



PEPAXTO[®] (melphalan flufenamide)

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Oncopeptides AB (publ)

Oncologic Drugs Advisory Committee

Introduction

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Primary Endpoint of PFS Met – Complex Heterogeneous OS Result

- OCEAN met primary endpoint of superior PFS based on prespecified IRC evaluation using IMWG guidelines
- OS HR (95% CI) in ITT = 1.14 (0.91 – 1.43)
 - PEPAXTO heterogeneity by ASCT, merits limitations of use
 - Unexpected pomalidomide heterogeneity driven by patient age confounds OS result interpretation
- OCEAN fulfills accelerated approval obligation for patients with RRMM

Heterogeneity Confounds OS and Identifies a Group at Risk

PEPAXTO Heterogeneity Prior ASCT

PEPAXTO + dex
n = 246

ASCT	Post-ASCT Progression ≤ 36 Months (n=101)	No ASCT or Post-ASCT Progression > 36 Months (n=145)
Median PFS (95% CI), months	4.3 (3.7-5.1)	9.3 (7.2-11.8)
Median OS* (95% CI), months	15.7 (11.9-20.5)	23.6 (18.9-28.0)

Pomalidomide Heterogeneity Age (Details provided in BD)

Pomalidomide + dex
n = 249

Age	< 65 Years (n=85)	≥ 65 to < 75 Years (n=125)	≥ 75 Years (n=39)
Median PFS (95% CI), months	4.9 (3.8-5.7)	4.9 (3.8-6.9)	4.9 (3.0-6.6)
Median OS* (95% CI), months	31.7 (21.3-NE)	20.9 (17.0-26.5)	17.5 (7.2-32.1)

Identification of Risk Using Prespecified Subgroups^{1,2,3}

- Study needs to meet prespecified primary endpoint
- Prespecified subgroups should be analyzed since ITT may not adequately characterize treatment effects
 - To identify subgroup that may represent risk
 - Should be supported by biologic rationale, precedent and other supportive endpoints
- Prior ASCT (Yes / No) prespecified subgroup in OCEAN

Biologic Rationale for Risk in Patients with Prior ASCT Treated with PEPAXTO

- Pre-ASCT conditioning therapy typically with high dose melphalan
- Tumors relapsing early after ASCT more resistant to further alkylator treatment
 - IMWG and ESMO guidelines define less successful ASCT as time-to-progression < 36 months after ASCT¹⁻²
- Identified risk isolated, post-hoc, in patients with less successful ASCT, a patient population defined in ASCT guidelines

Recommendation that PEPAXTO Label Include Limitations of Use

PEPAXTO is not recommended in patients who have progressed less than 3 years after an autologous stem cell transplant

OCEAN Data Support Positive PEPAXTO Benefit-Risk

FDA Issues	Key Considerations
PFS benefit	<ul style="list-style-type: none"> • PEPAXTO met primary endpoint, with statistically significant superior PFS • IRC used IMWG guidelines for disease progression
Overall survival	<ul style="list-style-type: none"> • Prespecified subgroup analysis identified risk in patients with prior ASCT <ul style="list-style-type: none"> • Biologically plausible risk • Removal of subgroup with risk* improves efficacy and safety <ul style="list-style-type: none"> • PFS, OS, ORR, DOR, AEs
Appropriate dose	<ul style="list-style-type: none"> • PEPAXTO is an alkylating cytotoxic dosed to MTD • Improved tolerability and less dose modifications by removal of subgroup with risk*

* Limitation of Use to exclude patients with post-ASCT progression \leq 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)

Agenda

Treatment Patterns and Unmet Need with TCR Multiple Myeloma

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R.J. Corman Professor of Medicine
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Dana-Farber Cancer Institute

OCEAN Study Clinical Results

Klaas Bakker, MD, PhD

Executive VP and Chief Medical Officer
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Treatment Patterns and Unmet Need in Patients with Triple-Class Refractory Multiple Myeloma

Paul G. Richardson, MD

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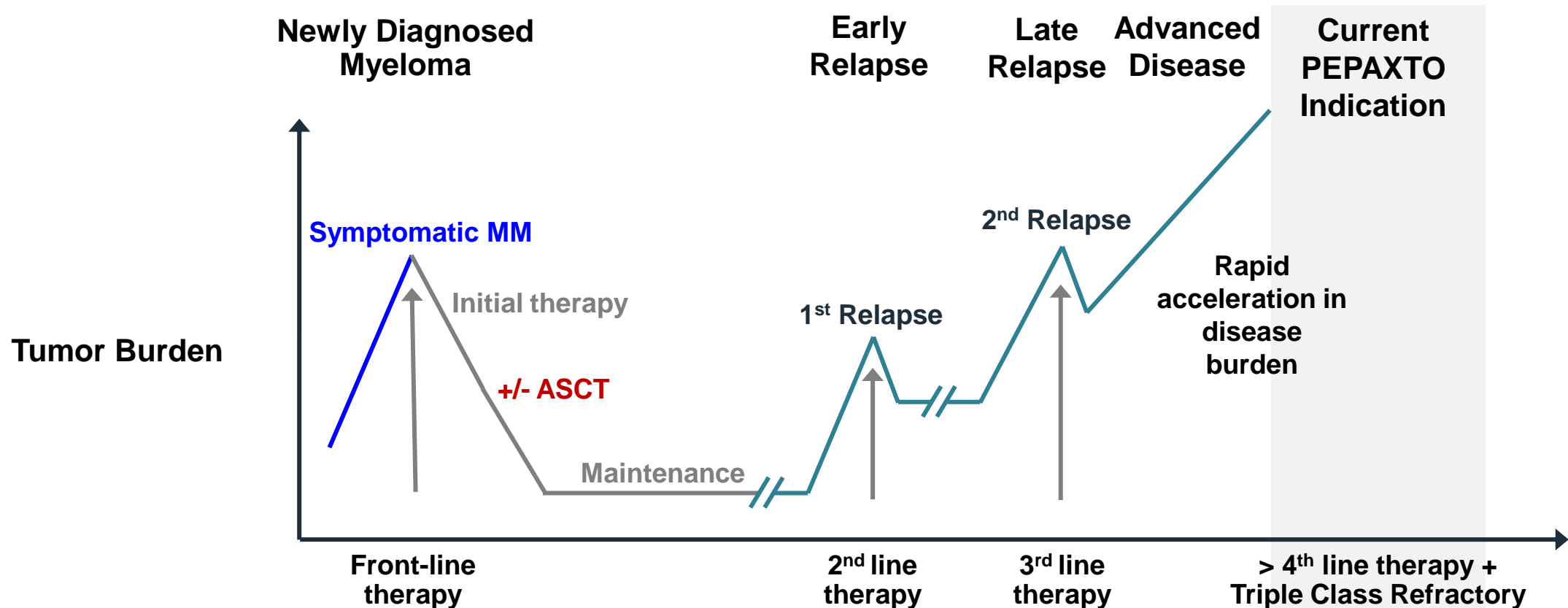
Clinical Program Leader, Director of Clinical Research

Jerome Lipper Multiple Myeloma Center

Dana-Farber Cancer Institute



Treatment of MM is a Marathon Not a Sprint – Strategic and Practical Considerations Key



Treatment options rapidly diminish with each progression

Goal in advanced RRMM: stop further progression, maintain disease control, preserve QoL

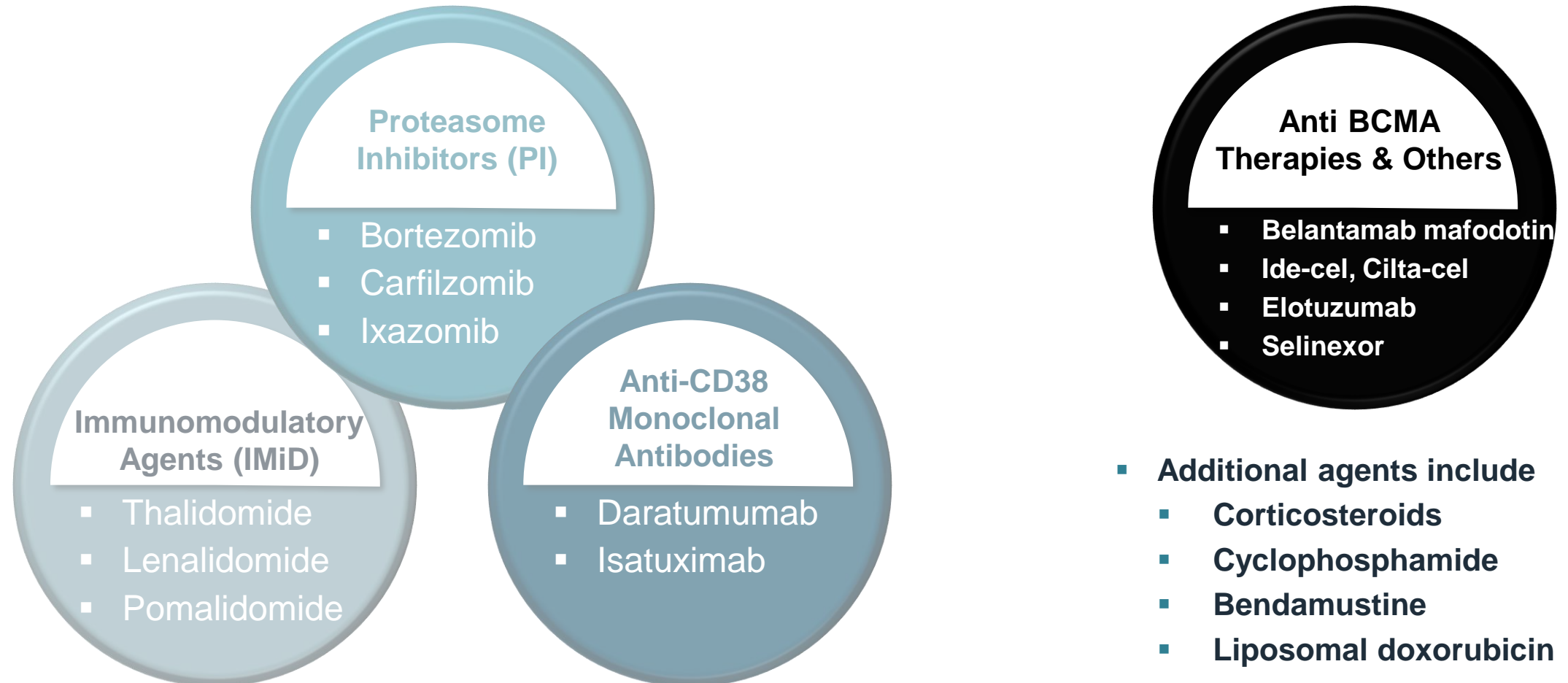
ASCT as a First Line Treatment in Younger, Fit and Eligible Patients¹

- ASCT is an important standard of care but most MM patients do not undergo transplant
- Eligibility often based on age and frailty, cardiac and pulmonary status
 - Only about half of patients with MM are eligible for ASCT²
 - Only about 1/3 of those eligible actually undergo ASCT²
- PFS benefit with ASCT, but no OS benefit³
- Novel therapies are critical to improving long-term outcome³⁻⁴

Current Treatment Landscape in RRMM

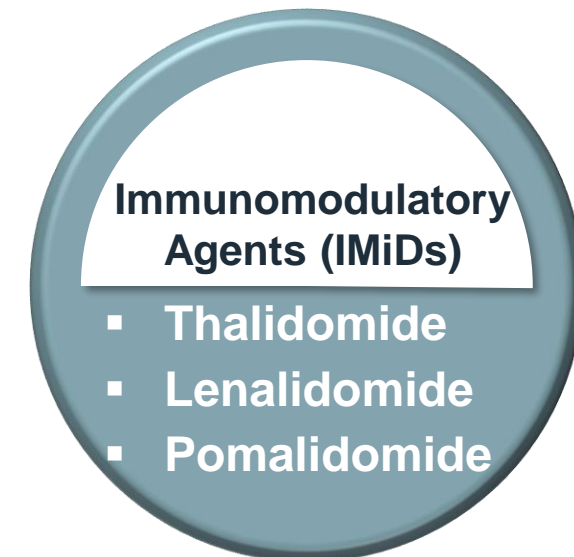
3 Primary Classes of Drugs:

Triplet and Quadruplet Combinations Evolving as Standards of Care

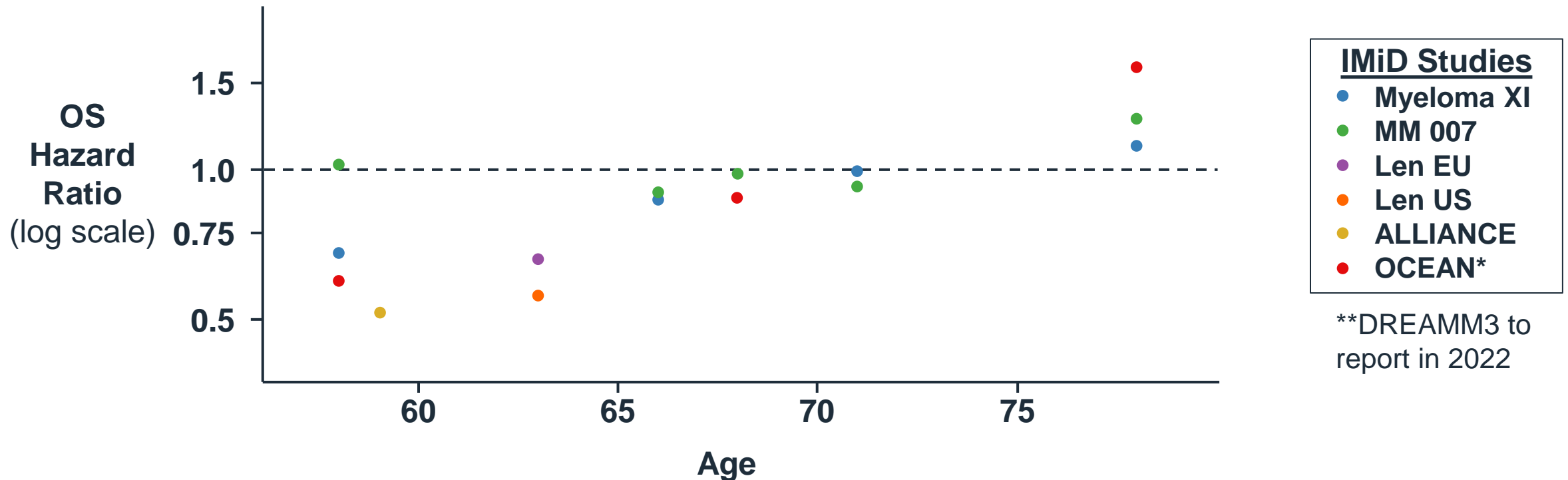


Challenges with the Efficacy of Current Therapies in RRMM

- OCEAN OS results call into question IMiD use and correlation between PFS and OS in elderly patients with RRMM
- IMiDs extensively used for patients with RRMM and are considered a back-bone of therapy
 - ~ 80% > 65 years with RRMM receive an IMiD¹



Recent Analysis and a Forthcoming Publication Identifies Important Age Interaction for IMiDs¹



Each included IMiD study reported OS by ITT and prespecified age subgroups, represented by common color for each study shown in legend

**DREAMM3 to report in 2022

*OS update February 2022

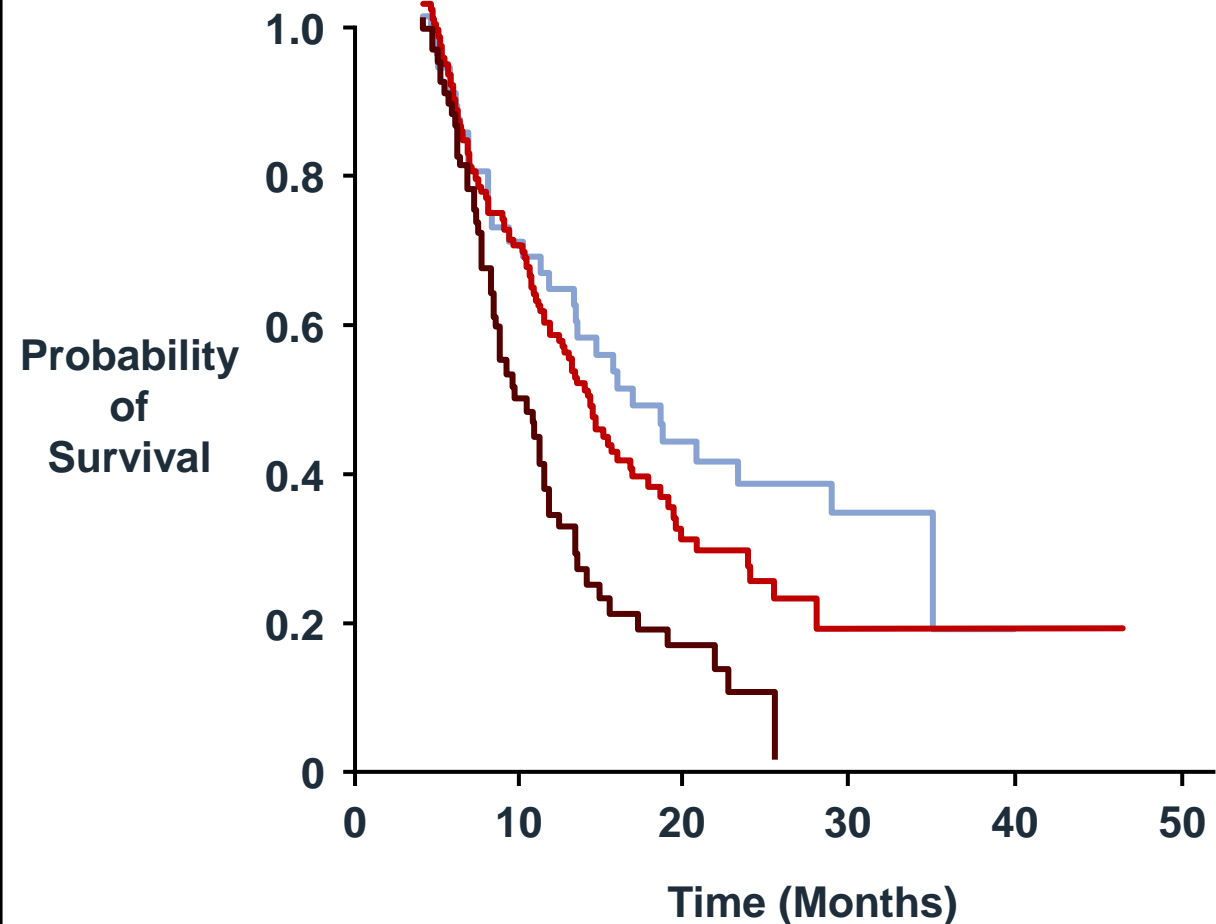
Other Recently Approved RRMM Therapies also have Limitations

- GI toxicity and asthenia with XPO1 inhibition (Selinexor)¹
 - Upwards of 40% discontinuation rates
- Ocular toxicity with ADC's (Belantamab Mafadotin)²
 - Not well tolerated and logistically challenging to follow, particularly in elderly
- Lack of timely accessibility with cellular therapies (Ide-cel, Cilta-cel)³
 - ~ 6 month wait time, not practical for patients in need of immediate treatments
 - CRS, CNS toxicity and need for hospitalization in the COVID era an ongoing challenge^{4,5}

XPO1 = exportin 1; ADCs = antibody drug conjugates; CRS = cytokine release syndrome

1. Selinexor USPI; 2. Belantamab Mafadotin USPI; 3. Kourelis et al., ASCO, 2022; 4. Madduri et al., ASH 2020 (177); 5. Munshi et al., ASCO 2020 (8503)

OS in Triple-Class Refractory Patients with RRMM; Multiple New Drugs Needed



	MAMMOTH Median OS Months (95% CI)¹
— Double refractory (N=57)	11.2 (5.4-17.1)
— Triple- and quad-refractory (N=148)	9.2 (7.1-11.2)
— Penta-refractory (N=70)	5.6 (3.5-7.8)

Majority Refractory Status	PEPAXTO Study	Median OS Months (95 % CI)
Double	O-12-M1 ² N = 45	20.7 (11.8-NR)
Double	OCEAN ³ N = 246	20.2* (15.8-24.3)
Penta	HORIZON ^{4,5} N = 97	9.1 (6.4-11.5)

1. Gandhi et al., Leukemia, 2019; 2. Richardson et al., Lancet Haematology, 2020; 3. Schjesvold et al., Lancet Haematology, 2022;
4. PEPAXTO USPI, 2021; 5. Inhouse ONCOPEPTIDES data, previously submitted to the FDA

*OS update February 2022

Special Considerations for Patients With RRMM

- Elderly and frail¹
- New mode of action / class switch¹
- Extra Medullary Disease (EMD), especially after CD38 mAb treatment failure¹
- Frequency of visits and outpatient-based treatment (especially in COVID era)²
- Reduction of infectious risk²
- Convenience and off the shelf, with ready application in real world practice³

Conclusion: Urgent Unmet Medical Need in Triple-Class Refractory RRMM

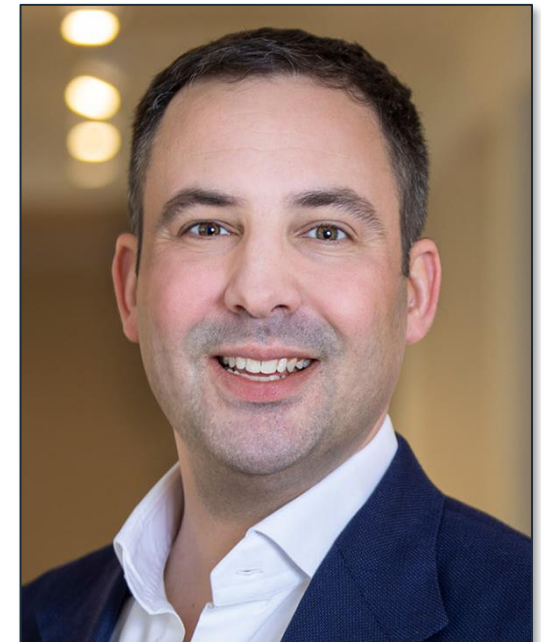
- Multiple myeloma remains an incurable disease
- More salvage therapy options urgently needed for triple-class refractory RRMM, and now after BCMA failure
- Importance of real-world, off the shelf agents with efficacy in out-patient setting, especially in COVID era
- Need clinically meaningful efficacy and a manageable safety profile, with minimal non-hematological side effects
- Importance of novel MoA and independence from immune exhaustion, as well as activity in EMD

OCEAN Study Clinical Results

Klaas Bakker, MD, PhD

Executive VP and Chief Medical Officer

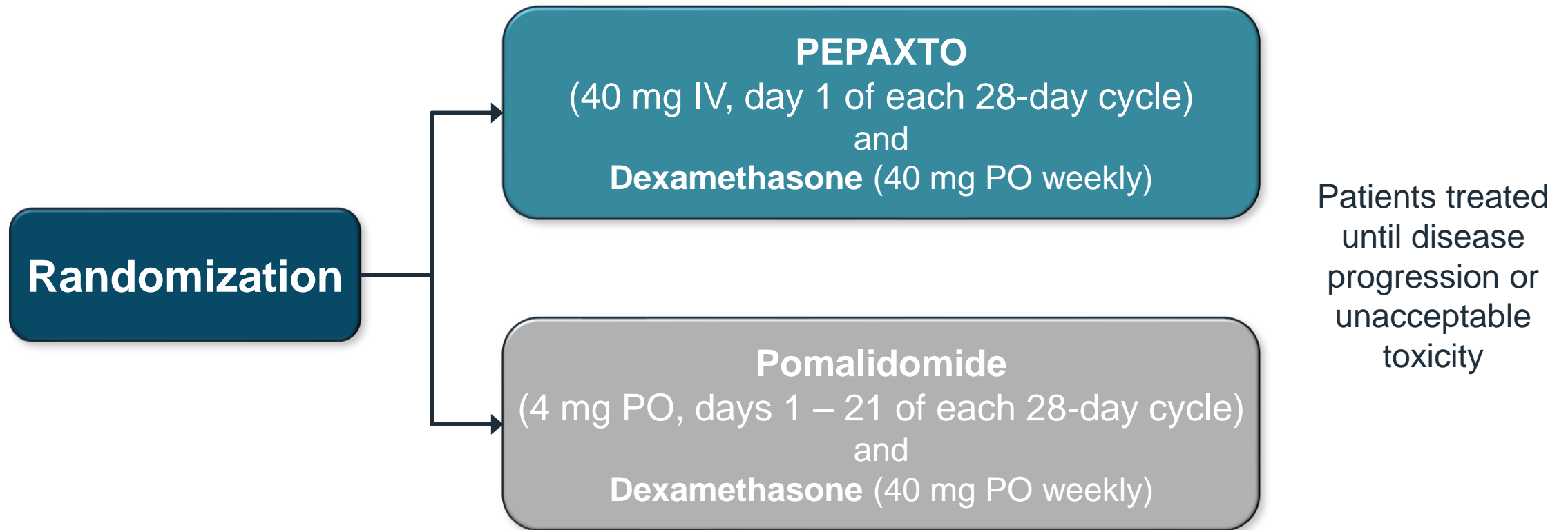
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OCEAN Results Confirm PEPAXTO Benefit-Risk

- Active-control, head-to-head study design
- Efficacy results in ITT
- Results in prespecified subgroups
 - ASCT interaction identified for PEPAXTO
 - Advise against use in patients with post-ASCT progression within 36 months
 - Age interaction with IMiDs impacts OS interpretation*
- Safety from safety population and recommended population

OCEAN: Randomized Active-Control Phase 3 Study Comparing PEPAXTO to Pomalidomide



OCEAN: Inclusion Criteria

- ≥ 18 years old
- 2 – 4 prior lines of therapy
- Refractory to lenalidomide and last line of therapy
- ECOG PS ≤ 2

- HORIZON enrolled patients
 - Average of 5 lines prior treatment
 - Mostly triple-class refractory

OCEAN: Efficacy Endpoints

- Primary endpoint (IRC assessed)
 - Progression free survival (PFS)
- Key secondary endpoints
 - Overall response rate (ORR)
 - Overall survival (OS)

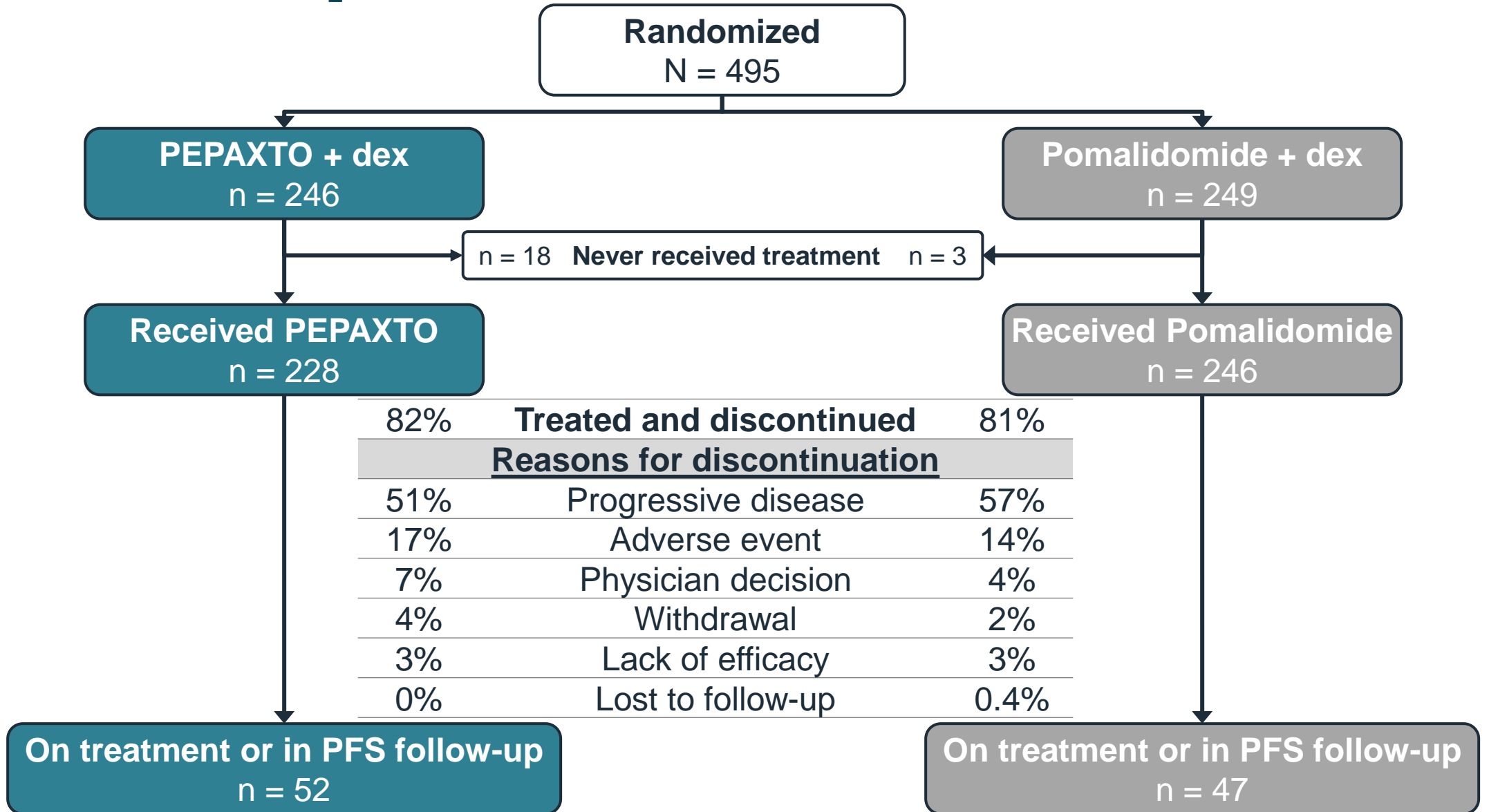
OCEAN: Statistical Analysis Plan

- Prespecified difference for superiority median PFS: 1.54 mos
 - Assumption: pomalidomide 3.6 and PEPAXTO 5.14 mos
- Prespecified censoring rules
 - Confirmed PD defined as two consecutive PD assessments unless
 - When progression of EMD confirmed PD
 - PD was the last assessment

OCEAN: Balanced Baseline Demographics and Characteristics

	PEPAXTO + dex (N = 246)	Pomalidomide + dex (N = 249)
Age, median (range), years	68 (41 – 91)	68 (39 – 87)
< 65	39%	34%
65 to < 75	46%	50%
≥ 75	15%	16%
Male	57%	56%
ISS stage at study entry		
I	48%	50%
II	38%	38%
III	13%	12%
Number of prior regimens		
2	46%	45%
3 – 4	54%	55%
Creatinine clearance		
< 45	2%	4%
45 – < 60	18%	23%
60 – < 90	48%	45%
≥ 90	31%	28%
EMD at study entry	13%	12%
≥ 1 ASCT	51%	48%

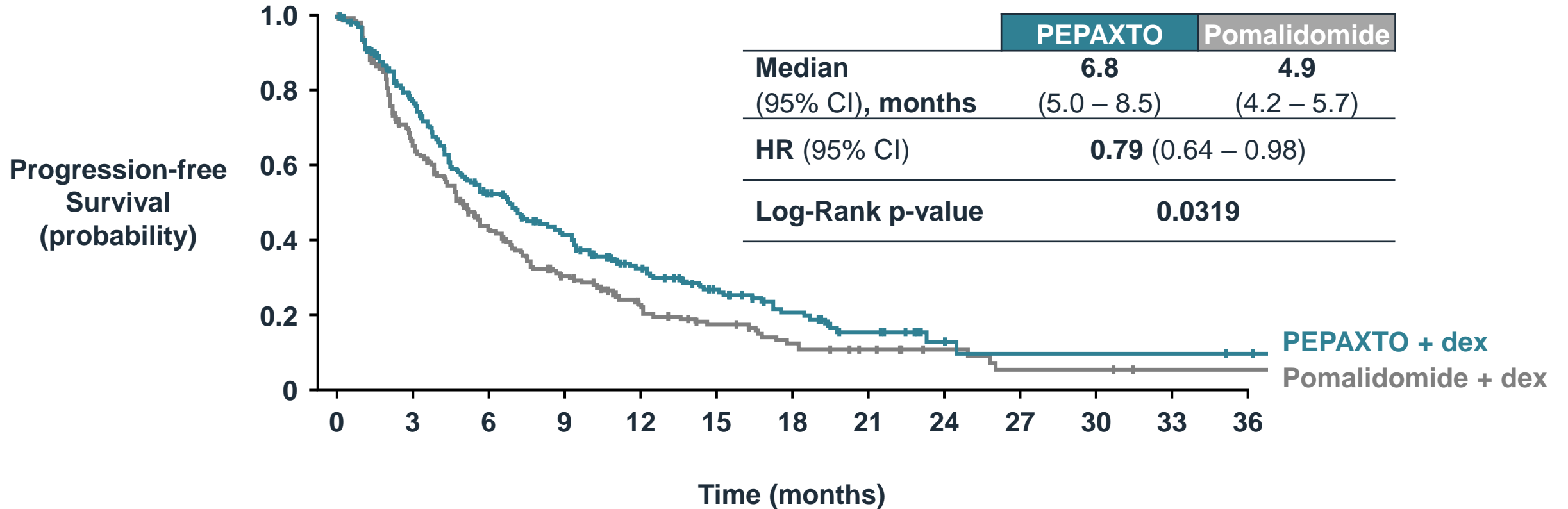
OCEAN: Disposition





OCEAN ITT Efficacy Results

OCEAN Study Met Primary Endpoint of PFS by IRC Per Statistical Analysis Plan



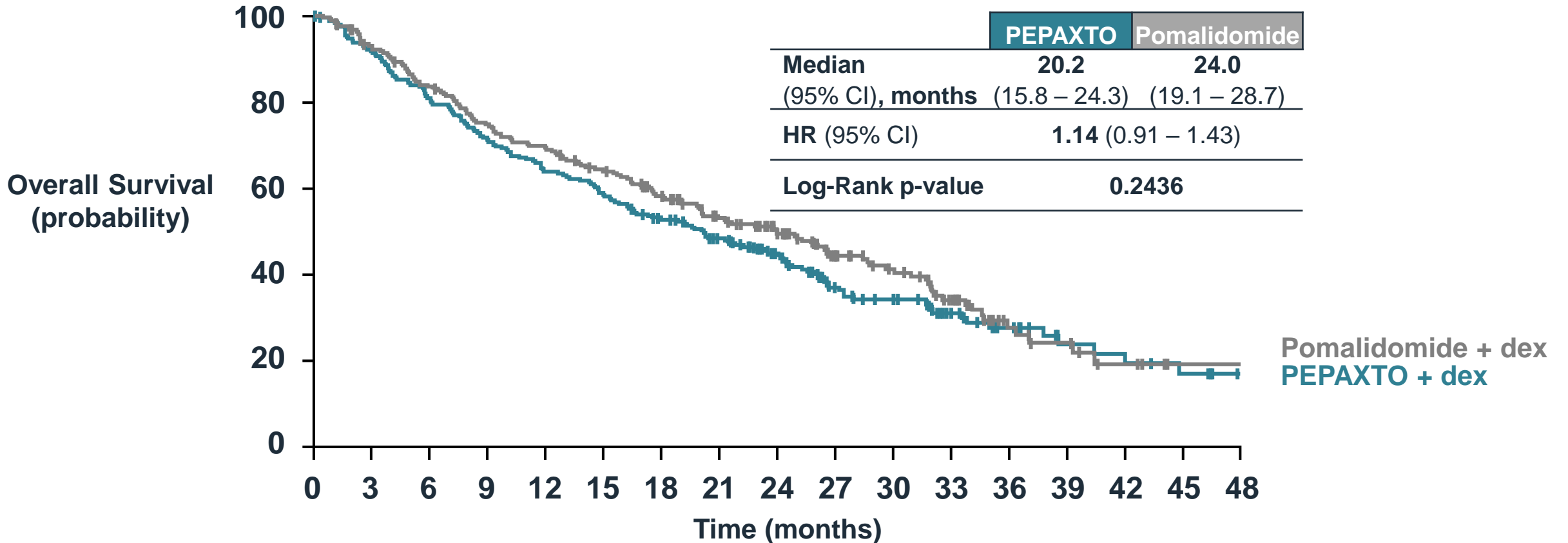
Number at Risk

PEPAXTO	246	168	109	80	50	34	22	13	5	3	3	3	2
Pomalidomide	249	150	90	58	37	23	15	10	6	3	3	1	1

OCEAN: ORR, CBR, and DOR

	PEPAXTO + dex (N = 246)	Pomalidomide + dex (N = 249)
Overall response rate (95% CI)	33% (27 – 39)	27% (22 – 33)
Clinical benefit rate (95% CI)	50% (43 – 56)	41% (35 – 47)
Median DOR (95% CI), months	11.2 (8.5 – 17.5)	11.1 (7.6 – 15.4)

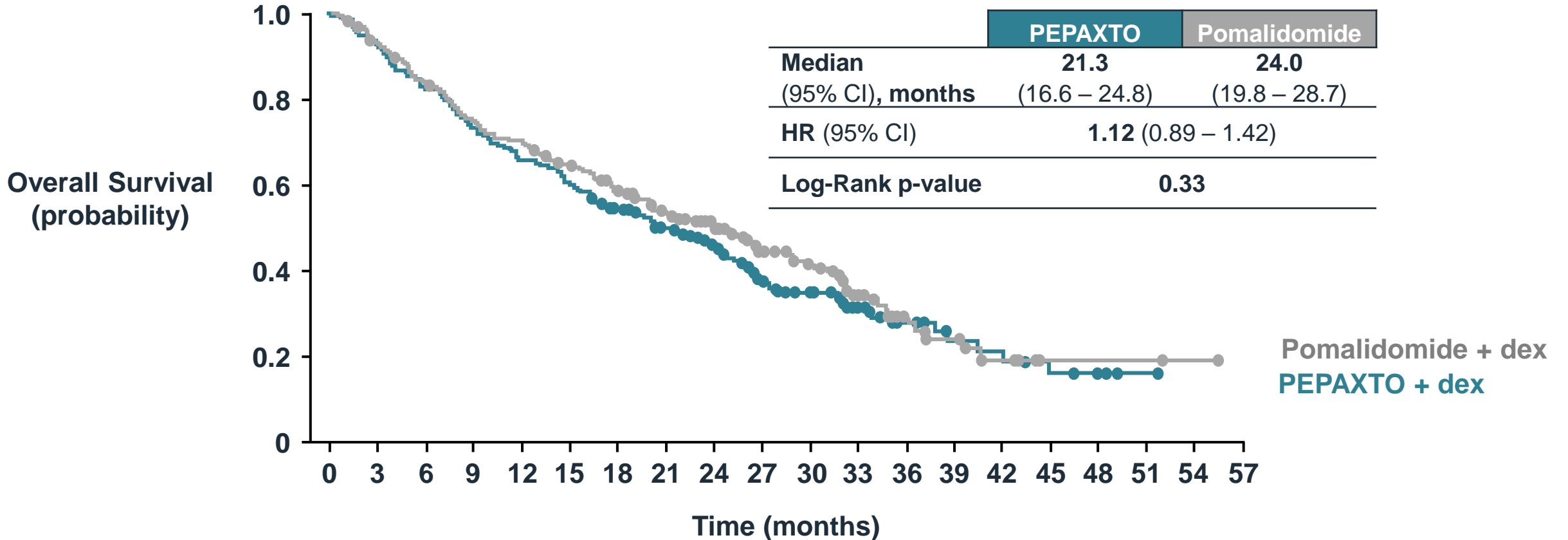
OCEAN: OS (ITT Population Through Feb 3, 2022)



Number at Risk

PEPAXTO	246	223	197	174	155	143	124	107	85	57	46	32	19	11	10	7	3
Pomalidomide	249	225	201	179	167	151	131	109	89	63	50	34	17	12	6	2	2

OCEAN: OS in Treated Population (Safety Population¹ Through Feb 3, 2022)

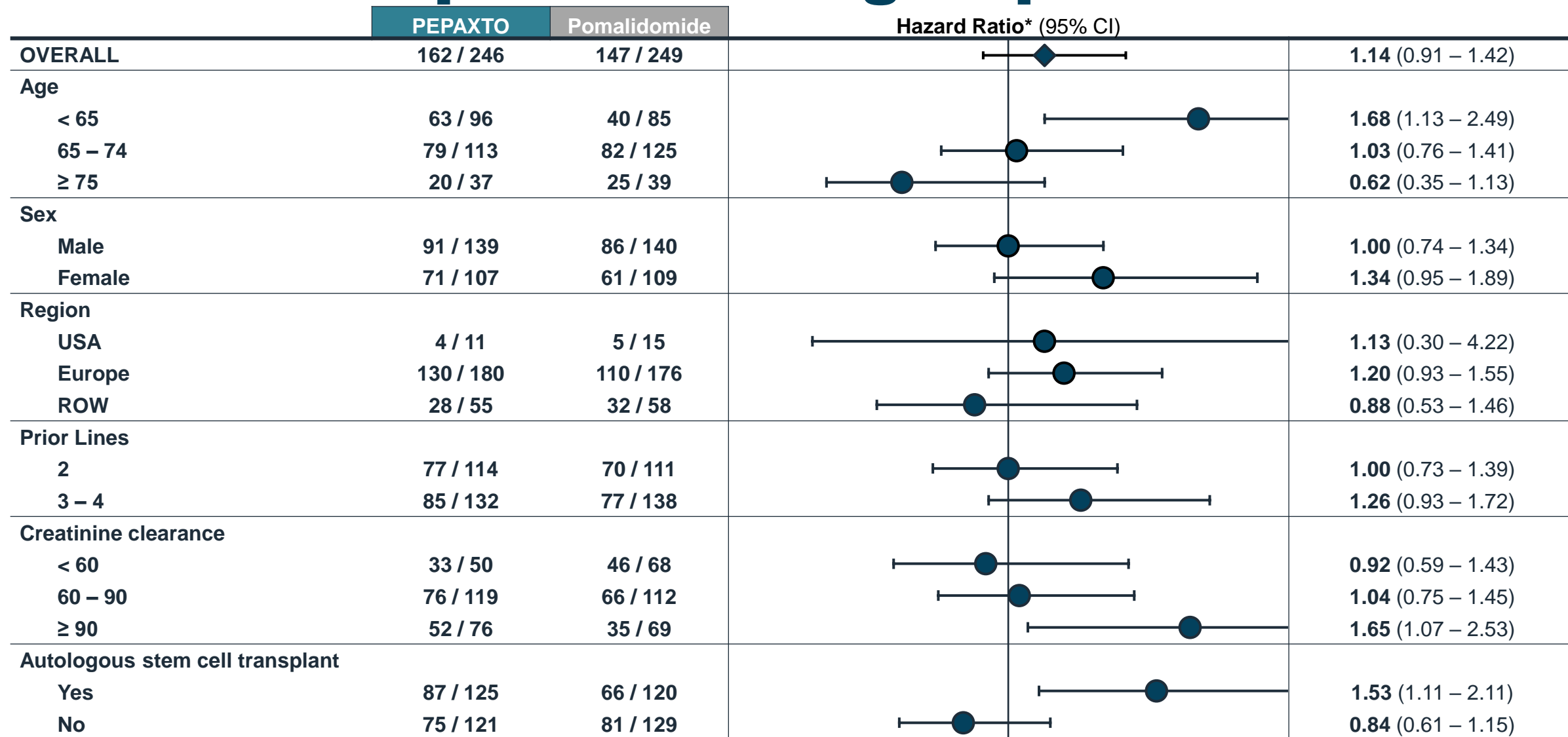


Number at Risk

PEPAXTO	228	213	189	169	150	139	120	105	83	55	44	30	17	10	9	6	3	1	0	0
Pomalidomide	246	223	200	178	167	151	131	109	89	63	50	34	17	12	6	2	2	2	1	0

1. Omits patients randomized but never treated (18 for PEPAXTO and 3 for pomalidomide)

OCEAN Prespecified Subgroups: OS



*Unstratified

0

Favors PEPAXTO

0.5

1

Favors Pomalidomide

1.5

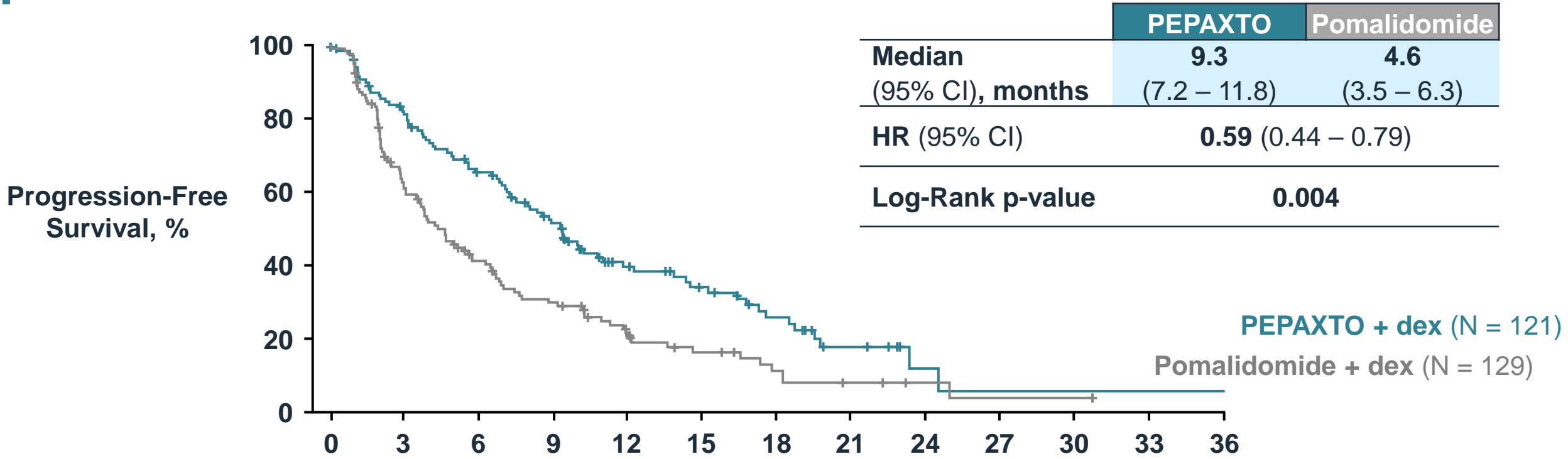
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OS update February 2022



OCEAN Efficacy Results in Prespecified Subgroup of Prior ASCT

OCEAN: PFS in Patients with No ASCT



Number at Risk

PEPAXTO	121	94	73	54	31	23	15	7	2	1	1	1	1
Pomalidomide	129	73	45	32	19	12	7	4	2	1	1	0	0

OCEAN: ORR, CBR, and DOR in Patients with No ASCT

	PEPAXTO + dex (N = 121)	Pomalidomide + dex (N = 129)
Overall response rate (95% CI)	42% (33 – 51)	27% (20 – 36)
Clinical benefit rate (95% CI)	60% (51 – 69)	41% (33 – 50)
Median DOR (95% CI), months	13.4 (8.5 – 17.5)	11.1 (7.4 – 16.3)

OCEAN: OS by ASCT Status

	N for PEPAXTO + dex / Pomalidomide + dex	Median OS, months		HR (95% CI)
		PEPAXTO + dex	Pomalidomide + dex	
No ASCT	121 / 129	22.2	17.5	0.84 (0.61 – 1.15)
ASCT	125 / 120	16.7	28.7	1.53 (1.11 – 2.11)

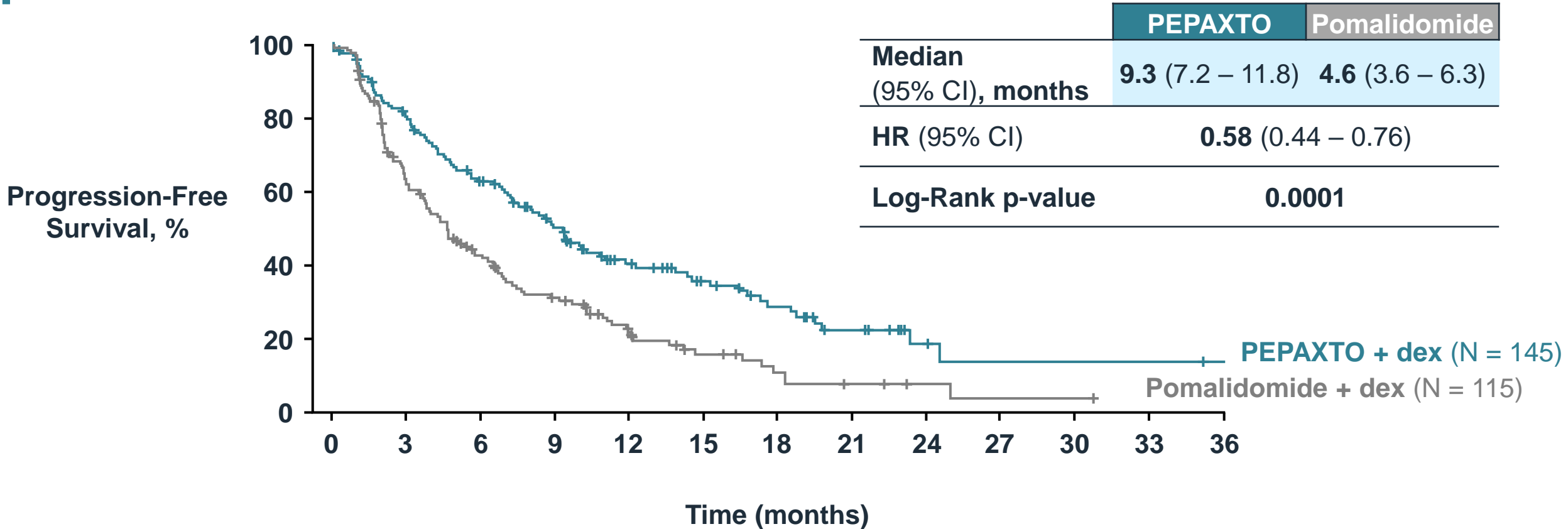
OCEAN Efficacy Results Based on Time to Progression Post ASCT

**No ASCT or Post-ASCT Progression > 36 Months*
[Supported by Biology and Guidelines]**

OCEAN: OS Associated with Time to Progression Post ASCT

	N for PEPAXTO + dex / Pomalidomide + dex	Median OS, months		HR (95% CI)
		PEPAXTO + dex	Pomalidomide + dex	
ITT	246 / 249	20.2 (15.8 – 24.3)	24.0 (19.1 – 28.7)	1.14 (0.91 – 1.43)
Progression following ASCT				
< 12 months	31 / 32	13.1 (5.8 – 19.3)	20.5 (13.6 – 37.1)	1.74 (0.95 – 3.21)
12 – 24 months	47 / 51	14.8 (7.6 – 20.5)	30.1 (20.1 – NA)	2.50 (1.49 – 4.19)
24 – 36 months	23 / 18	26.2 (15.1 – 40.4)	30.9 (20.1 – 34.7)	1.11 (0.52 – 2.38)
> 36 months	24 / 19	35.0 (10.0 – NA)	32.6 (11.2 – NA)	0.79 (0.33 – 1.89)

OCEAN: PFS in Patients with No ASCT or Post-ASCT Progression > 36 Months*



Number at Risk

PEPAXTO	145	110	84	62	39	28	20	12	5	3	3	3	2
Pomalidomide	148	86	54	37	21	12	7	4	2	1	1	0	0

Data cut: Feb 3, 2022

* Limitation of Use to exclude patients with post-ASCT progression ≤ 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)

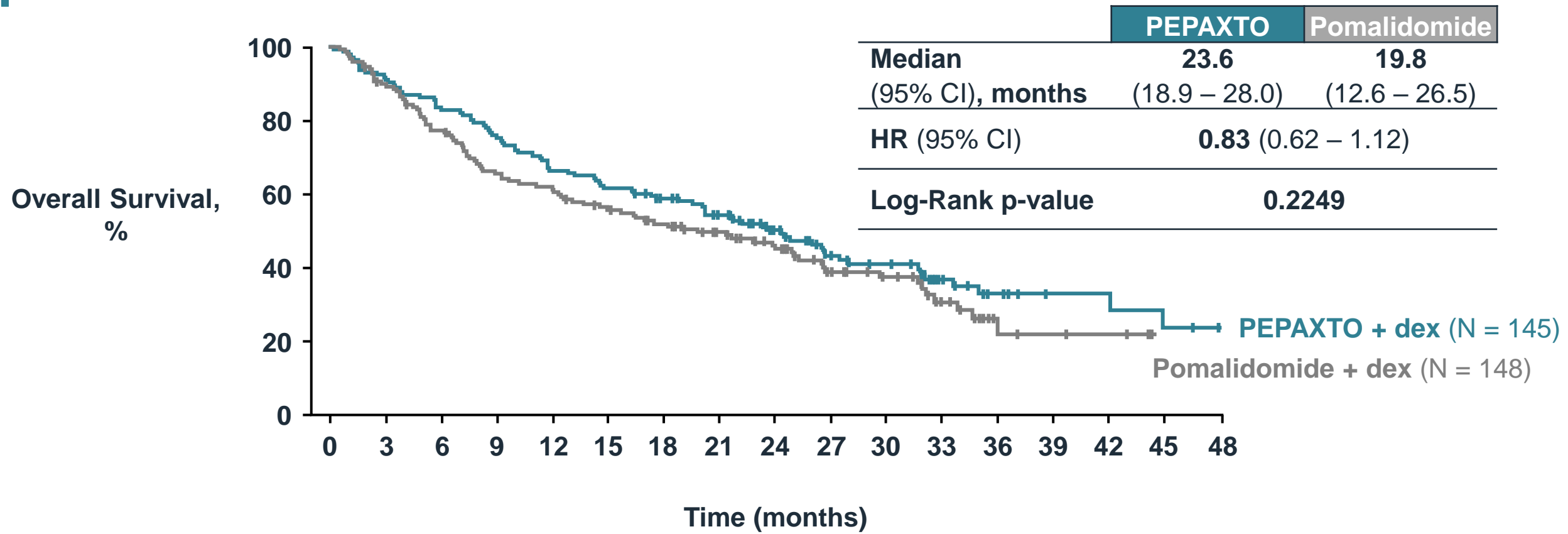
OCEAN: Identified Risk in Patients with Post-ASCT Progression \leq 36 Months*

	N PEPAXTO + dex / Pomalidomide + dex	Median OS, months		HR (95% CI)
		PEPAXTO + dex	Pomalidomide + dex	
ITT	246 / 249	20.2 (15.8 – 24.3)	24.0 (19.1 – 28.7)	1.14 (0.91 – 1.42)
No ASCT or Post-ASCT progression > 36 mos*	145 / 148	23.6 (18.9 – 28.0)	19.8 (12.6 – 26.5)	0.83 (0.62 – 1.12)
Post-ASCT progression \leq 36 mos	101 / 101	15.7 (11.9 – 20.5)	28.7 (20.2 – 34.1)	1.80 (1.27 – 2.55)

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* Limitation of Use to exclude patients with post-ASCT progression \leq 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)

OCEAN: OS in Patients with No ASCT or Post-ASCT Progression > 36 Months*



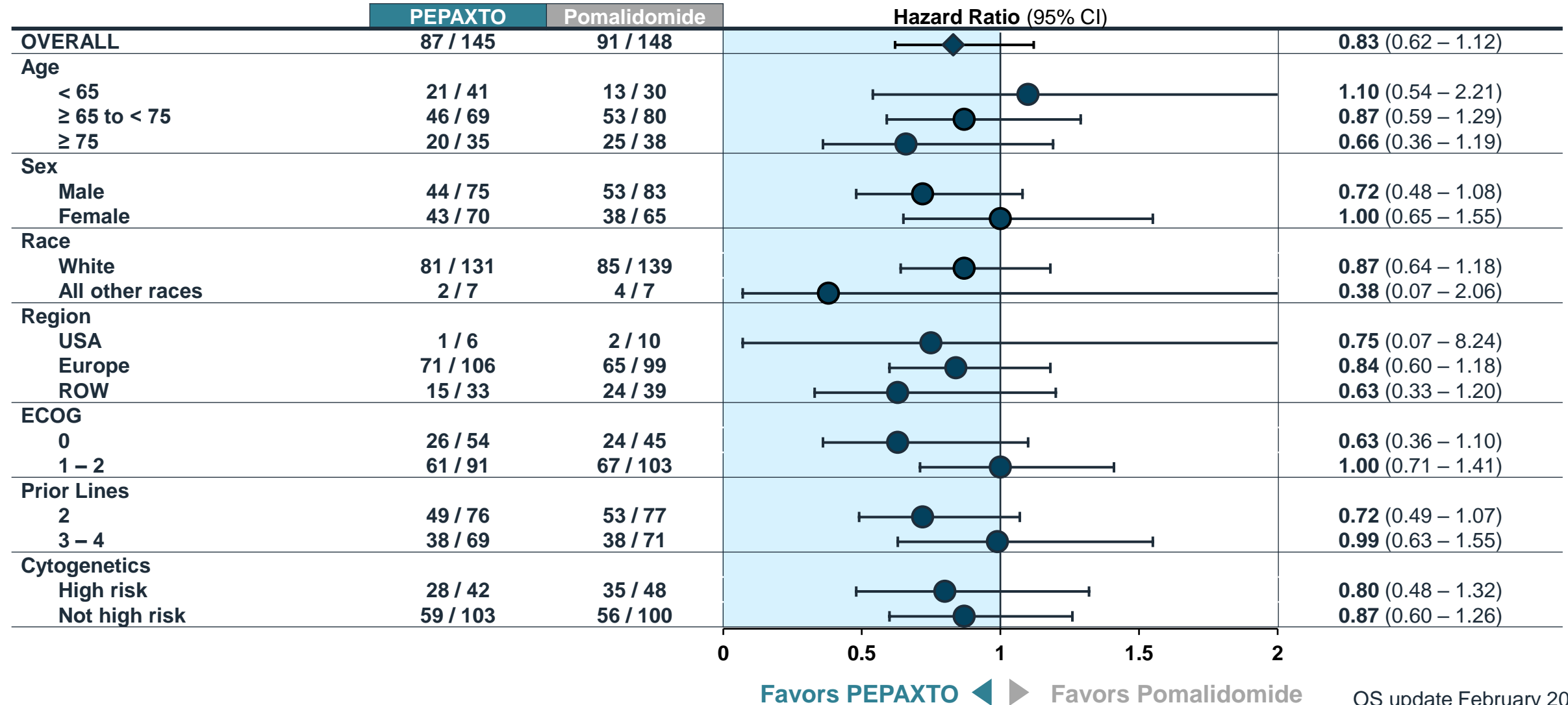
Number at Risk

PEPAXTO	145	133	121	110	96	89	80	70	54	39	32	21	11	7	7	5	3
Pomalidomide	148	130	111	93	88	78	68	58	47	33	25	15	5	4	3	0	0

OS update February 2022

* Limitation of Use to exclude patients with post-ASCT progression ≤ 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)

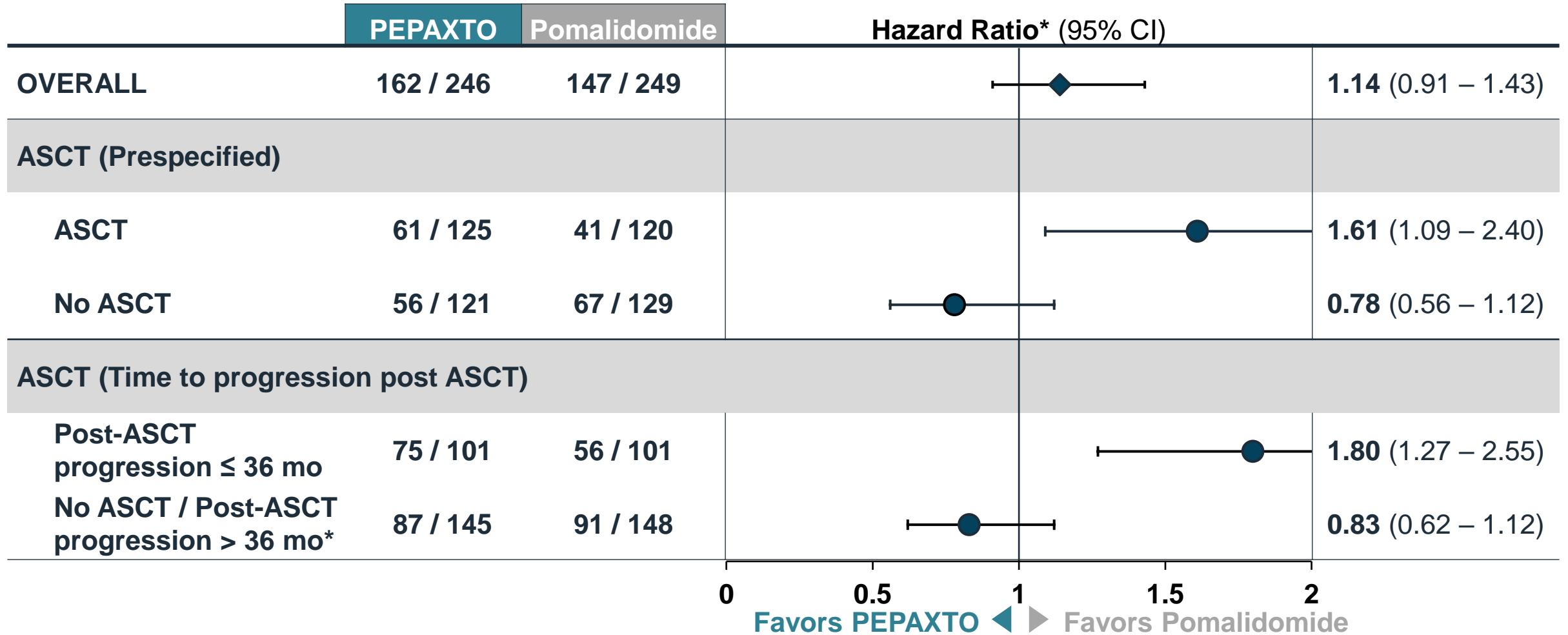
OCEAN: OS in Patients with No ASCT or Post-ASCT Progression > 36 Months*



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* Limitation of Use to exclude patients with post-ASCT progression ≤ 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)

OCEAN: Identified ASCT Interaction and OS



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* Limitation of Use to exclude patients with post-ASCT progression ≤ 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)



OCEAN Safety Population

Ocean: Overview of Adverse Events

Patients with	PEPAXTO + dex (N = 228)	Pomalidomide + dex (N = 246)
Adverse event	99%	98%
Grade 3 or 4 AE	90%	74%
Serious adverse events	42%	46%
AEs leading to dose modification	78%	59%
AEs leading to discontinuation	26%	22%
Total deaths	46%	43%

OCEAN: Important Grade 3/4 AEs

Patients with	PEPAXTO + dex (N = 228)	Pomalidomide + dex (N = 246)
≥ 1 Grade 3 or 4 AEs	90%	74%
Thrombocytopenia	76%	13%
Bleeding	2.2%	0.4%
Grade 3/4 Thrombocytopenia with Grade 3/4 Bleeding	0.9%	0
Neutropenia	64%	49%
Infection	13%	22%
Grade 3/4 Neutropenia with Grade 3/4 Infection	3%	7%

* Limitation of Use to exclude patients with post-ASCT progression ≤ 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)



OCEAN Safety in Recommended Population

No ASCT or Post-ASCT Progression > 36 Months*

OCEAN: AEs per Patient Year Decreases with Post ASCT Time to Progression

Safety Population PEPAXTO + dex	Events/Patient Year				
	Time to Progression Post ASCT				No ASCT
	< 12 Months (n = 29)	12 – 24 Months (n = 42)	24 – 36 Months (n = 20)	> 36 Months (n = 21)	(n = 116)
Grade 3/4 AEs	17	16	17	8	12
SAEs	2	2	1	1	1
AEs leading to dose modification	6	6	7	4	4
AEs leading to discontinuation	0.8	0.6	0.9	0.5	0.3
Fatal AEs	0.4	0.3	0.1	0.1	0.1

* Limitation of Use to exclude patients with post-ASCT progression \leq 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)

OCEAN: Safety by ASCT, With Longer PEPAXTO Exposure in Target Population

Safety Population	Post-ASCT progression ≤ 36 months		No ASCT or Post-ASCT progression > 36 months*	
	PEPAXTO + dex (N = 91)	Pomalidomide + dex (N = 99)	PEPAXTO + dex (N = 137)	Pomalidomide + dex (N = 147)
Exposure to study drug, Median	3.7 months	5.5 months	8.1 months	5.1 months
Patients with				
Grade 3/4 AEs	92%	79%	88%	71%
SAEs	38%	47%	44%	45%
AEs leading to dose modification	84%	57%	74%	60%
AEs leading to discon.	31%	17%	23%	27%
Fatal AEs	13%	7%	11%	17%

* Limitation of Use to exclude patients with post-ASCT progression ≤ 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)

OCEAN: Less AEs per Patient Year in Patients With No ASCT or Post-ASCT Progression > 36 Months

Safety Population	Post-ASCT progression ≤ 36 months		No ASCT or Post-ASCT progression > 36 months*	
	PEPAXTO + dex (N = 91)	Pomalidomide + dex (N = 99)	PEPAXTO + dex (N = 137)	Pomalidomide + dex (N = 147)
	Events/ Patient Year	Events/ Patient Year	Events/ Patient Year	Events/ Patient Year
Grade 3 or 4 AEs	16.6	4.8	11.2	5.7
SAEs	1.6	1.3	1.1	1.8
AEs leading to dose modification	6.8	2.3	4.5	3.3
AEs leading to discon.	0.85	0.36	0.40	0.69
Fatal AEs	0.32	0.13	0.17	0.30

* Limitation of Use to exclude patients with post-ASCT progression ≤ 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)

Fewer Deaths in Recommended Population*

Pepaxto + dex (Safety Population)	Post-ASCT progression ≤ 36 months (N = 91)	No ASCT or Post-ASCT progression > 36 months* (N = 137)
Total number of deaths n (%)	47 (51.6%)	59 (43.1%)
Number of deaths ≤ 30 days after last dose n (%)	8 (8.8%)	15 (10.9%)
Progressive disease n (%)	1 (1%)	6 (4%)
Adverse event n (%)	7 (8%)	9 (7%)
Number of deaths > 30 days after last dose n (%)	39 (42.9%)	44 (32.1%)
Progressive disease n (%)	26 (29%)	27 (20.0%)
Adverse event n (%)	4 (4%)	2 (1%)
Other n (%)	5 (5%)	6 (4%)
Unknown n (%)	4 (4%)	9 (7%)

* Limitation of Use to exclude patients with post-ASCT progression ≤ 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression > 36 months)



PEPAXTO Dosing in Recommended Population*

PEPAXTO Recommended Dosing in Patients with RRMM and No ASCT or Post-ASCT Progression > 36 Months*

- MTD appropriate strategy for cytotoxic therapies
 - Dose modifications to manage hematological AEs
- 40 mg dose for most patients
- Proposed dose changes
 - 30 mg for patients with body weight \leq 60 kg
 - Based on PK data and cytopenias
 - Modification guidance with earlier dose reductions

MTD: Maximum tolerated dose

*Recommended population for PEPAXTO treatment

OCEAN Confirms Positive Benefit-Risk for PEPAXTO with Proposed Limitations of Use

- PEPAXTO has positive benefit-risk when used in patients with no ASCT or post ASCT progression > 36 months
 - Improved efficacy
 - Better safety
 - Fewer dose modifications
- Future use and development only in recommended population

Clinical Perspective

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RRMM Remains Incurable: Patients Continue to Need Options

- Once a disease becomes multi-refractory, survival quickly diminishes as there are few options for our patients
- PEPAXTO MoA acts in a different pathway
- PEPAXTO benefit consistently observed across clinical studies in patients with high unmet need

The Right Patient Continues to Need PEPAXTO: Patient Example

- Myeloma, a disease of the elderly, > 80% of patients \geq 65 years
- Patient narrative
 - 74 year-old Caucasian woman, diagnosed with MM in 2005
 - 4 prior lines of treatment between 2005 – 2019
- Past medical history
 - Insulin dependent diabetes, hyperlipidemia, hypertension, CHF, COPD and class III obesity
 - Not considered an ASCT candidate due to co-morbidities
- 2019 – 2021: PEPAXTO given: VGPR followed by PD
 - Well tolerated, no hospitalizations and heme toxicity only
 - Two dose reductions (40 to 30 mg after 6 months, 20 mg after 12 months – 2 years)

EMD in RRMM: Clinical Considerations

- Associated with poor patient outcome and is not well studied¹
 - Patients typically excluded from clinical trials – though in high unmet need
- HORIZON represents largest cohort of patients with EMD evaluated to date in a prospective clinical trial (N = 55)²
- PEPAXTO showed activity in patients with advanced RRMM²
 - ORR: 24%
 - Median PFS: 2.9 months
 - Median OS: 6.5 months
- Safety profile consistent to overall population

OCEAN (OP-103): Important Trial to Inform the Benefit/Risk Profile of PEPAXTO

- Subgroup data key from OCEAN
 - Data in patients with no prior ASCT or TTP > 36 months post ASCT
 - Median PFS: 9.3 months vs 4.6 months for pomalidomide
 - Median OS: 23.6 months vs 19.8 months for pomalidomide
- Clear biological rationale supporting these subgroup data

Expected and Manageable Safety Profile

- Tolerable drug profile
- Limited non-hematologic AEs (e.g absence of alopecia, no cardiac toxicity, no neuropathy, minimal mucositis)
 - Majority grade 1 – 2
- Myelosuppression is expected with active cytotoxic agents
- Hematologic AEs managed with dose modifications and supportive care
 - Dose modifications as standard approach proved effective
 - Comparable discontinuation rates between PEPAXTO and pomalidomide
- Convenient monthly infusion schedule

Patients with RRMM Should Have PEPAXTO as an Option

- Triple-class refractory RRMM is an urgent unmet medical need
- Multiple studies demonstrate PEPAXTO's benefit in this setting
- Consistent and manageable safety profile
- Clinically meaningful data in patients who progressed > 36 months after an ASCT and in patients without prior ASCT

OCEAN Data Support Positive PEPAXTO Benefit-Risk

FDA Issues	Key Considerations
PFS benefit	<ul style="list-style-type: none"> • PEPAXTO met primary endpoint, with statistically significant superior PFS • IRC used IMWG guidelines for disease progression
Overall survival	<ul style="list-style-type: none"> • Prespecified subgroup analysis identified risk in patients with prior ASCT <ul style="list-style-type: none"> • Biologically plausible risk • Removal of subgroup with risk* improves efficacy and safety <ul style="list-style-type: none"> • PFS, OS, ORR, DOR, AEs
Appropriate dose	<ul style="list-style-type: none"> • PEPAXTO is an alkylating cytotoxic dosed to MTD • Improved tolerability and less dose modifications by removal of subgroup with risk*

* Limitation of Use to exclude patients with post-ASCT progression \leq 36 months (i.e., use in patients with no prior ASCT or post-ASCT progression $>$ 36 months)



PEPAXTO[®] (melphalan flufenamide)

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