
Post-EHA Webcast
June 17th 2019
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oncopeptides

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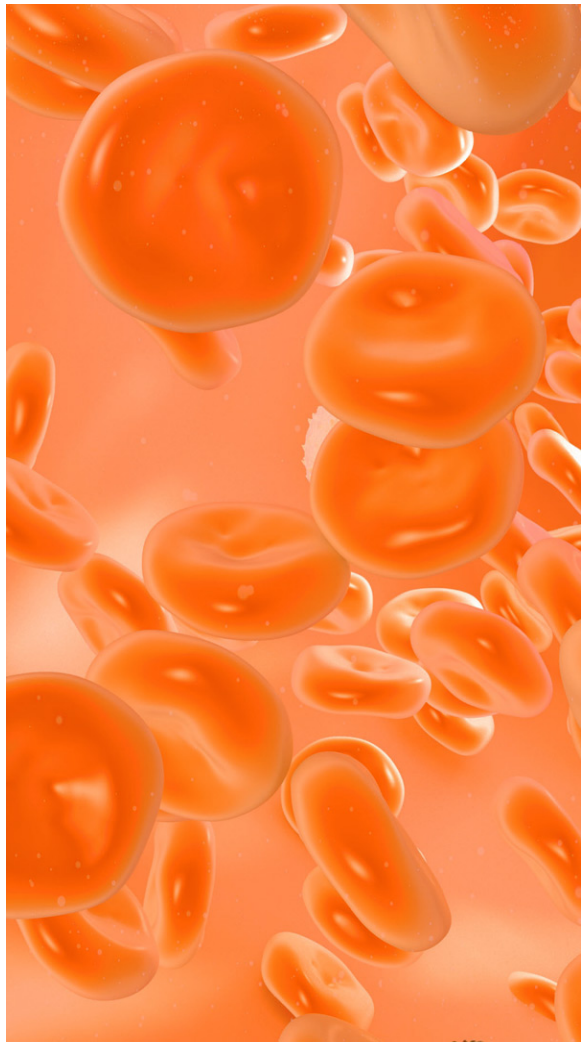
Today’s Agenda

Walkthrough of data from Oncopeptides presented at EHA

Key data from other Companies

Q&A



- Largest conference event for Oncopeptides ever
- One oral presentation (HORIZON)
- Three poster presentations (ANCHOR, O-12-M1 and cross-study safety analysis)
- Data-sets very well received reinforcing that melflufen has the clear potential to play a key role in the treatment of multiple myeloma

What does good combination data look like in RRMM?

1x RMM	2x RMM
OPTIMISMM **Velcade + Pom** ORR: 82.2% mPFS: 11.2m mOS: NR	**ELOQUENT-3** **Elotuzumab + Pom** ORR: 53% mPFS: 10.3m mOS: NR
	Daratumumab + Pom ORR: 60% mPFS: 8.8m mOS: 17.5m
	Carfilzomib + Pom ORR: 50% mPFS: 7.2m mOS: NR
	Isatuximab + Pom ORR: 60% mPFS: 11.5m mOS: NR
Melflufen + Dara ORR: 82% mPFS: NR mOS: NR	**Melflufen + Vel** ORR: 100% mPFS: NR mOS: NR

Strong data for melflufen together with daratumumab in RRMM patients

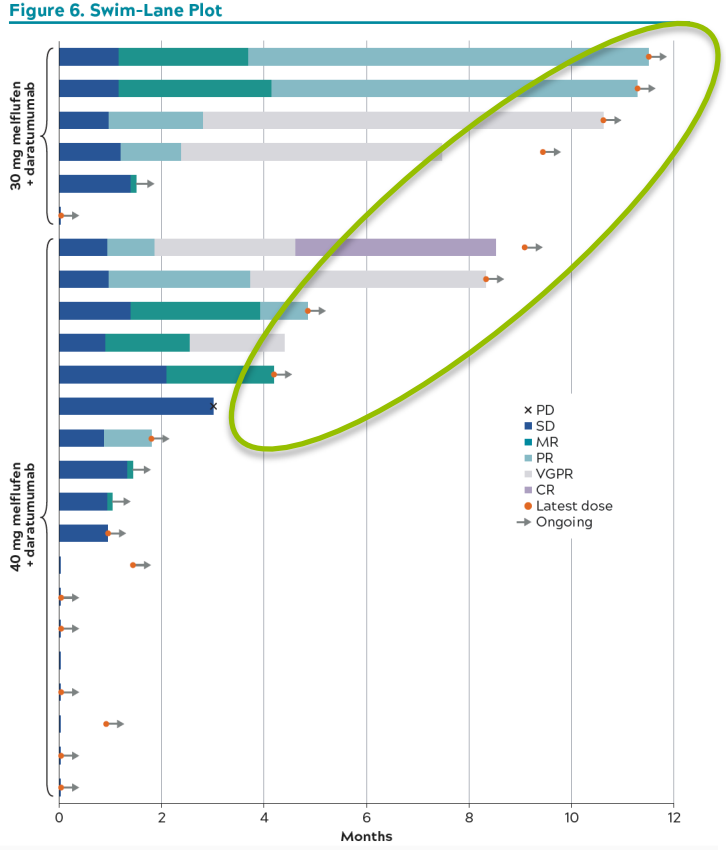
ANCHOR

Table 4. Patient Characteristics: Regimen B

Characteristics	30 mg[a] (n=6)	40 mg (n=18)
Median age, years (range)	57.0 (49-78)	62.0 (35-77)
Gender, n (%) Male/female	3 (50)/3 (50)	13 (72)/5 (27)
Median time since diagnosis, years (range)	3.1 (1.9-8.0)	4.4 (0.7-8.2)
Median number of previous lines (range)	2.5 (1-3)	2 (1-4)
Prior ASCT/ alkylator exposed, n (%)	5 (83)/ 3 (50)	14 (78)/ 10 (56)
Alkylator refractory, n (%)	1 (17)	4 (22)
IMiD refractory, n (%)	3 (50)	11 (61)
PI refractory, n (%)	0	10 (56)
Last-line refractory, n (%)	2 (33)	10 (56)
IMiD + PI refractory, n (%)	0	8 (44)
ISS at study entry,[b] n (%) I/II/III	6 (100)/0/0	13 (76)/2 (12)/2 (12)
High-risk cytogenetic by FISH,[c] n (%)	2 (40)	5 (36)
Median albumin level, g/dL (range)	4.1 (3.1-4.5)	3.9 (3.1-4.9)

ASCT, autologous stem cell transplant; FISH, fluorescence in situ hybridization; ISS, International Staging System; PI, proteasome inhibitor.
[a]Three patients erroneously dosed with 30-mg melflufen instead of the assigned 40 mg.
[b]Missing data for 1 patient.
[c]High-risk defined as: t(4;14), t(14;16), t(14;20), del(17/17p), or gain(1q). Missing data for 5 patients.

Figure 6. Swim-Lane Plot



Source: EHA June 2019.

RRMM Data – Single Agent

1x RMM	2x RMM	3x RMM

Pomalidomide
ORR: 23.5-31%
mPFS: 3.6-4.1m
mDOR: 7.0-7.4m
mOS: 12.7-14.4m

Carfilzomib
ORR: 22.9%
mPFS: 3.7m
mDOR: 7.8m
mOS: 15.6m

Daratumumab
ORR: 29%
mPFS: 3.7m
mDOR: 7.4m
mOS: 17.5m

Melflufen (O-12-M1)
ORR: 31%
mPFS: 5.7m
mDOR: 8.4m
mOS: 20.7m

Melflufen (HORIZON)
ORR: 55%
mPFS: 4.6m
mDOR: NR
mOS: 17.6m

Selinexor
ORR: 25%
SD+: 75%
mPFS: 3.7m
mDOR: 4.4m
mOS: 8.6m
EMD%: ??

Melflufen (HORIZON)
ORR: 20%
SD+: 81%
mPFS: 4.0m
mDOR: 3.6m
mOS: 8.5m
EMD%: 60%

Baseline Patient Characteristics (N=121)

Characteristic	N=121
Age, median (range), years	64 (35-86)
Gender (male / female), %	55 / 45
Time since diagnosis, median, years	6.2 (0.7-25)
No. of prior lines of therapy, median (range)	5 (2-12)
ISS stage I / II / III / unknown,[a] %	38 / 30 / 29 / 4
ECOG PS 0 / 1 / 2,[a] %	24 / 61 / 14
High-risk cytogenetics,[b] %	62
≥2 high-risk abnormalities, %	19
Del(17p), %	17
Extramedullary disease,[c] %	60

ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System.
[a]ISS stage and ECOG PS at study entry, with data pending for 16 and 10 pts, respectively.
[b]High-risk cytogenetics [t(4;14), del(17/17p), t(14;16), t(14;20), nonhyperdiploidy, gain(1q) or karyotype del(13)] at study entry; data pending for 40 pts; 5 pts with unknown status at study entry had high-risk cytogenetics at diagnosis and were included in the high-risk group.
[c]Data pending for 54 pts.

Data cutoff 06 May 2019.

Prior Treatment and Refractory Status (N=121)

HORIZON

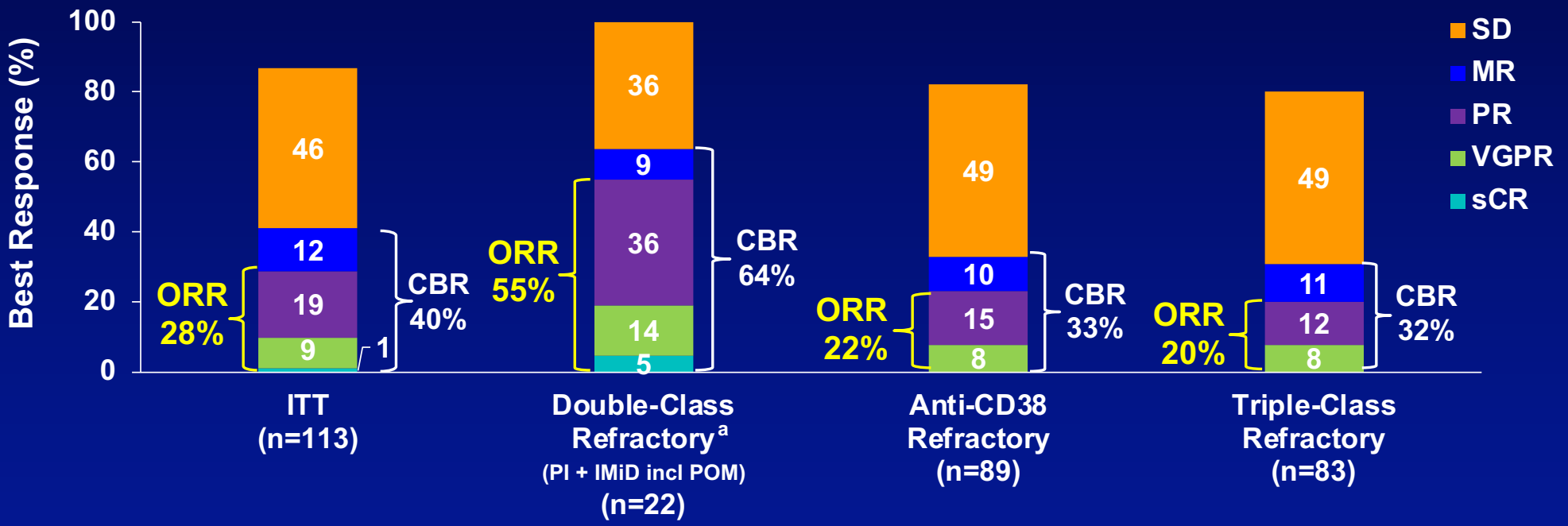
Prior Therapy Status	N=121
Double-class (IMiD + PI) exposed / refractory	100% / 91%
Anti-CD38 mAb exposed / refractory	79% / 79%
Triple-class (IMiD + PI + anti-CD38 mAb) exposed / refractory	79% / 74%
Alkylator exposed / refractory	86% / 59%
≥1 Prior ASCT	69%
≥2 Prior ASCTs	11%
Relapsed ≤1 year after ASCT	20%
Refractory in last line of therapy	98%

ASCT, autologous stem cell transplantation; IMiD, immunomodulatory agent; PI, proteasome inhibitor; mAb, monoclonal antibody.

- 36% used ≥ 3 treatment regimens in last 12 months prior to enrolment

Data cutoff 06 May 2019.

Best Response (IMWG[1])



- 8 pts did not have available response information at data cutoff; 2 pts response evaluable, PI exposed, but refractoriness to PI subject to confirmation, so excluded from subgroup analysis
- One pt with sCR also confirmed as MRD negative (10^{-6} sensitivity), with ongoing progression-free period of 13.6 mos
- Median time to response 1.2 mos

1. Rajkumar SV, et al. *Blood*. 2011;117:4691-4695.

[a]Not anti-CD38 refractory.

Data cutoff 06 May 2019.

Best Response for EMD and Non-EMD Patients (n=67)

	ORR, %
EMD-relapsed/refractory pts[a] (n=40)	29
Non–EMD-relapsed/refractory pts[a] (n=27)	38
EMD triple-class refractory[a] (n=37)	23
Non-EMD triple-class refractory[a] (n=20)	26

EMD, extramedullary disease; EoT, end of treatment; ORR, overall response rate.

[a]2, 1, 2, 1 ps, respectively, did not have any available response data or EoT data at the time of data cutoff.

- Poor outcomes observed across the limited clinical trial datasets available[1-5]
- Studies have failed to demonstrate any significant and/or durable response in pts with relapsed EMD: only dara and pom have shown response with ORRs of 17% and 9%, respectively (≥3 prior lines of therapy; dara and pom naïve)[1-5]
- HORIZON is one of the largest clinical trial cohorts of EMD-relapsed/refractory pts to date
  - EMD data pending for 54 pts (across 3 major participating centers with recently enrolled pts, limited data entry to date)

1. Jiménez-Segura R, et al. *Blood*. 2016;128:Abstract 5709. 2. Rosiñol L, et al. *Haematologica.* 2004;89:832-836. 3. Jiménez-Segura R, et al. *Eur J Haematol.* 2019;102:389-394. 4. Usmani SZ, et al. *Blood.* 2016;128:37-44. 5. Ichinohe T, et al. *Exp Hematol Oncol.* 2016;5:11.

Data cutoff 06 May 2019.

Duration of Response – Subgroup Analysis

	Median DOR, mos	Events, n (%)
All responders[a] (n=32)	4.4	21 (66)
Non-EMD (n=10)	8.1	5 (50)
EMD (n=11)	3.7	7 (64)
Triple-class refractory[a] (n=17)	3.6	12 (71)
Non-EMD (n=5)	7.5	3 (60)
EMD (n=8)	3.7	5 (63)

[a]11 and 4 responding pts respectively had missing EMD data.
DOR, duration of response; EMD, extramedullary disease; ITT, intention-to-treat.

Data cutoff 06 May 2019.

Clinical Trial Data in EMD Relapsed RRMM Patients

Median Prior Lines	Reference	Treatment Regimen	ORR, %
1	Jiménez-Segura et al, n=8	Thalidomide	0
2	Jiménez-Segura et al, n=16	Lenalidomide	25
2	Rosiñol et al, n=11	Thalidomide	0
3	Jiménez-Segura et al, n=4	Carfilzomib	0
3	Jiménez-Segura et al, n=21	Pomalidomide	9
5	Usmani et al, n=18	Daratumumab	17
6.5	Ichinohe et al, n=5	Pomalidomide	0

Dose Modifications Due to TEAEs

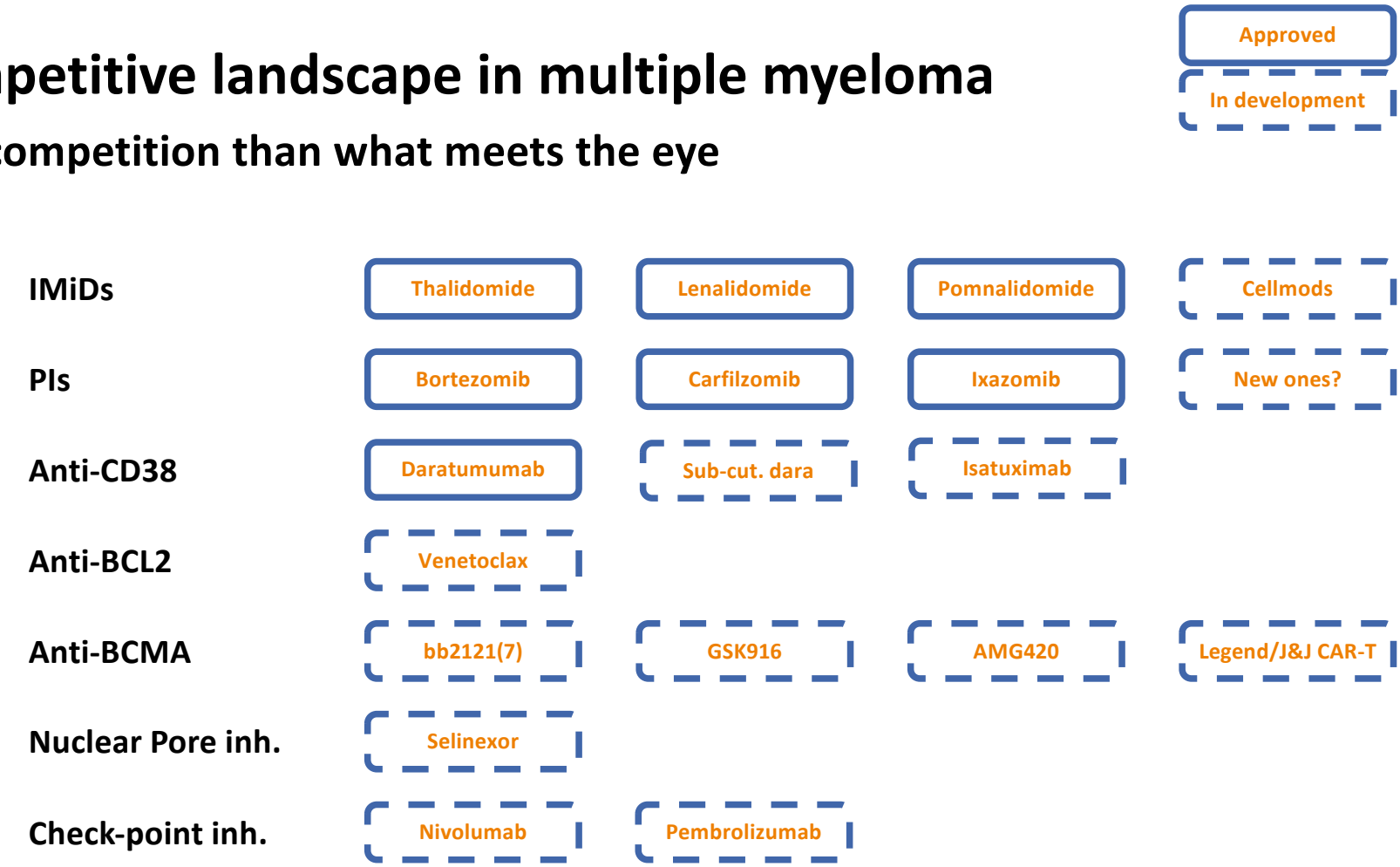
Action Taken With Melflufen (N=121)	n (%)
Dose modification due to TEAE	56 (46)
Dose reduced	27 (22)
Dose delayed	43 (36)
Drug discontinued	29 (24)

Dose modification calculated as the number of pts with a TEAE requiring a dose modification at any time point. Dose delayed calculated as number of pts with a TEAE leading to a dose delay. Pts may have had more than 1 action taken with melflufen and may be included in more than 1 category.

Data cutoff 06 May 2019.

Competitive landscape in multiple myeloma

Less competition than what meets the eye



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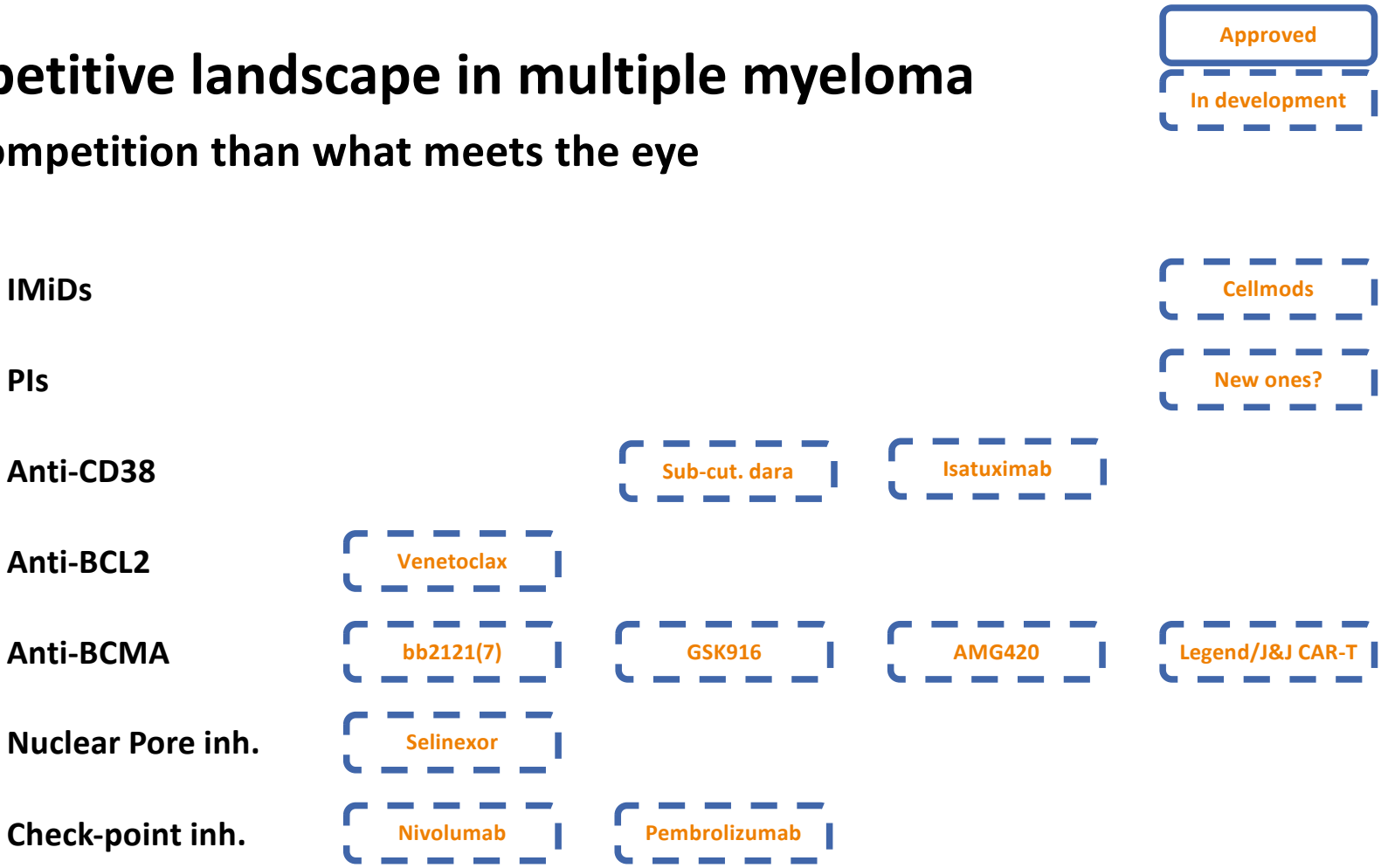

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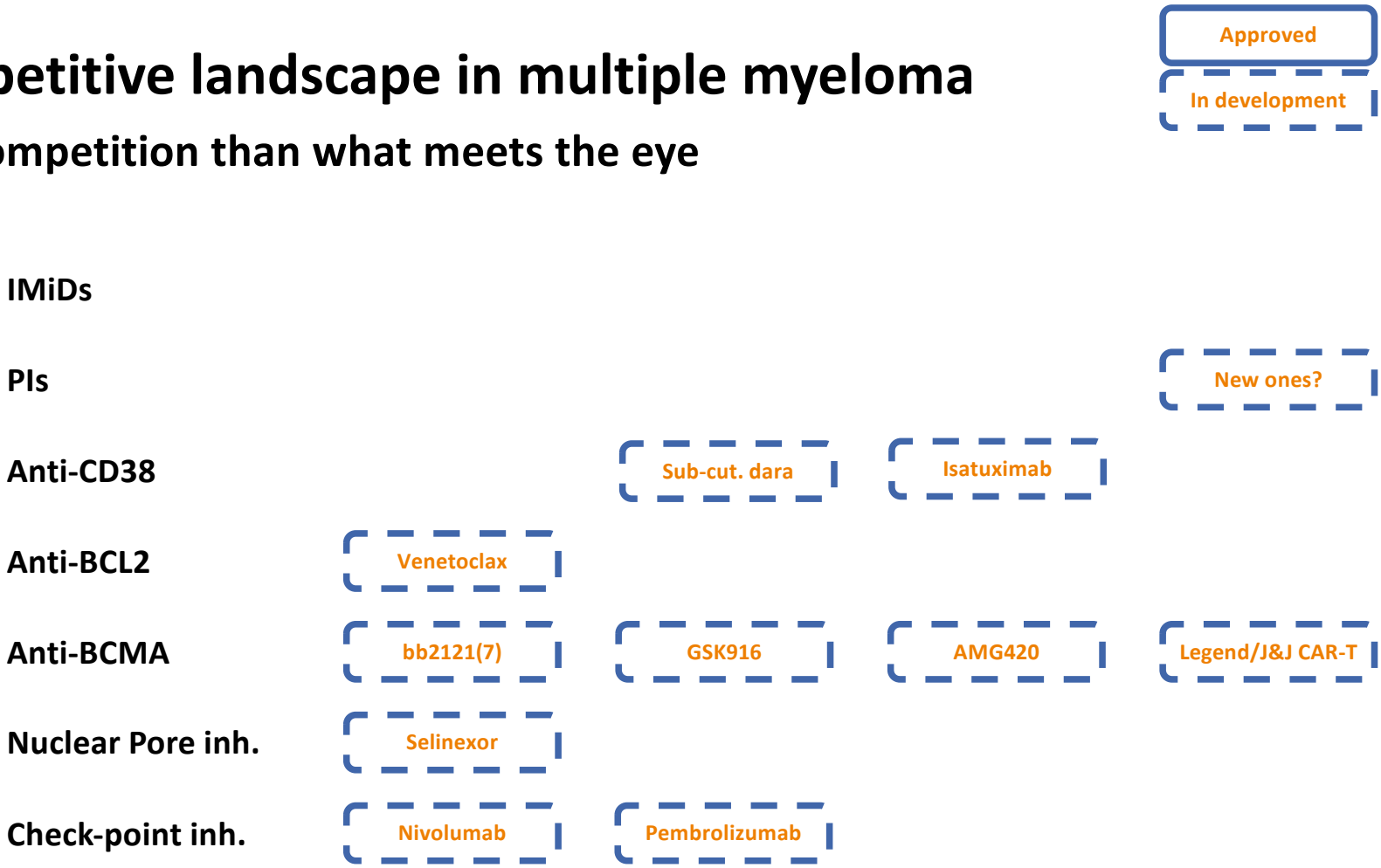

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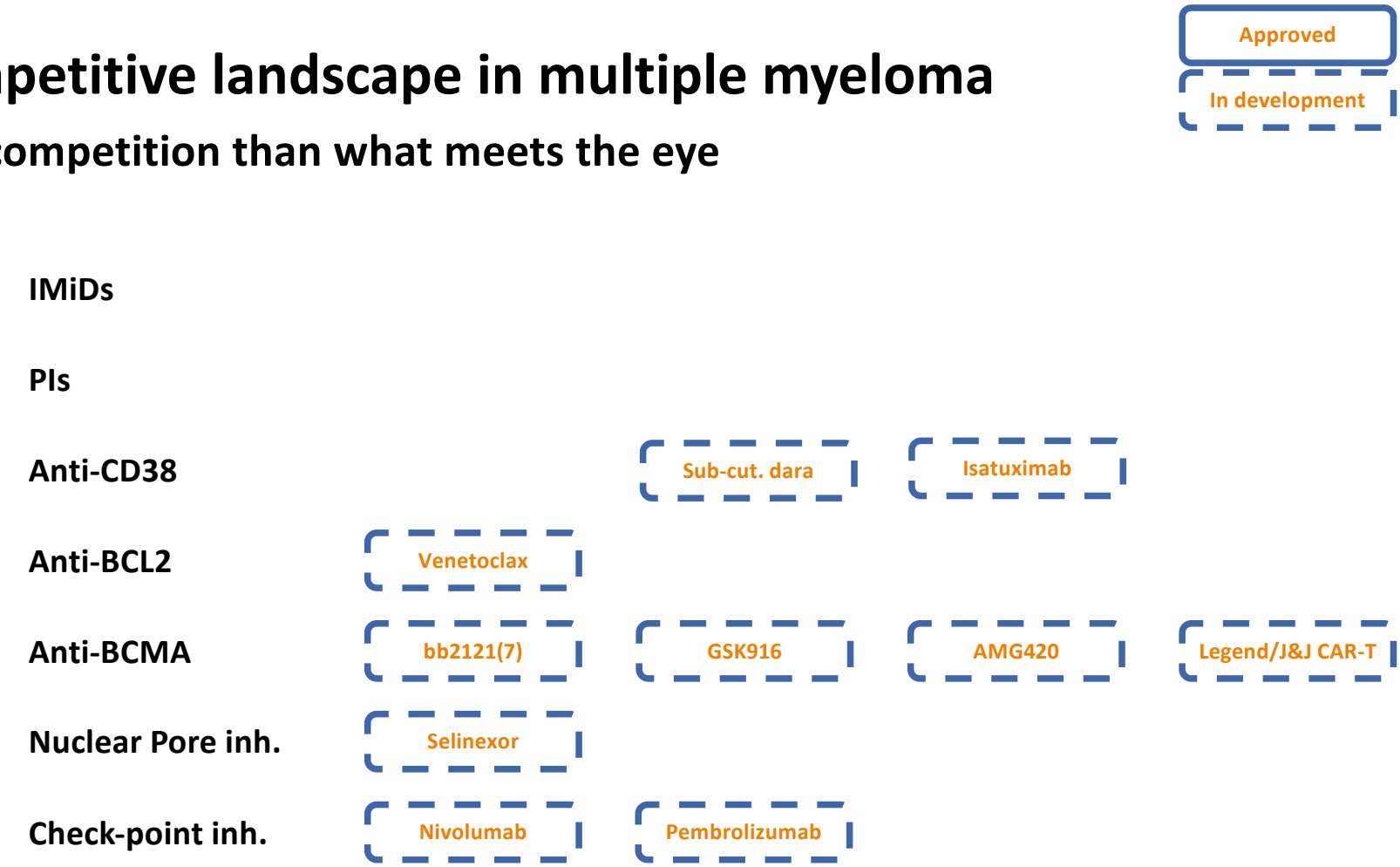

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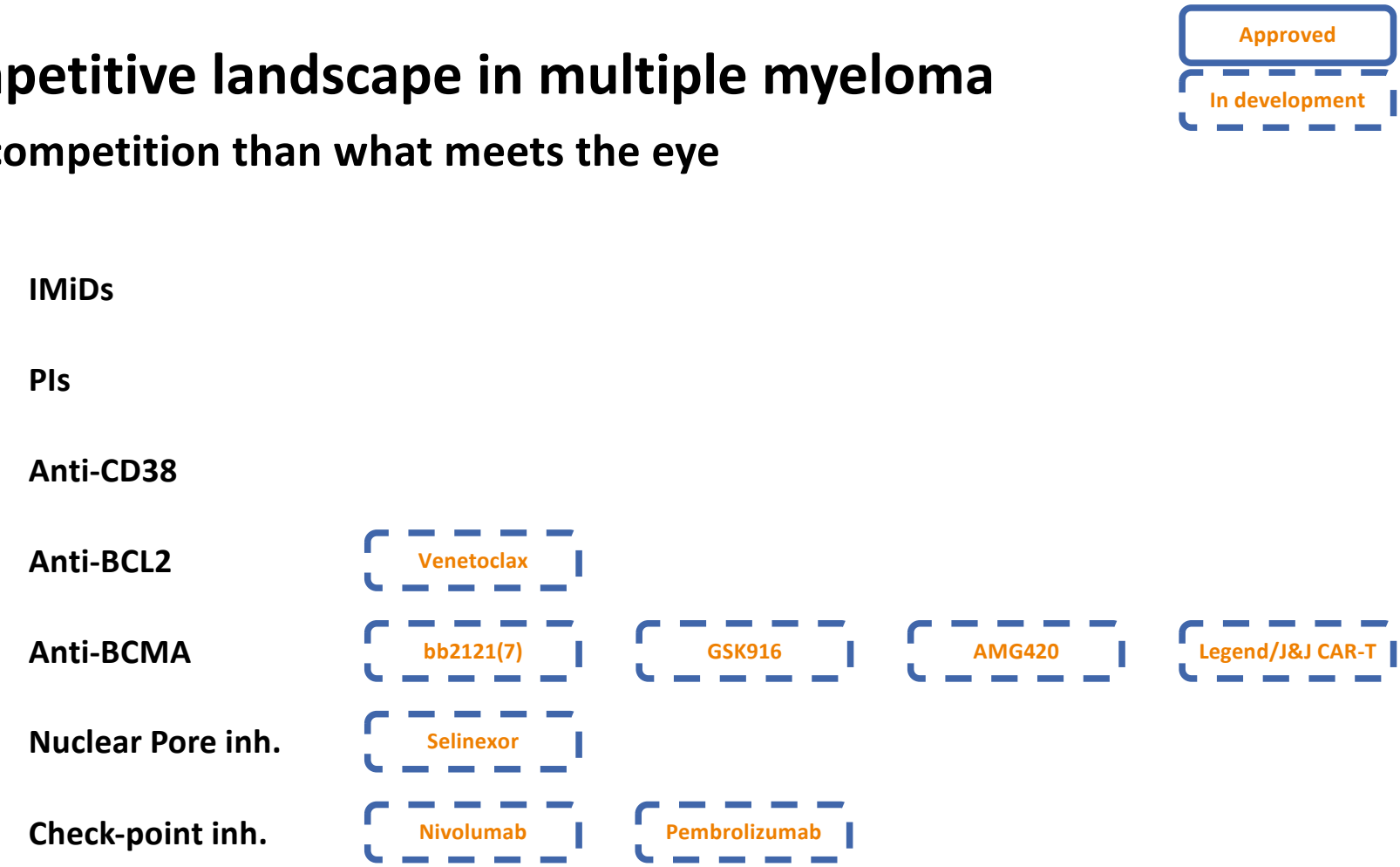

Competitive landscape in multiple myeloma

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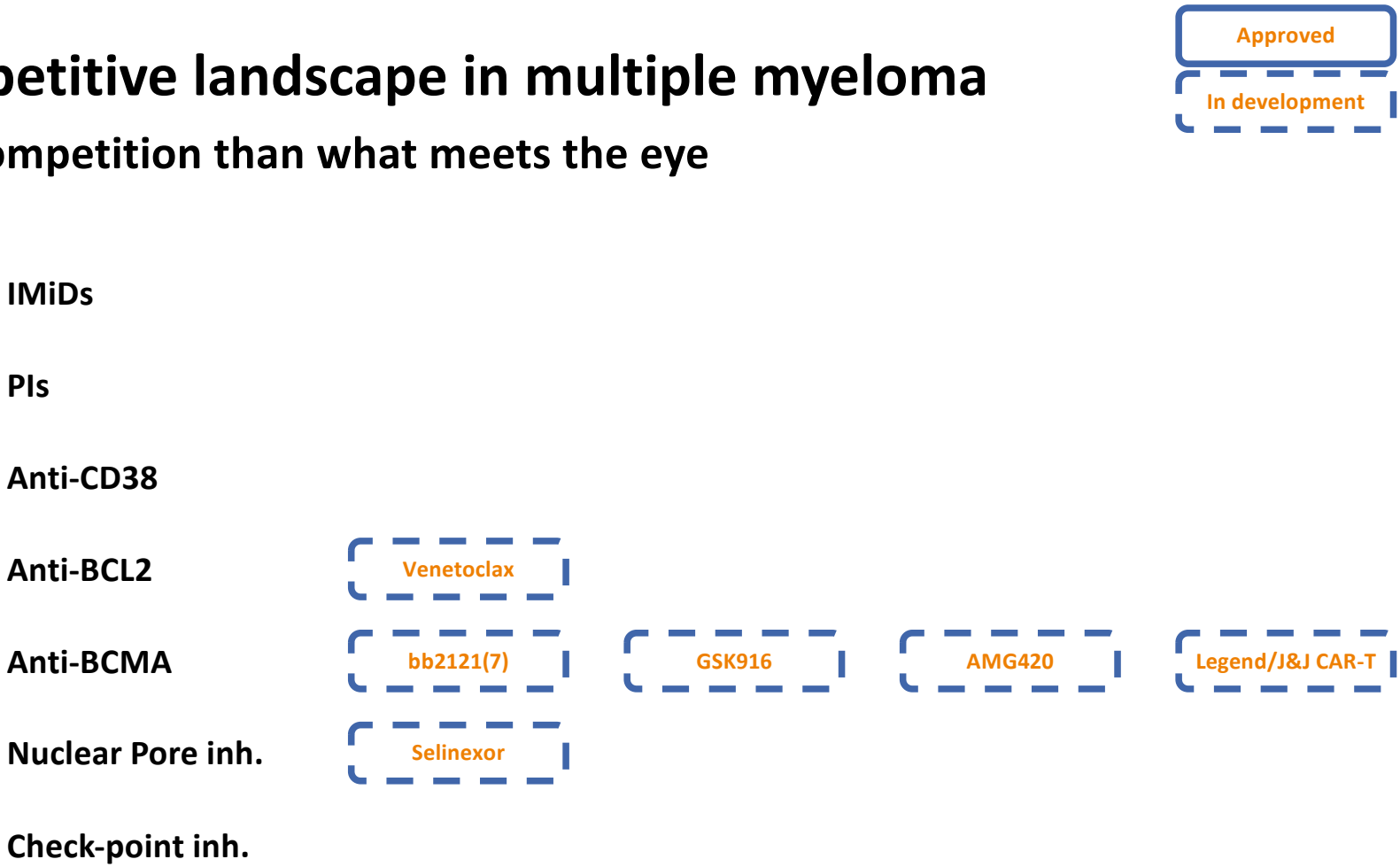
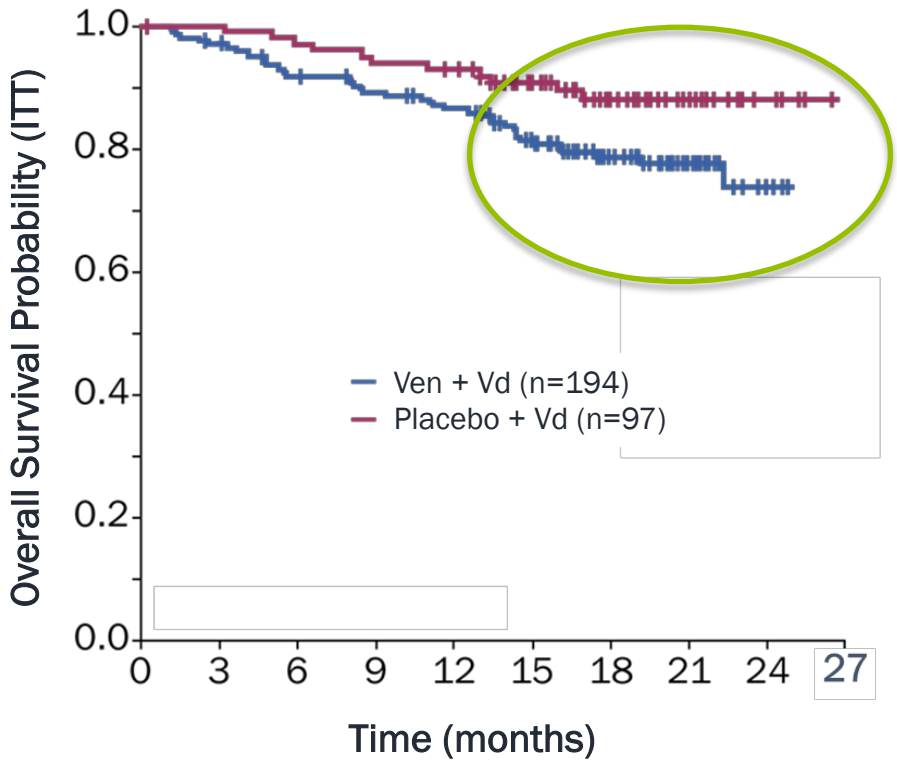


BELLINI Phase 3: Venetoclax With Bortezomib and Dexamethasone in RRMM With 1 to 3 Prior Lines

- Double-blind, randomized trial of venetoclax + Vd vs placebo + Vd
- Median follow-up 17.9 months
- Interim OS analysis:
  - 41/194 (21.1%) deaths on venetoclax arm vs 11/97 (11.3%) deaths on placebo arm (HR, 2.03; 95% CI, 1.04-3.94)
- Median PFS:
  - 22.4 months with venetoclax vs 11.5 months with placebo (HR, 0.63; 95% CI, 0.44-0.90)
- Put on clinical hold by FDA in March 2019



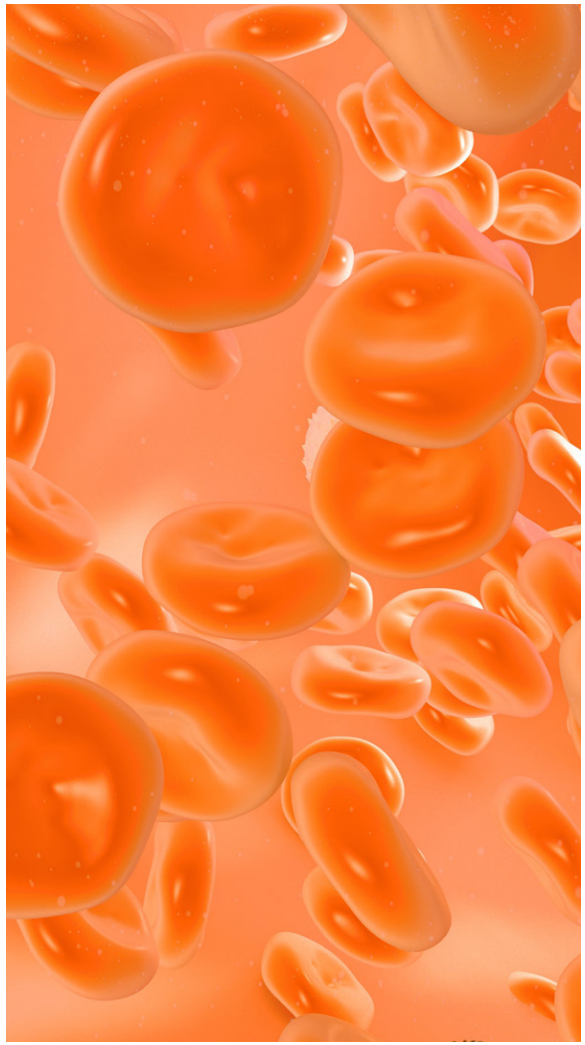
d, low-dose dexamethasone; FDA, Food and Drug Administration; HR, hazard ratio; OS, overall survival; PFS, progression-free survival; RRMM, relapsed/refractory multiple myeloma; V, bortezomib.
https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-risks-associated-investigational-use-venclexta-multiple-myeloma. Accessed June 3, 2019.

Summary

Strong activity data in ANCHOR – both in combination with daratumumab and bortezomib. Very positive signal with regard to durability of responses (and hence PFS) in comparison with most recent and novel combination data in RRMM

Strong efficacy data in HORIZON with good tolerability – both in double-class refractory and triple-class refractory patients.

First clinically tested compound with significant activity in patients with EMD at relapse. Rapidly growing problem in RRMM



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