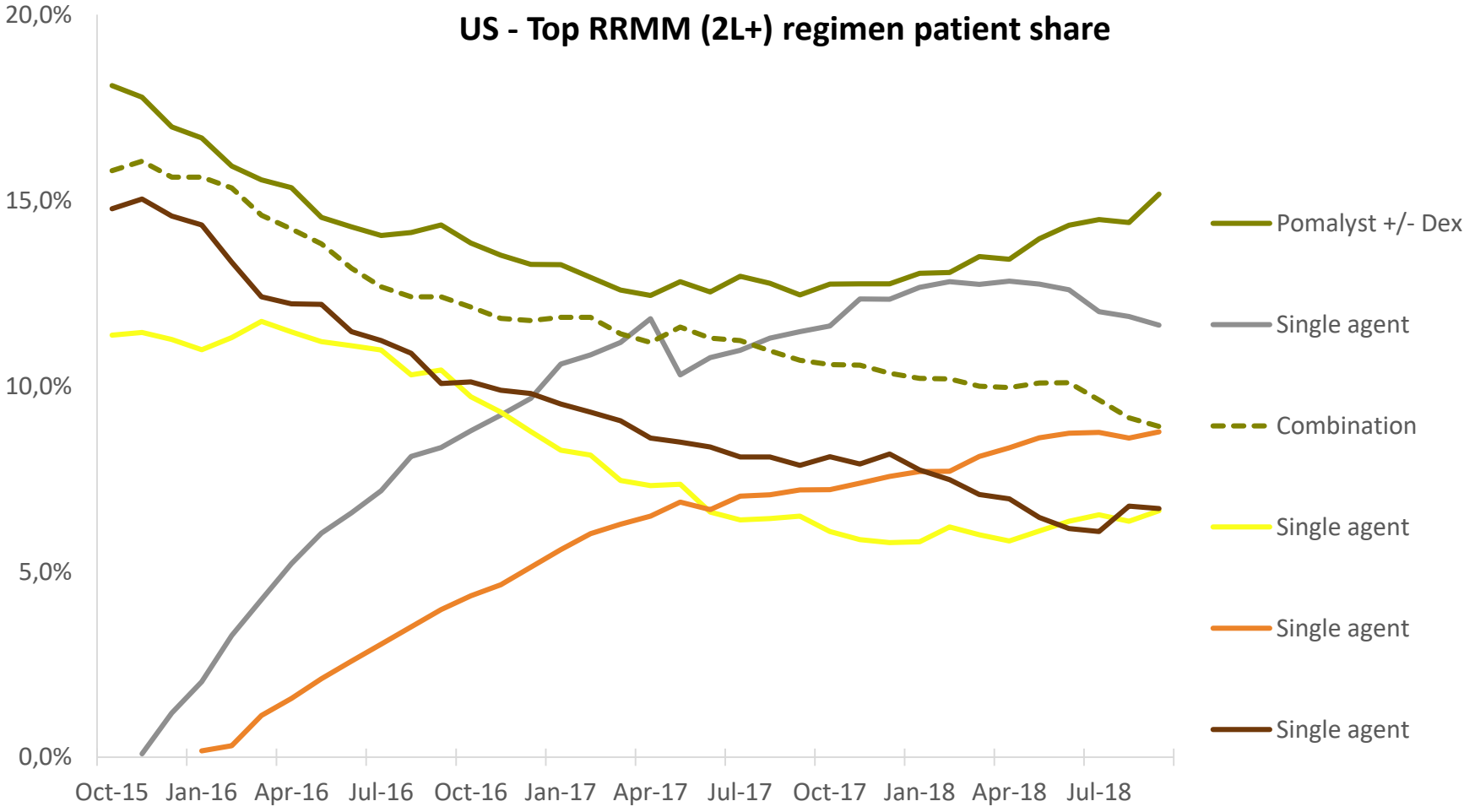
Lines of therapy throughout the disease stages



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

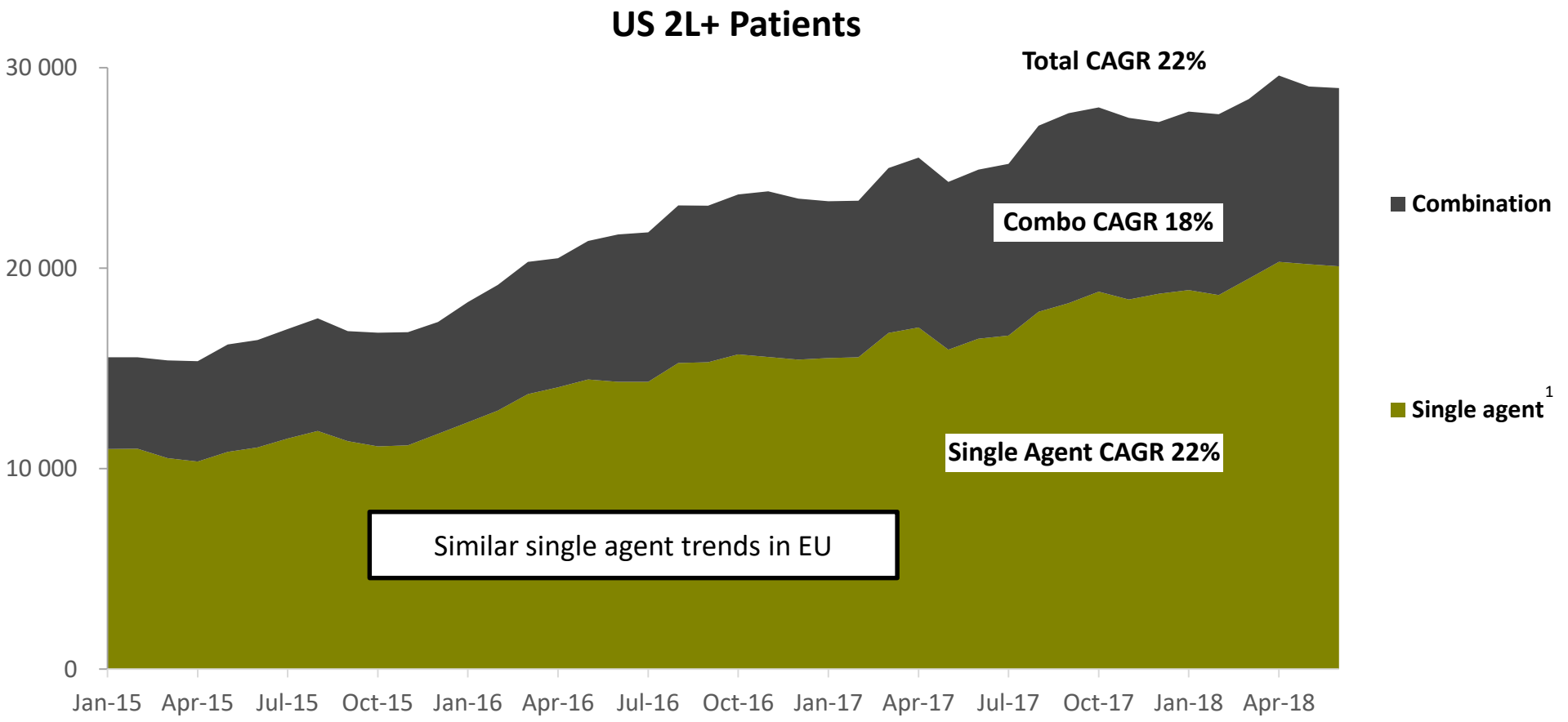
Single agent +/- steroid predominantly used in 2L+ despite guidelines

Pomalyst is the most commonly used regimen in 2L+ (US data)



Source: Intrinsiq, Sep MAT 2018
Note: Assume regimens include Dexamethasone although steroid use not reported. Regimens below 5% not shown.

Single agent regimens are growing faster than combinations in 2L+, seemingly cementing the rise of single agent +/- steroid

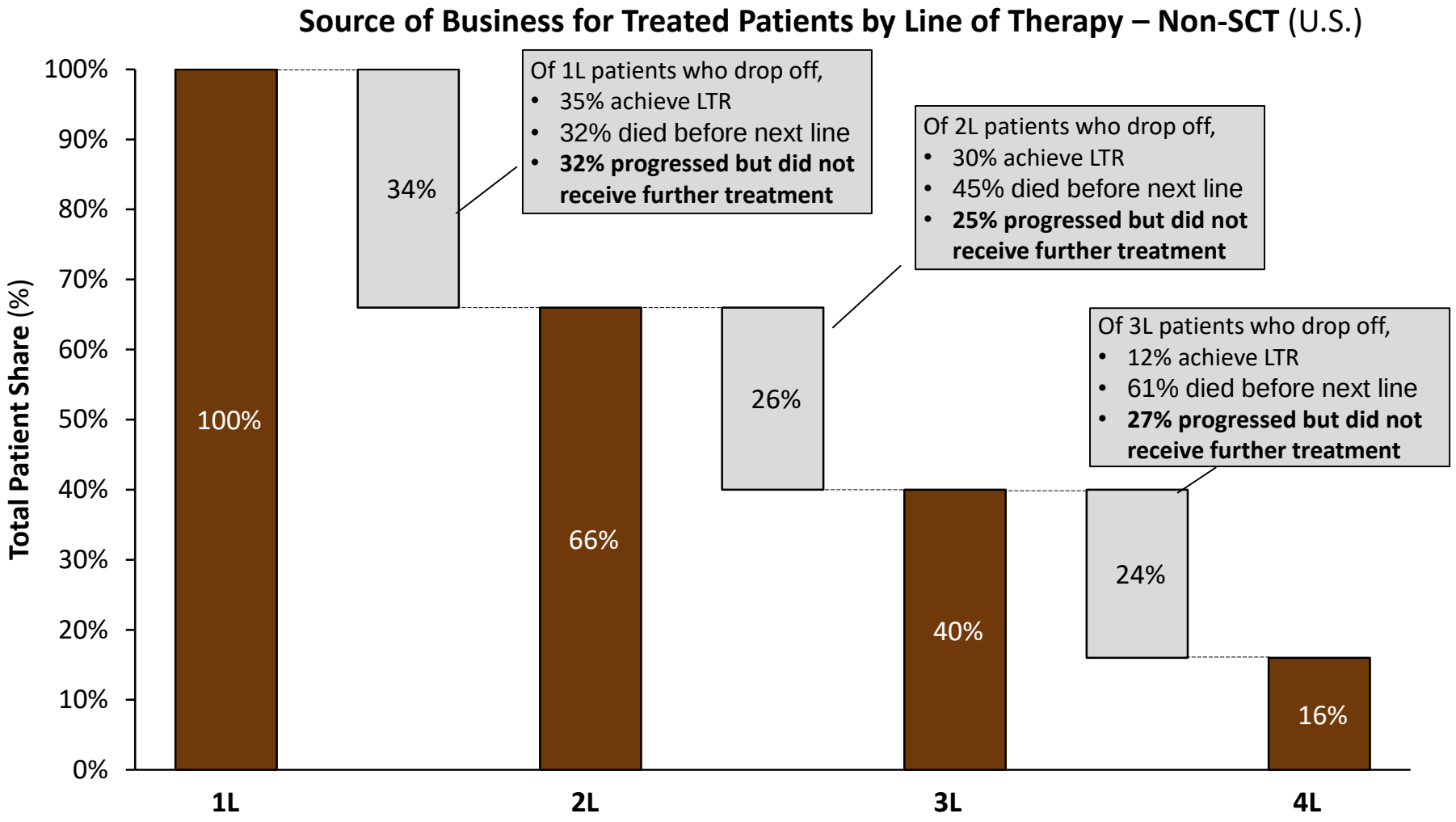


Source: Intrinsiq, Mar 2018 , CAGR for YE15-17, EU trend based on Kantar Health report.

1. Single agent is drug plus dexamethasone (± steroids)

A significant number of patients do not tolerate additional therapy

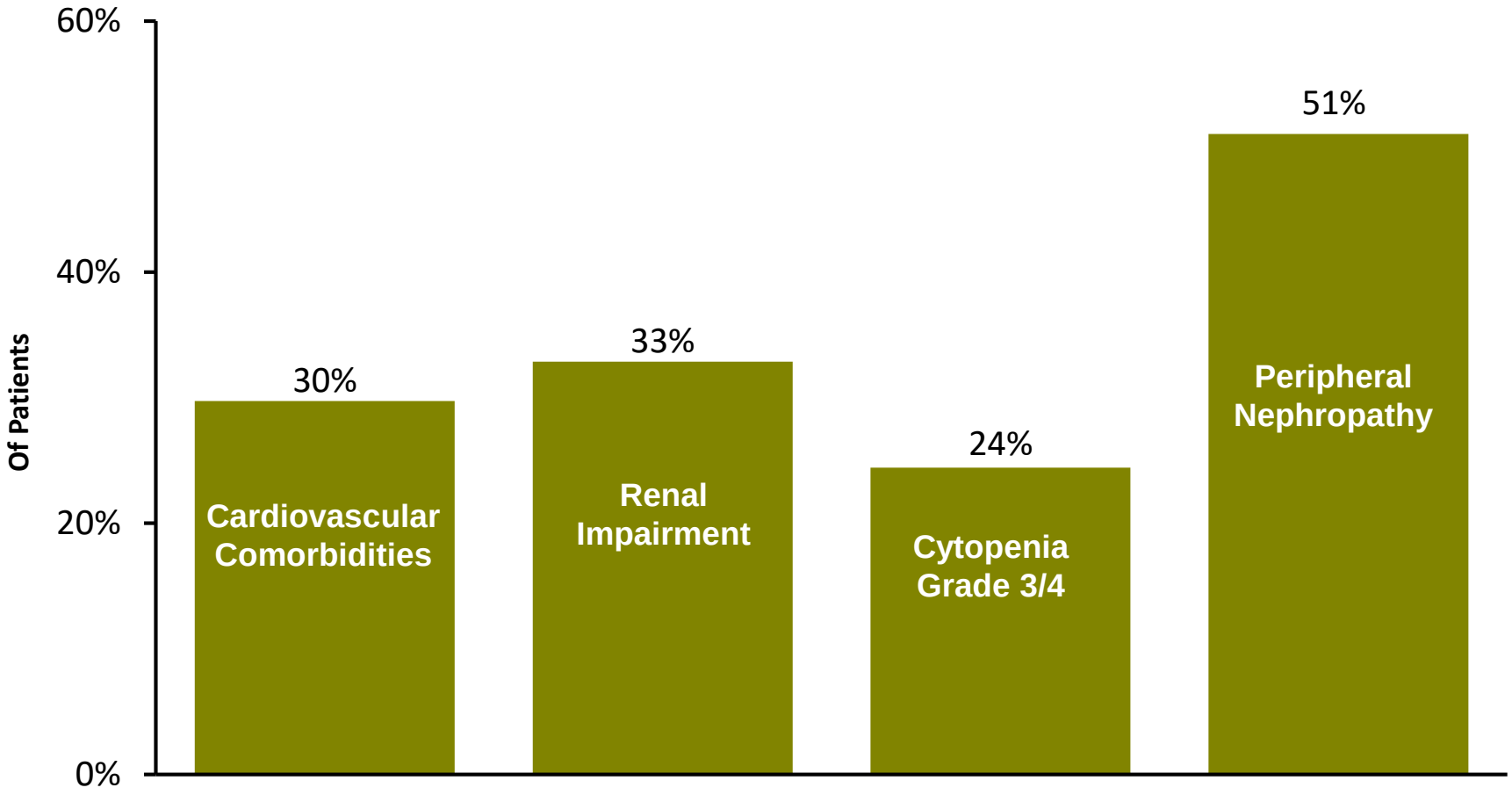
One in four patients drop out of treatment - mainly due to tolerability



Source: Kantar Health
LTR: Long-Term Remission

Co-morbidities restrict treatment selection in all stages of treatment

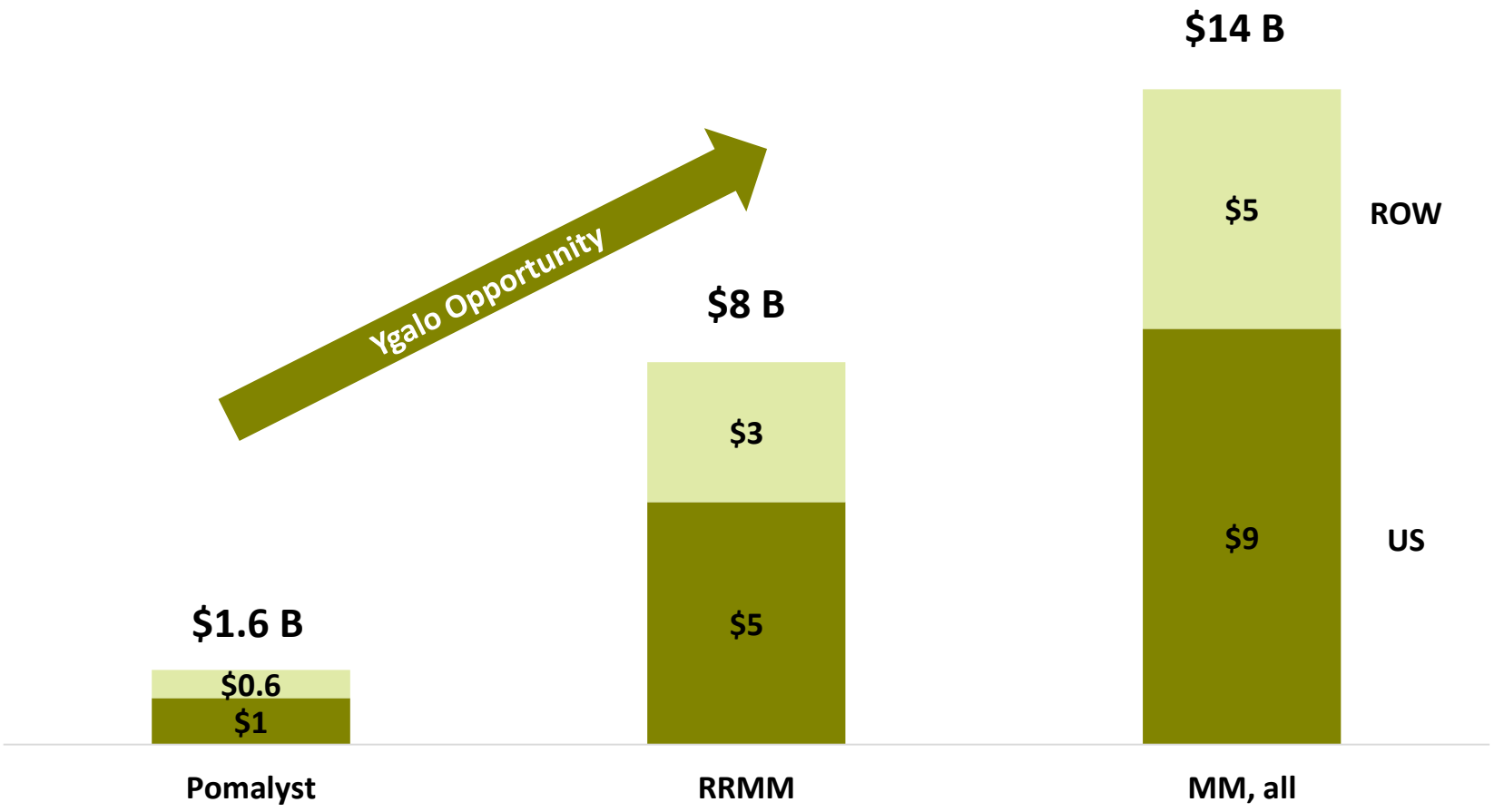
Comorbidities significantly restrict therapy choice, with surveyed comorbidity rates reflecting both qualitative research findings and literature estimates



Source: Physician market research; Terpos, et al. *Eur J Haematol*, 2018.

Melflufen (Ygalo®) opportunity in RRMM

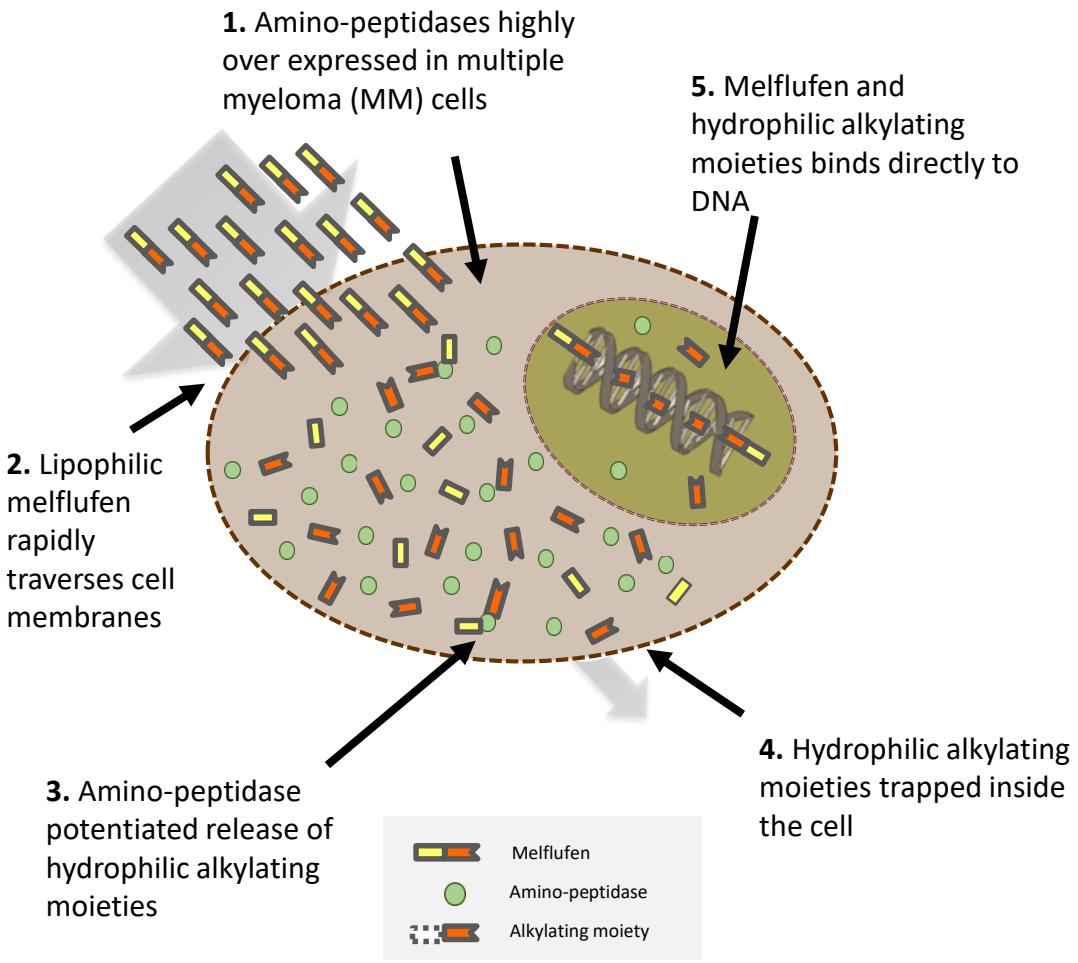
2017 Multiple Myeloma Net Sales Breakdown



Source: EvaluatePharma, Intrinsiq, company analysis

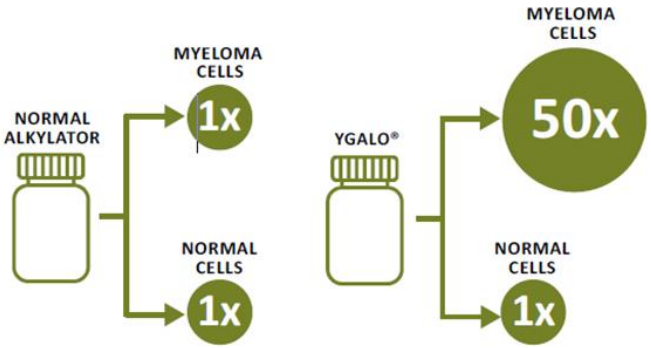
Melflufen is a first in class peptidase enhanced compound (PEnC)

Aminopeptidases overexpressed up to 250x as part of transformation process



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]



1. Chauhan et al. (2013) Clin Cancer Res 19(11): 3019-303.
2. Wickstrom et al. (2008) Invest New Drugs 26(3): 195-204.
3. Ray et al. (2016) Br J Hematol 174: 397-409.
4. Strese et al. (2013) Biochem Pharmacol 86: 888–895.
5. Wickström et al. (2017) Oncotarget E-pub June 08.

Melflufen (Ygalo®) is a highly differentiated selective compound

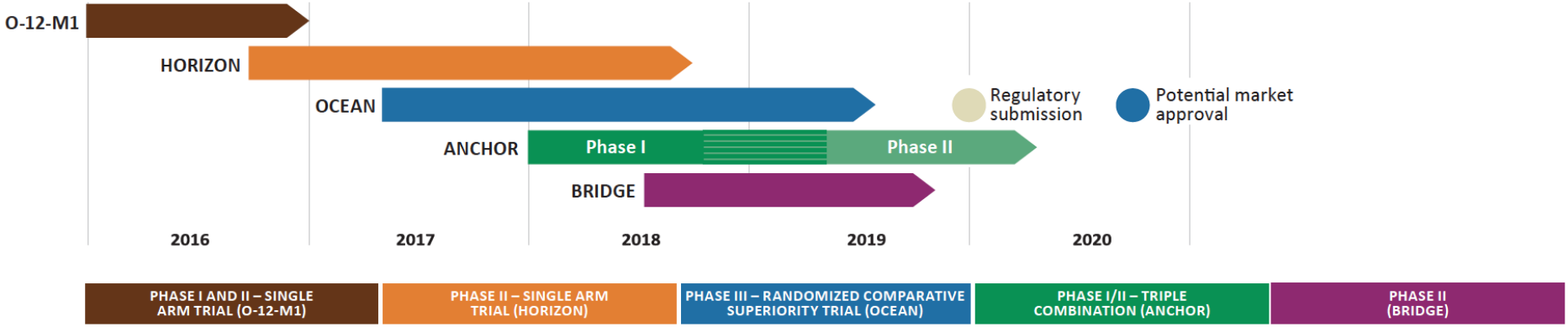
Well positioned to become the next backbone agent in myeloma

- Ygalo®is an PEnC peptide with a well defined mechanism of action
- Ygalo® is highly selective for transformed cells, with significant increase in therapeutic index
- 50x+ activity increase in transformed cells with no increase against bone-marrow cells
- Ygalo® does not share resistance mechanisms with other classes of agents
- Phase 2 demonstrated the best overall survival data to date in late-stage myeloma
- Well tolerated with limited adverse events negatively impacting patient quality of life
- Bone pain improvement seen in first-cycle of treatment
- Does not rely on renal excretion (renal function often severely impacted in myeloma)
- Convenient once monthly 30 min infusion (simplifying community hospital use where majority of patients treated)
- Covered by Medicare Part B vs Part D

Development program for melflufen is designed to support its potential as a new broad spectrum backbone agent after IMiD and PI failure

Must have characteristics	Melflufen
• Single agent +/- steroid activity in multi-refractory patients of 20%+ ORR	• O-12-M1 showed an ORR of 31% and HORIZON an ORR of 32% in multi-refractory patients
• Single agent +/- steroid approval in refractory patients	• OCEAN is designed to give single-agent approval
• Efficacy synergy in combination with other main myeloma drugs with good tolerability	• ANCHOR, first dataset from ongoing trial to be presented at ASH in December
• No major QoL tolerability issues	• Very good QoL with almost no non-hematological AEs
• No co-morbidity limitations	• No co-morbidity limitations, Drug-Drug Interaction
Nice to have characteristics	
• Easy administration schedule	• Once monthly 30min infusion

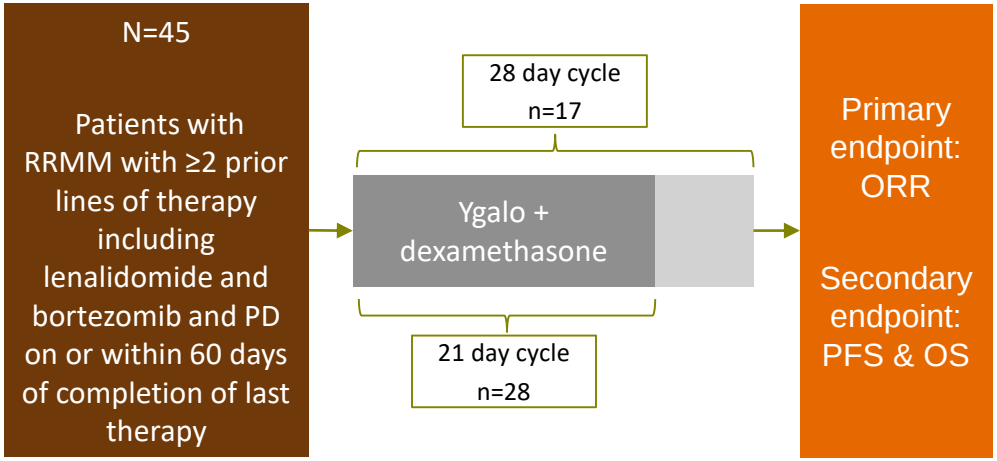
Our clinical development program is designed to establish a tier 1 drug in RRMM



O-12-M1	HORIZON	OCEAN	ANCHOR	BRIDGE
Show single-agent activity in RRMM	Show single-agent activity in RRMM	Show single-agent superiority over SoC in RRMM (pomalidomide)	Show combination synergy and tolerability with daratumumab and bortezomib	Show that melflufen can be used in patients with renal impairment

Phase II (O-12-M1) study design and patient disposition

Patients were IMiD and PI exposed with refractory disease

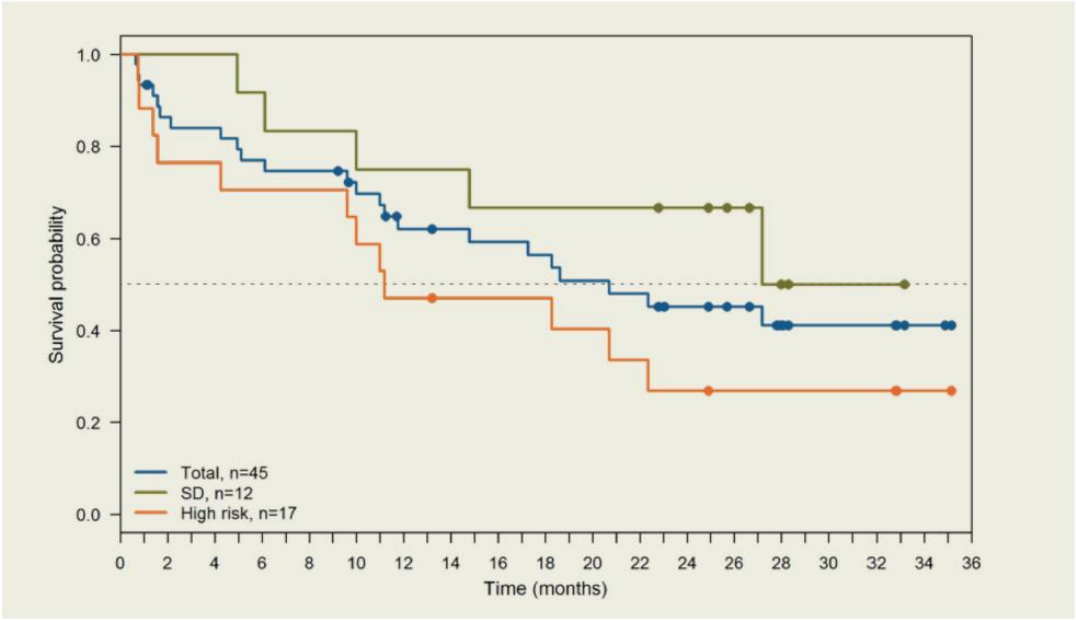


	N = 45
Median age, years (range)	66 (47-78)
Years since diagnosis, median (range)	5.1 (1.4 – 21.2)
Number of previous lines of therapy, median (range)	4 (2-14)
ISS, stage at study entry, n (%)	
I	15 (33)
II or III	27 (60)
Unknown	3 (7)
ECOG performance status, n (%)	
0	23 (51)
1	22 (49)
2	0
High-risk cytogenetic risk factors by FISH, n (%)*	17 (38)
Double-refractory, n (%) (IMiD +PI)	29 (64)
Last line refractory, n (%)**	42 (93)
Pomalidomide refractory, n (%)	20 (44)
Refractory to an alkylator (melphalan, cyclophosphamide or bendamustine), n (%)	24 (53)

* t(4;14), t(14;16), t(14;20), del(17/17p) or gain(1q)

** 3 patients had PR or better in the last line of therapy and PD within 180 days of last dose

Melflufen (Ygalo®) demonstrated best-in-class survival data in late-stage RRMM



- >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 tumor Response Rates (ORR and CBR)
- Better tolerated by the patients – non-hematological toxicity is rare
- Ygalo demonstrated a larger benefit on OS than PFS suggesting that Ygalo may improve response to subsequent treatments. A possible mechanism for this is clonal resetting which requires further exploration in ongoing studies

N	PD	SD	MR	PR	VGPR	ORR	CBR	PFS	OS
ITT (N=45)[1]	7	12	8	9	5	31%	49%	5.7 months (95% CI:3.7-9.3)[2]	20.7 months (95% CI:11.8-∞)[3]
Efficacy evaluable (N=34)	1	11	8	9	5	41%	65%		

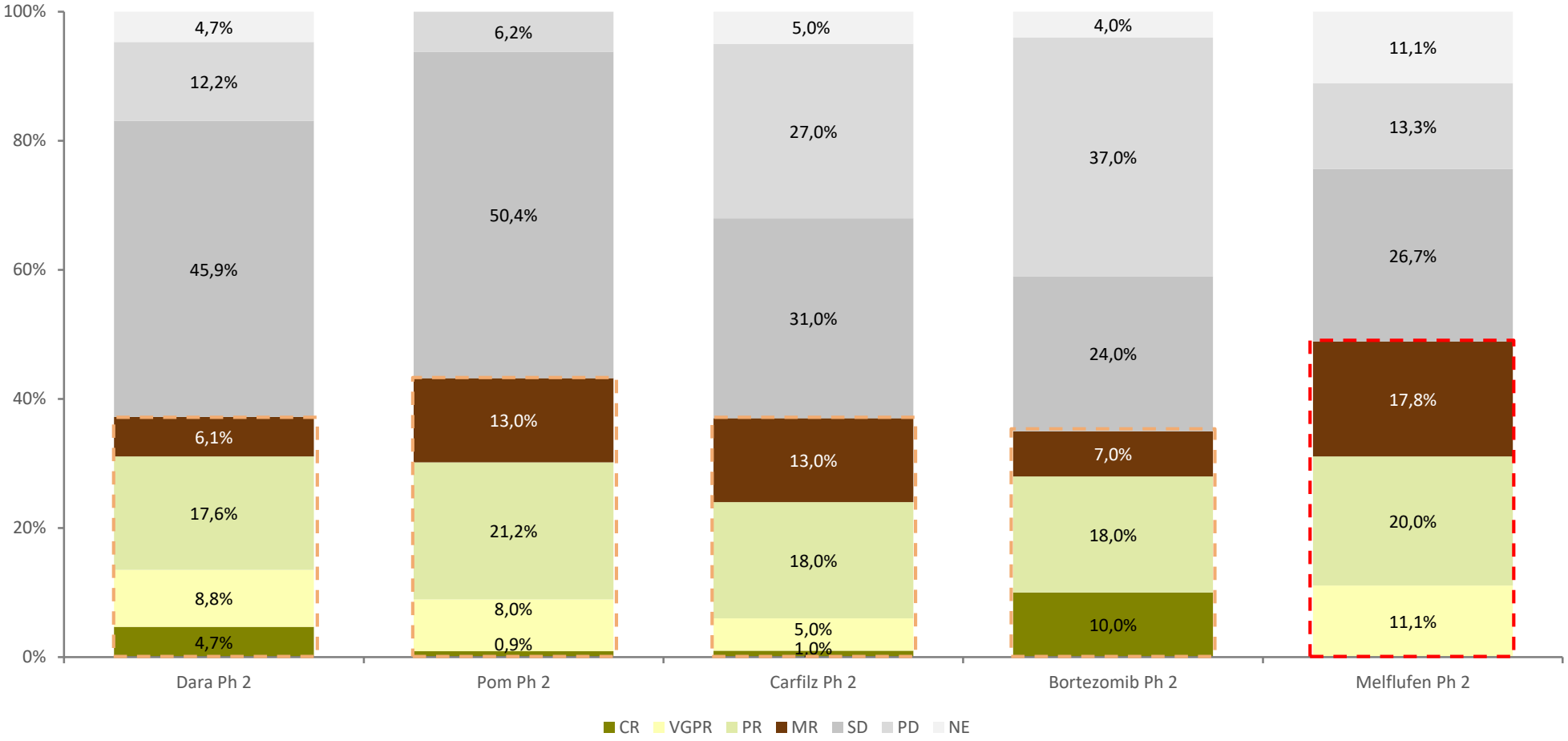
1. 4 patients did not have a response assessment.
2. Based on 41 events in 45 pts. In pts with ≥PR, the median PFS was 11.7 months (95% CI: 9.8 – ∞, event rate 93%). The median DOR was 8.4 months (95% CI: 5.8 – ∞).
3. Based on 23 events in 45 pts. Among the 12 pts that achieved stable disease, the mOS was 30.2m (95% CI: 14.8 – ∞, event rate 42%), and in pts with high-risk cytogenetics the mOS was 11.2 m (10.0 – ∞, event rate 71%). Fourteen (31%) pts were alive 24m after end of treatment, including 4 pts with high-risk cytogenetics.

Best overall survival data to date in late stage myeloma

	Melflufen	Daratumumab	Pomalidomide	Carfilzomib
N	45	106	302	257
Year	2017	2016	2013	2012
Population	Refractory to last, exposed to iMID, PI and alkylator, IMiD and PI refractory	Refractory to last, ≥ 3 lines with IMiDs and PI, double refractory to PI and IMiD	Refractory to last, at least 2 lines with bort and len and received alklylator	> 2 prior for relapsed including Bor, Len or thal, alk or anthra alone or in combo
Time from diag.	5.1 years	4.8 years	5.3 years	5.4 years
High risk Cytog.	38%	39%	~30%	28%
Number of lines	4	5, 82 % ≥ 3 lines	5, 94 % ≥ 2 lines	82% ≥ 4 lines
Refract. to last	87%	97%	100%	74%
ORR	31%	29.2 %	31.0 %	23.7%
ORR high risk	41%	26.2 %	-	29.6 %
Med duration treat	3.6 months	5.3 months	Progressive Disease or Unacceptable Toxicity	3.0 months
Med. Dur response	8.4	7.4	7.0	7.8
Median PFS	5.7 months (11.7 in ≥ PR)	3.7 months	4.0 months (TTP 4.7 months)	3.7 months
Median OS	20.7 months (30.2 in SD)	17.5 months	12.7 months	15.6 months

Source: Richardson PG *et al.,* ASH 2017; Usmani SZ *et al.,* 2016: Miguel JS *et al.,* 2013; Siegel DS *et al.,* 2012

Significant clinical benefit, in comparison with other approved drugs in late-stage RRMM



NE: Non-evaluable. PD: Progressive Disease. SD: Stable Disease. MR: Minimal Response.
PR: Partial Response. VGPR: Very Good Partial Response. CR: Complete Response.

Excellent tolerability – key in a palliative care setting

Treatment-related G3/4 AEs occurring in ≥ 2 patients (N=62)

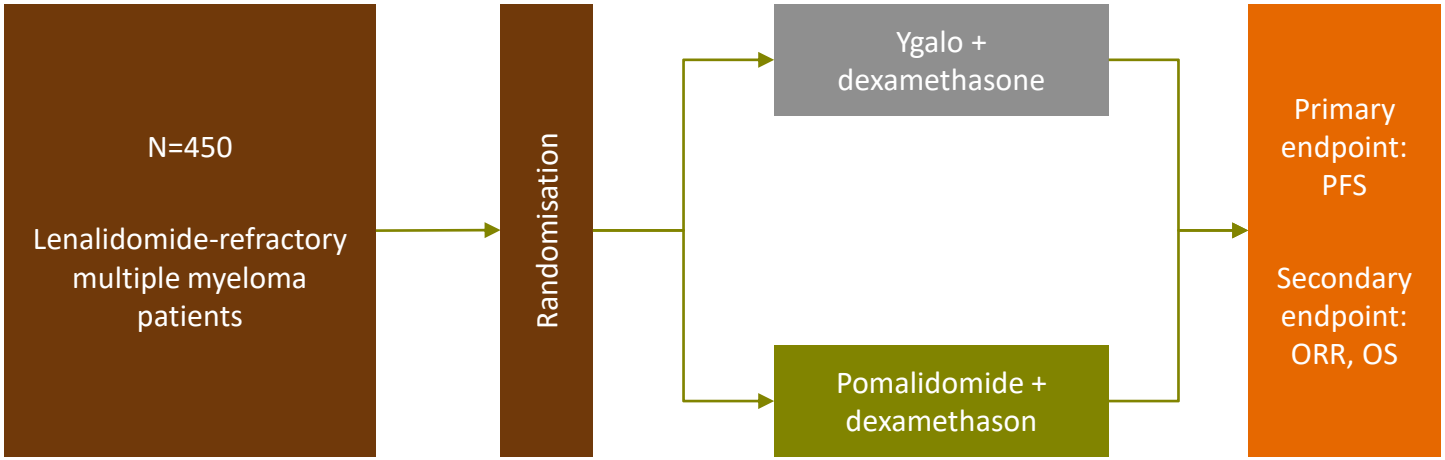
	GRADE 3 OR 4, n (%)	GRADE 4, n (%)
Any treatment-related AE	**48 (77)**	**32 (52)**
Blood and lymphatic system disorders	**46 (74)**	**31 (50)**
Neutropenia	37 (60)	21 (34)
Thrombocytopenia	37 (60)	25 (40)
Anemia	19 (31)	1 (2)
Leukopenia	4 (6)	3 (5)
Lymphopenia	4 (6)	1 (2)
Febrile neutropenia	4 (6)	1 (2)

- No treatment related G3/4 AEs outside of the hematological compartment
- Good indication of Quality of Life while on treatment

Source: ”A preliminary report on efficacy and safety of melflufen in late stage relapsed-refractory myeloma patients refractory to pomalidomide and/or daratumumab”, HORIZON study EHA June 2018.

Data to date provides high conviction for success in OCEAN

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



Late-Stage Relapsed Refractory

OCEAN

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

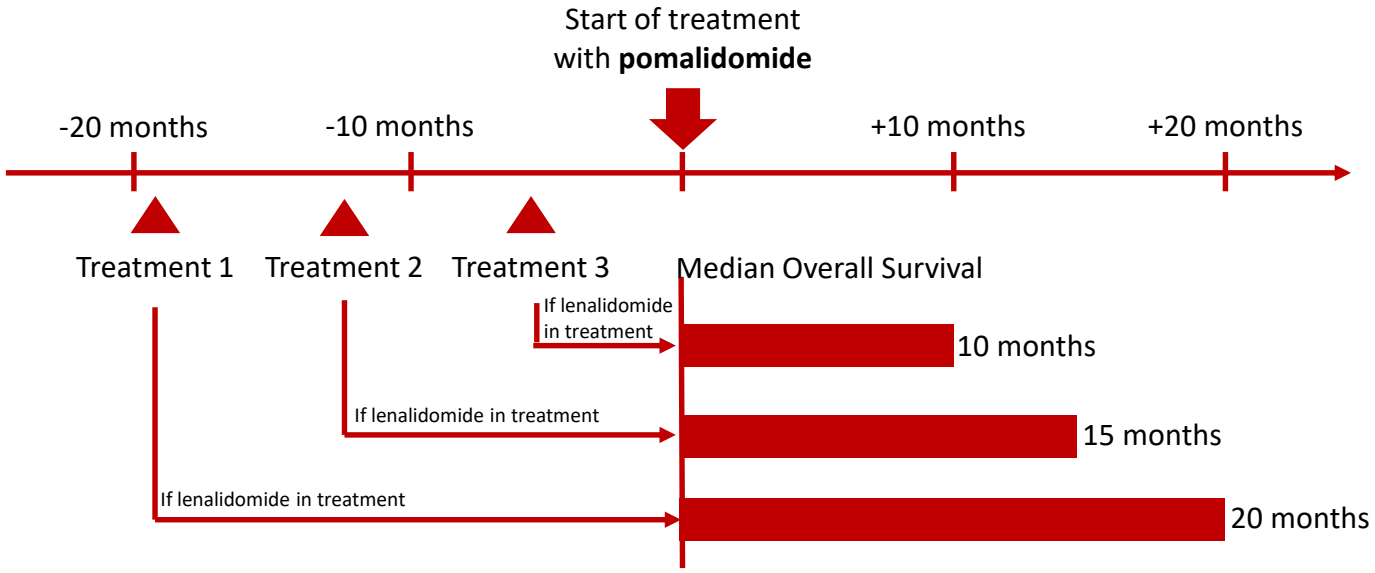
Note: NR=Not Reported. Ygalo® is not market approved.

Source: FDA Label.

Pomalidomide shares resistance mechanism with lenalidomide

No assumption has been made in OCEAN power calculation about this factor

Dimopoulos research supporting an IMiD free period



50% reduction in efficacy if patient recently failed on lenalidomide - suggests significant resistance overlap between lenalidomide and pomalidomide

Source: Pomalidomide with Low Dose Dexamethasone Is Effective Irrespective of Primary or Secondary Resistance to Lenalidomide but the IMiD-Free Interval Is Important (Dimopoulos et. al. ASH poster 2016).

Pomalidomide shares resistance mechanism with lenalidomide (cont'd.)

No assumption has been made in OCEAN power calculation about this factor

Siegel data of pom+dex in len-refractory patients

Median prior lines of 2, 91% len-refractory, median 4.5 years since diagnosis, 5.4% ISS III,

- 33.9% ORR
- 9.6m PFS

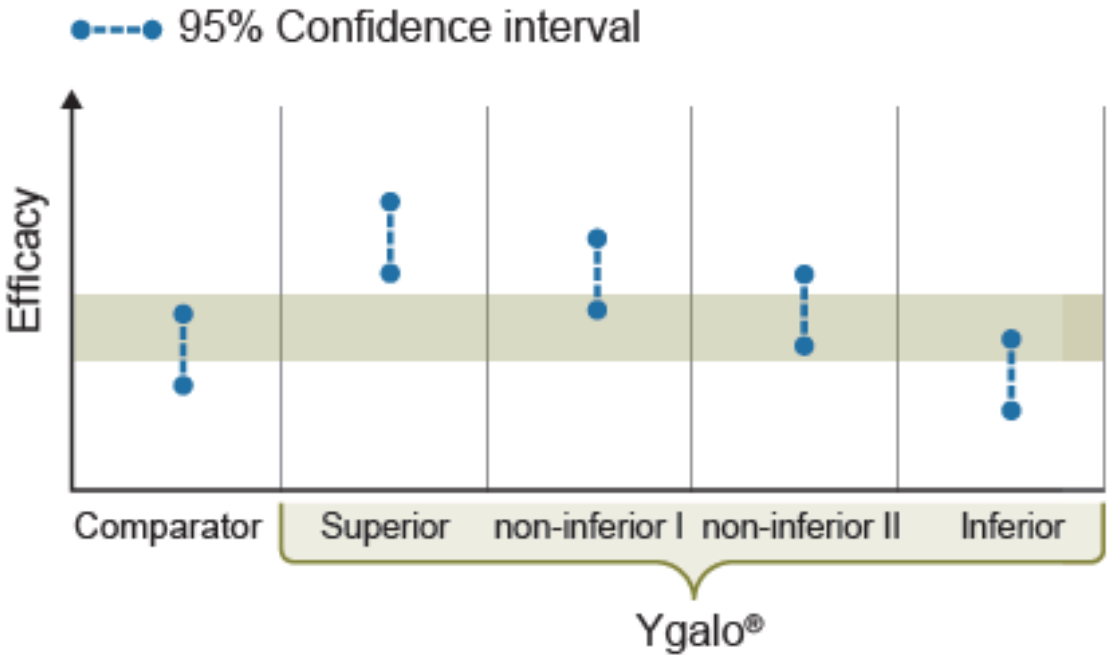
Len-registration data as 2nd line agent together with dex

Median prior lines of 2, 30.1% thalidomide exposed, median 3.4 years since diagnosis, 65.3% Durie-Salmon III

- 60.2% ORR (includes thalidomide exposed patients)
- 13.5m PFS

29-44% reduction in efficacy in a significantly healthier population (the difference in staging should be based on data resulting in a 39% difference to the benefit of pom) in len-refractory patients

HORIZON and BRIDGE support the result in OCEAN



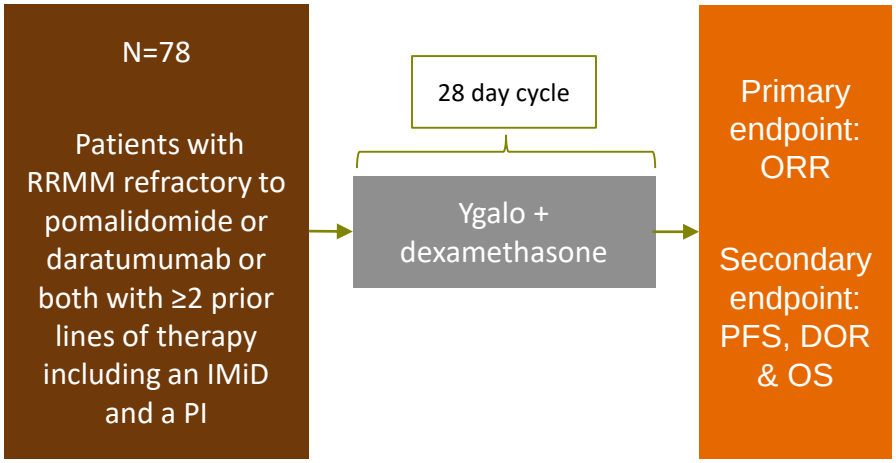
In a non-inferiority outcome scenario, differentiation is key, e.g.

- Better tolerability (OCEAN)
- No overlap in resistance mechanism (HORIZON)
- Renal clearence not required for Ygalo® (BRIDGE)

Source: IntrinsiQ September 2017. US data.

HORIZON study overview

Impact of Melflufen (Ygalo®) on patients with very limited treatment options



- Once patients become IMiD/PI/Dara refractory, they have an extremely poor prognosis
- Growing evidence that dara refractory patients are extremely difficult to treat
- Very ill patient population (54% High-risk patients, 46% ISS stage III patients)
- In last line of treatment 46% of patients received triplet or quadruplet combination treatments and 77% received Ab based therapy, carfilzomib or pomalidomide

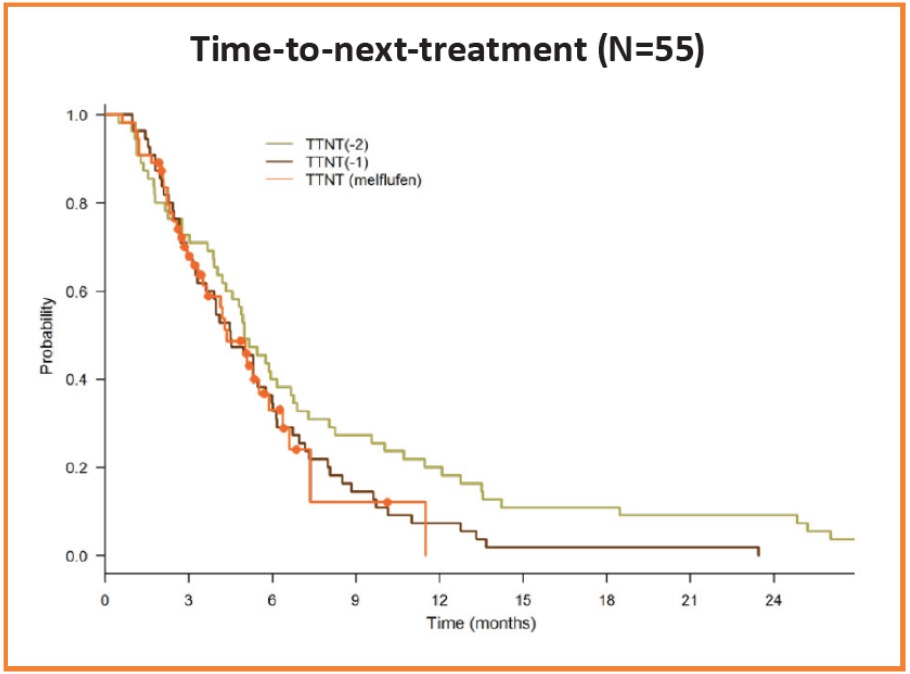
CHARACTERISTICS	
Median age, years (range)	62.5 (41-82)
Median time since diagnosis, years (range)	6.1 (0.7-16)
Number of previous lines (range)	5.5 (2-12)
ISS at study entry, n (%)*	
I	16 (28)
II	15 (26)
III	26 (46)
ECOG performance status, n (%)	
0	15 (24)
1	38 (61)
2	9 (15)
High-risk, cytogenetic risk factor by FISH**, n (%)	25 (54)

CHARACTERISTICS	n (%)
Pomalidomide or daratumumab refractory	62 (100)
Pomalidomide and daratumumab refractory	35 (56)
Double refractory (1 IMiD+1 PI)	55 (89)
Last line refractory	60 (98)
Received triple combination therapy in last line	28 (46)
Received regimens containing antibodies (CD38/BCMA/CS-1), carfilzomib or pomalidomide in last line	47 (77)
Double + daratumumab + last line refractory	36 (58)
Alkylator refractory	36 (58)

Source: EHA June 2018.
*Missing data for 5 patients.
**[t(4;14), t(14;16), t(14;20), del(17/17p) or gain(1q)]; missing data for 16 patients.

Promising results in patients without treatment options (HORIZON)

N	ORR	CBR	CR	VGPR	PR	MR	SD	PD
Total, N=56	32.1%	39.3%	2%	9%	21%	7%	45%	16%
ISS stage III, N=24	25.0%	29.2%	4%	4%	17%	4%	50%	21%
HR cytogenetics, N=22	27.3%	27.3%	5%	9%	14%	0%	55%	18%
Pom but not dara refractory, N=20	40.0%	55.0%	5%	5%	30%	15%	40%	5%
Dara but not pom refractory, N=6	66.7%	66.7%	0%	17%	50%	0%	33%	0%
Pom + dara refractory, N=30	20.0%	23.3%	0%	10%	10%	3%	50%	27%
ISS stage I + II, N=13	38.5%	38.5%	0%	15%	23%	0%	54%	8%



- Strong overall response rate with 32.1%
- Great activity in dara refractory patients
- No deterioration of time-to-next treatment from previous line
  - Standard in myeloma is a reduction of 25-50% from one line to the next

Executive summary

- Relapse in MM is inevitable despite advances with novel agents
- Fundamentally only four treatment modalities available – IMiDs, PIs, alkylators and anti-CD38
- 9 out of 10 patients treated with broad spectrum backbone agents due to heterogeneity of the tumor
- Aggressive front line use of IMiD/PI combinations until disease progression results in need to switch treatment already in 2L patients. With only four available treatment modalities this drives a heterogeneous 2L+ treatment landscape
- As a consequence, there is a significant need for novel MoAs in relapsed-refractory MM patients
- Treatment with single-agent +/- steroid most common in 2L+ patients with pomalidomide +/- dex having the largest market share
- QoL is a key factor for patients – one MM patient out of four opt out of treatment mainly due to tolerability
- Melflufen's clinical profile to date and current clinical development program addresses a significant clinical need in myeloma with its level of efficacy, tolerability profile, administration schedule, lack of co-morbidity drug/drug interaction limitations and expected label.
- Initial market revenue will be generated from a USD 8bn+ opportunity.