R&D Update and 2018 ASH Data Review

December 3, 2018 Live in San Diego and via Webcast 20:00 – 21:30 PST





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Agenda

20:00	Welcome & Introduction	Dr. Jan van de Winkel, President & CEO
20:05	Daratumumab: Efficacy in Newly Diagnosed Multiple Myeloma: MAIA & GRIFFIN	Dr. Saad Usmani, FACP, University of NC at Chapel Hill, Levine Cancer Institute
20:15	Daratumumab: Efficacy in Newly Diagnosed Multiple Myeloma: ALCYONE & CASSIOPEIA	Dr. Meletios A. Dimopoulos, National and Kapodistrian University of Athens, School of Medicine
20:30	Daratumumab: Deepening Responses in Relapsing/Refractory Multiple Myeloma & Additional Updates: CASTOR, POLLUX, PAVO	Dr. Nizar Bahlis, University of Calgary, Charbonneau Cancer Institute
20:45	Daratumumab Q&A	All
21.00	Genmab: DuoBody-CD3xCD20 and DuoHexaBody- CD37 Pre-Clinical Data	Dr. Kate Sasser, Translational Research, Genmab
21:05	Genmab 2019 & Beyond: An Exciting Future Founded on Innovation & Expertise	Dr. Jan van de Winkel
21:10	Genmab 2019 & Beyond: Key 2019 Priorities	Dr. Jan van de Winkel
21:18	General Q&A	All
21:30	Refreshments	



Genmab's Solid Foundation: Our Focus



Core Purpose

 To improve the lives of patients by creating & developing innovative antibody products



Our Strategy

- Turn science into medicine
- Build a profitable & successful biotech
- Focus on Core Competence



Vision

 By 2025, our own product has transformed cancer treatment and we have a pipeline of knock-your-socks off antibodies



Genmab's Solid Foundation: Supporting Future Growth





Genmab's Solid Foundation: Supporting Future Growth

Key 2018 Achievements





Daratumumab

Transforming the Treatment of Multiple Myeloma



Daratumumab: Efficacy in **Newly Diagnosed Multiple Myeloma:** MAIA (MMÝ3008) & **GRIFFIN (MMY2004)**

Presented by Dr. Saad Usmani, M.D., FACP, University of North Carolina at Chapel Hill, Levine Cancer Institute



MAIA (MMY3008)

Presented by Dr. Saad Usmani, M.D., FACP, University of North Carolina at Chapel Hill, Levine Cancer Institute



Phase 3 Randomized Study of Daratumumab Plus Lenalidomide and Dexamethasone (D-Rd) Versus Lenalidomide and Dexamethasone (Rd) in Patients with Newly Diagnosed Multiple Myeloma (NDMM) Ineligible for Transplant (MAIA)

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Introduction & Methods

- Lenalidomide (R)-based therapies are a standard of care for patients with newly diagnosed, transplantineligible multiple myeloma (NDMM)
- As previously reported in 3 Phase III studies, addition of daratumumab (D) to standards of care in both relapsed refractory MM (POLLUX; D-Rd & CASTOR; D-Vd) or transplant-ineligible NDMM (ALCYONE; D-VMP) resulted in a ≥50% reduction in the risk of disease progression or death¹
- Of these, the POLLUX study with D-Rd showed the greatest benefit: 63% reduction in risk of disease progression or death in patients with MM who had at least one prior line of therapy
- Based on efficacy & tolerable safety profile of D-Rd, conducted a Phase III study (MAIA) to evaluate D-Rd vs Rd in transplant-ineligible NDMM
- Patients ≥65 years or otherwise ineligible for high-dose chemo. with ASCT due to age ≥65 years
 randomized 1:1 to Rd ± D
- The primary endpoint was PFS
- Key secondary endpoints: ORR, MRD negativity rate, and safety.

Patient Characteristics & Dosing

- Total patients
 - 368 D-Rd
 - 369 Rd
- Median age
 - 73 (45 90) years
 - 44% ≥75 years
- 52% male
- 67% had ECOG scores ≥1
- ISS stage
 - I: 27%
 - II: 43%
 - III: 29%
- FISH/karyotyping cytogenetic analysis
 - 642 patients evaluable
 - 86% standard risk
 - 14% high risk

- All patients received 28-day cycles of treatment with Rd ± D
- R: 25 mg (oral) QD on Days 1 21;
- d: 40 mg (oral) on Days 1, 8, 15 and 22
- In D-Rd arm, D was given at 16 mg/kg (intravenously) QW for Cycles 1-2, Q2W for Cycles 3-6, and Q4W thereafter
- In both arms, patients were treated until disease progression or unacceptable toxicity

Results

Median follow-up: 28 mo.



Rd (%)

53.1%

24.7%

D-Rd (%)

79.3%

47.6%

Odds Ratio

(95% CI)

3.4

2.75



Patients treated with D-Rd:

- 45% reduction in risk of progression or death
 - HR 0.55, 95% CI, 043 to 0.72; p<0.0001
- Median PFS not reached vs 31.9 mo. in Rd
 - Median follow-up 28 months
 - HR for OS was 0.78 (95%Cl, 0.56 to 1.1)
 - OS data immature; follow-up ongoing

P value

< 0.0001

< 0.0001

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Safety



- Pneumonia
- Neutropenia
- Leukopenia
- Safety profile overall well tolerated and consistent with previously reported daratumumab studies

Conclusion

- Addition of D to Rd in patients with transplant-ineligible NDMM significantly reduced the risk of progression or death by 45%
- No new safety signals

These data, together with the Phase III ALCYONE study, support the addition of daratumumab to standard of care combinations in transplant ineligible newly-diagnosed multiple myeloma

GRIFFIN (MMY2004)

Presented by Dr. Saad Usmani, M.D., FACP, University of North Carolina at Chapel Hill, Levine Cancer Institute



Efficacy and Updated Safety Analysis of a Safety Run-in Cohort from GRIFFIN, a Phase 2 Randomized Study of Daratumumab (DARA), Bortezomib (V), Lenalidomide (R), and Dexamethasone (d; DARA-VRd) vs. VRd in Patients (Pts) With Newly Diagnosed Multiple Myeloma (NDMM) Eligible for High-dose Therapy (HDT) and Autologous Stem Cell Transplantation (ASCT)*

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GRIFFIN: Safety Run-in Phase (N = 16)



• Patients who complete maintenance cycles 7-32 may continue single-agent lenalidomide thereafter

Safety run-in phase in 16 patients to assess dose-limiting toxicities during 1 Cycle of D-VRd

ECOG, Eastern Cooperative Oncology Group; CrCl, creatinine clearance; D, daratumumab; IV, intravenously; D, day; V, bortezomib; SC, subcutaneously; PO, orally; d, dexamethasone; D-R, daratumumab/lenalidomide; R, lenalidomide.

^aLenalidomide dose adjustments were made for patients with CrCl ≤50 mL/min; ^bConsolidation was initiated 60-100 days post-transplant.

Demographics and Disease Characteristics

Characteristic	(N = 16)
Median (range) age, years	62.5 (46-65)
Male, n (%)	8 (50)
Race, n (%)	
White	11 (69)
Black/ African American	4 (25)
Asian	1 (6)
ECOG performance status, n (%)	
0	3 (19)
1	10 (63)
2	3 (19)
ISS, n (%)	
Stage I	12 (75)
Stage II	2 (13)
Stage III	2 (13)
High-risk cytogenetics ^a , n (%)	5 (31)

- As of October 24 2018, 16 patients were enrolled in the safety run-in and all completed
 ≥9 cycles of treatment, including
 ≥3 cycles of maintenance
- Patients have received a median (range) of 17 (10-19) cycles, including 4-13 maintenance cycles

^aHigh risk cytogenetics were defined by any of del17p, t(4:14), t(14:16). All 5 patients with high-risk cytogenetics had a del17p abnormality. Percentages may not add up to 100% due to rounding. ISS, International Staging System; ECOG, Eastern Cooperative Oncology Group.

Safety: Most Common TEAEs^a

Hematologic TEAEs, n (%)	Any grade	Grade 3 or 4			
Neutropenia	12 (75)	5 (31) ^b			
Febrile neutropenia	2 (13)	2 (13)			
Lymphopenia	12 (75)	3 (19)			
Thrombocytopenia	8 (50)	4 (25)			
Leukopenia	8 (50)	2 (13)			
Anemia	7 (44)	1 (6)			

- TEAEs occurred in all 16 patients
 - TEAEs related to daratumumab^c occurred in 15 patients (94%)
- Grade 3 or 4 TEAEs occurred in 14 patients (88%)
 - Grade 3 or 4 TEAEs related to daratumumab^c occurred in 10 patients (63%)

TEAE, treatment-emergent adverse event.

 $^{\rm a}\text{Any}$ grade TEAEs in >25% of patients and grade 3 or 4 TEAEs in >10% of patients. $^{\rm b}\text{All}$ grade 3.

 $^{\rm c}$ Includes TEAEs that were very likely, probably, or possibly related to daratumumab.

	Nonhematologic TEAEs, n (%)	Any grade	Grade 3 or 4
İ	Diarrhea	9 (56)	1 (6)
	Fatigue	9 (56)	1 (6)
	Hypocalcemia	8 (50)	1 (6)
	Constipation	8 (50)	0
	Nausea	6 (38)	0
	Vomiting	6 (38)	0
1	Peripheral edema	6 (38)	0
	Pyrexia	6 (38)	0
	Upper respiratory tract infection	6 (38)	0
	Hypokalemia	6 (38)	0
	Cough	5 (31)	0
	Hypoalbuminemia	5 (31)	0
	Hypomagnesemia	5 (31)	0
	Insomnia	5 (31)	0
	Pain in extremity	5 (31)	0
	Peripheral sensory neuropathy	5 (31)	0
	Pneumonia	4 (25)	4 (25)
	Hypophosphatemia	4 (25)	2 (13)
	Rash	4 (25)	2 (13)

Safety: Infusion Reactions^a

	N = 16						
IRs, n (%)	Any grade	Grade 3 or 4					
Peripheral edema	1 (6)	0					
Vascular access site swelling	1 (6)	0					
Pruritus	1 (6)	0					
Maculo-papular rash	1 (6)	0					
Flushing	1 (6)	0					

- DARA IRs were reported in 4 (25%) patients
- No grade 3 or 4 IRs
- All patients recovered with no discontinuations due to IRs

ASCT Parameters

Stem cell yield, $ imes$ 10 ⁶ CD34 ⁺ cells/kg (n = 16) Median (range)	8.05 (3.5-17.6)
Days to neutrophil engraftment (0.5 $ imes$ 10 ⁹ /L; n = 14) Median (range)	13.0 (1-29)
Days to platelet engraftment (20 $ imes$ 10 ⁹ /L; n = 12) Median (range)	13.5 (9-29)

Adding daratumumab to VRd did not negatively affect stem cell collection and engraftment¹

Efficacy: Investigator-assessed Response Rate



Responses continued to deepen over time

ORR, overall response rate; CR, complete response; VGPR, very good partial response; PR, partial response.

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MRD Negativity (10⁻⁵; ITT) and Outcomes



• Median (range) follow-up: 16.8 (15.9-18.7) months

 15/16 (94%) patients remain progression free on study treatment

^aEvaluated by next generation sequencing (NGS; ClonoSEQ v2.0). ^b13 patients were evaluated for MRD at each timepoint.

50% of patients achieved MRD negativity at 10^{-5}

MRD rate expressed as a percentage of all patients (N =16). Note that 3 patients were not evaluable due to technical issues.

Conclusions

- The overall safety profile of D-VRd was consistent with prior experience with daratumumab and VRd, and toxicity was manageable
- All patients underwent successful stem cell collection and transplantation
- Depth of response improved with consolidation and continued to deepen over time
- MRD negativity (10⁻⁵ threshold by NGS) was achieved in 50% of all patients after consolidation
- One patient experienced disease progression by the clinical cutoff date

D-VRd is well-tolerated and effective in ASCT-eligible NDMM

Daratumumab: Efficacy in **Newly Diagnosed Multiple Myeloma: ALCYONE (MMY3007) &** CASSIOPEIA (MM3006)

Presented by Dr. Meletios A. Dimopoulos, M.D., National and Kapodistrian University of Athens, School of Medicine



ALCYONE (MMY3007)

Presented by Dr. Meletios A. Dimopoulos, M.D., National and Kapodistrian University of Athens, School of Medicine



One-year Update of a Phase 3 Randomized Study of Daratumumab Plus Bortezomib, Melphalan, and Prednisone (D-VMP) Versus Bortezomib, Melphalan, and Prednisone (VMP) in Patients (Pts) With Transplant-ineligible Newly Diagnosed Multiple Myeloma (NDMM): ALCYONE^{*}

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Background

- NDMM patients ≥65 years of age or with comorbidities are ineligible for autologous stem-cell transplant¹
- In VISTA, the bortezomib, melphalan, and prednisone (VMP) registration study, the addition of V to MP improved efficacy in these patients at the cost of increased toxicity (eg, peripheral sensory neuropathy)^{2,3}
- PETHEMA/GEM2005MAS65⁴ and GIMEMA⁵ optimized VMP by reducing toxicity and maintaining cumulative bortezomib dose and efficacy
- In the primary analysis of the phase 3 ALCYONE study, the addition of daratumumab to VMP (D-VMP) reduced the risk of progression or death by 50% in NDMM patients ineligible for transplant⁶

We report updated efficacy and safety from ALCYONE after 1 year of additional follow-up

Mohty M, Harousseau JL. *Haematologica*. 2014;99(3):408-416.
 San Miguel J, et al. *N Engl J Med*. 2008;359(9):906-917.
 Harousseau JL, et al. *Blood*. 2010;116(19):3743-3750.

Mateos MV, et al. *Lancet Oncol.* 2010;11(10):934-941.
 Palumbo A, et al. *J Clin Oncol.* 2010;28(34):5101-5109.
 Mateos MV, et al. *N Engl J Med.* 2018;378(6):518-528.

ALCYONE Study Design



- ISS (I vs II vs III)
- Region (EU vs other)

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• Age (<75 vs ≥75 years)

- Cycles 1-9: 6-week cycles
- Cycles 10+: 4-week cycles

Statistical analyses 360 PFS events: 85% power for

8-month PFS improvement^a

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ECOG, Eastern Cooperative Oncology Group; ISS, International Staging System; EU, European Union; SC, subcutaneously; PO, orally; IV, intravenously; D, daratumumab; PD, progressive disease; PFS, progression-free survival; ORR, overall response rate; VGPR, very good partial response; CR, complete response; MRD, minimal residual disease; NGS, next-generation sequencing; OS, overall survival. ^a8-month PFS improvement over 21-month median PFS of VMP.

Baseline Characteristics (ITT; N = 706)

	D-VMP (n = 350)	VMP (n = 356)	
Age			
Median (range), years	71.0 (40-93)	71.0 (50-91)	
Distribution, n (%)			
<65 years	36 (10)	24 (7)	
65-74 years	210 (60)	225 (63)	
≥75 years	104 (30)	107 (30)	
Male, n (%)	160 (46)	167 (47)	
Race, n (%)			
White	297 (85)	304 (85)	
Other	53 (15)	52 (15)	
ECOG performance status, ^a n (%)			
0	78 (22)	99 (28)	
1	182 (52)	173 (49)	
2	90 (26)	84 (24)	

ITT, intent to treat.

^aECOG performance status is scored on a scale from 0 to 5, with 0 indicating no symptoms and higher scores indicating increasing disability.

Patient Disposition

- Median (range) follow-up: 27.8 (0-39.2) months
- At the clinical cutoff date of June 12, 2018, all patients had either discontinued or completed 9 treatment cycles of VMP
- 194 (56%)^a of patients in the D-VMP arm continue to receive daratumumab monotherapy

	VMP ^b	D-VMP ^b				
	Cycles 1-9 (n = 354)	Cycles 1-9 (n = 346)	Cycles 10+ (n = 278)			
Patients still on treatment, n (%)	0	0	194 (56)ª			
Patients who discontinued study treatment, n (%)	118 (33)	68 (20)	84 (30)			
Reason for discontinuation, n (%)						
Progressive disease	47 (13)	23 (7)	69 (25)			
Adverse event	34 (10)	18 (5)	5 (2)			
Death	8 (2)	11 (3)	7 (3)			
Noncompliance with study drug	15 (4)	10 (3)	2 (<1)			
Physician decision	7 (2)	0	0			
Withdrawal by subject	6 (2)	2 (<1)	1 (<1)			
Other	1 (<1)	4 (1)	0			

Efficacy: PFS

• Median (range) follow-up: 27.8 (0-39.2) months



57% reduction in the risk of progression or death in patients receiving D-VMP

Efficacy: PFS in Prespecified Subgroups

	D-VMP		/MP VMP					D-VMP		VMP			
		Median		Median					Median		Median		
	n	(mos)	n	(mo)		HR (95% CI)		n	(mo)	n	(mo)		HR (95% CI)
Sex							Baseline hepatic						
Male	160	30.9	167	18.9	H	0.50 (0.37-0.68)	function						
Female	190	NE	189	19.8	M	0.38 (0.28-0.52)	Normal	301	NE	303	19.4	M	0.45 (0.36-0.57)
A							Impaired	46	NE	52	13.5	⊢●⊣	0.41 (0.23-0.72)
Age	• • •		240	10.0			ISS staging						
<75 years	246	NE	249	19.0		0.41 (0.32-0.53)	I	69	NE	67	24.7	⊢●⊣	0.47 (0.28-0.79)
≥75 years	104	32.2	107	20.1	⊣	0.51 (0.34-0.75)	II	139	NE	160	18.3	I⊕I	0.43 (0.31-0.60)
Race						1	III	142	NE	129	18.2	ЮH	0.43 (0.31-0.60)
White	297	NE	304	19.3	M	0.46 (0.37-0.58)	Type of MM						
Other	53	NE	52	18.9	⊢●−∣	0.32 (0.17-0.58)	lgG	207	NE	218	18.5	H	0.41 (0.31-0.54)
							Non-IgG ^{a,b}	82	30.9	83	21.3	⊢●⊣	0.58 (0.38-0.89)
Region							Cytogenetic risk						
Europe	289	NE	295	19.1	I	0.47 (0.38-0.60)	High risk	53	19.2	45	18.0	⊢ ● ∔	⊣ 0.78 (0.49-1.26)
Other	61	NE	61	19.0	₩	0.28 (0.15-0.52)	Standard risk	261	NE	257	18.9		0.34 (0.26-0.45)
Baseline renal function (CrCl)						1 1 1 1 1	ECOG performance status						
>60 mL/min	200	NE	211	19.1	₩H	0.45 (0.34-0.60)	0	78	NE	99	20.1	₩	0.39 (0.25-0.62)
≤60 mL/min	150	NE	145	18.9	₩H	0.42 (0.30-0.59)	1-2	272	NE	257	18.8	Юł	0.45 (0.35-0.58)
				0	.0 1	.0 2.0					0	.0 1.0) 2.0
	Favor D-VMP Favor VMP Favor VMP Favor VMP												

D-VMP prolonged PFS across all subgroups analyzed

NE, not evaluable; CrCl, creatinine clearance. ^aPatients with measurable disease in serum. ^b95% of non-IgG patients were IgA.

Efficacy: ORR^a

• Median duration of response: not reached in D-VMP versus 21.1 months in VMP



Significantly higher ORR, ≥VGPR rate, and ≥CR rate with D-VMP; >2-fold increase in sCR rate with D-VMP

Efficacy: MRD^a (NGS; 10⁻⁵ Sensitivity Threshold)



- Deepening MRD-negative rate with longer follow-up for D-VMP
- Lower risk of progression or death in all MRD-negative patients
 - ~4-fold higher MRD negativity achieved with D-VMP
Definition of PFS During Next Line of Therapy (PFS2)



- PFS2 is the time from randomization to disease progression on first subsequent anti-cancer therapy or death, whichever occurs first
 - Recommended surrogate endpoint for OS¹
 - Demonstrates whether the PFS benefit of an experimental therapy is sustained during the subsequent line of therapy

Efficacy: PFS2^a



• Median (range) follow-up: 27.8 (0-39.2) months

Based on PFS2 results, we project better survival outcomes with D-VMP vs VMP

^aPatients who did not progress on study treatment before death or progression on subsequent line of therapy were counted as a PFS2 event. ^bKaplan-Meier estimate.

Safety: TEAEs During DARA Monotherapy (Cycle 10+)

	All-grade (≥5%) (n = 278)	Grade 3/4 (n = 278)
Hematologic, n (%)		
Anemia	18 (7)	10 (4)
Neutropenia	13 (5)	5 (2)
Nonhematologic, n (%)		
Upper respiratory tract infection	43 (16)	2 (<1)
Bronchitis	29 (10)	3 (1)
Viral upper respiratory tract infection	27 (10)	0
Cough	23 (8)	0
Diarrhea	20 (7)	0
Arthralgia	20 (7)	0
Back pain	18 (7)	2 (<1)
Influenza	16 (6)	2 (<1)
Pyrexia	14 (5)	0
Pain in extremity	13 (5)	0

Conclusions

- D-VMP significantly improves PFS with longer follow-up
 - 57% reduction in the risk of progression or death
 - PFS benefit extended to patients ≥75 years of age
- D-VMP induces deep and durable responses that continue to improve on daratumumab monotherapy, including ~4-fold higher MRD-negativity rate compared with VMP
- Longer use of daratumumab monotherapy following D-VMP is tolerable
- Based on PFS2 results, longer survival outcomes are projected with D-VMP vs VMP
- Positive MAIA data reported for D-Rd vs Rd in transplant-ineligible NDMM: PFS HR of 0.56 (P <0.0001)¹

Along with MAIA findings, these results support addition of daratumumab to a standardof-care regimen in transplant-ineligible NDMM

^{1.} Facon T, et al. ASH 2018. Abstract LBA-2.

Poster 3550: Comparative Efficacy and Safety of Daratumumab in Combination With Bortezomib, Melphalan, and Prednisone (D-VMP) in ALCYONE Versus Bortezomib, Melphalan, and Prednisone (VMP) in VISTA in Newly Diagnosed Multiple Myeloma (NDMM) Patients Using Propensity Score Matching (PSM)

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Progression Free Survival of D-VMP versus VISTA VMP Based on Naïve Comparisons (A) or After Matching (B).



Poster 3550: Comparative Efficacy and Safety of Daratumumab in Combination With Bortezomib, Melphalan, and Prednisone (D-VMP) in ALCYONE Versus Bortezomib, Melphalan, and Prednisone (VMP) in VISTA in Newly Diagnosed Multiple Myeloma (NDMM) Patients Using Propensity Score Matching (PSM)

Markedly Improved Safety Profile of D-VMP Versus VISTA VMP Based on Unmatched and Matched Comparisons

Table 3. All-grade and Grade 3/4 TEAEs of Interest in Unmatched and Matched D-VMP-treated and VISTA VMP-treated Patients

	Unma	atched®	Matched		
	D-VMP (n = 346)	D-VMP VISTA VMP (n = 346) (n = 340)		VISTA VMP (n = 277)	
All-grade hematologic AEs, n (%)					
Anemia	97 (28.0)*	147 (43.2)	81 (29.2)*	120 (43.3)	
Thrombocytopenia	169 (48.8)	178 (52.4)	137 (49.5)	142 (51.3)	
Neutropenia	172 (49.7)	165 (48.5)	136 (49.1)	138 (49.8)	
All-grade nonhematologic AEs, n (%)					
Peripheral sensory neuropathy	98 (28.3)*	151 (44.4)	78 (28.2)*	125 (45.1)	
Diarrhea	82 (23.7)*	157 (46.2)	71 (25.6)*	129 (46.6)	
Pyrexia	80 (23.1)	99 (29.1)	67 (24.2)	78 (28.2)	
Nausea	72 (20.8)*	164 (48.2)	56 (20.2)*	130 (46.9)	
Infections	231 (66.8)	234 (68.8)	187 (67.5)	183 (66.1)	
Upper respiratory tract infection	91 (26.3)*	30 (8.8)	80 (28.9)*	24 (8.7)	
Pneumonia	53 (15.3)	56 (16.5)	46 (16.6)	43 (15.5)	
All grade infusion-related reaction, n (%) ^b	96 (27.7)*	4 (1.2)	80 (28.9)*	4 (1.4)	

55 (15.9)	62 (18.2)	46 (16.6)	51 (18.4)
119 (34.4)	127 (37.4)	98 (35.4)	104 (37.6)
138 (39.9)	136 (40.0)	108 (39.0)	112 (40.4)
5 (1.4)*	44 (12.9)	3 (1.1)*	37 (13.4)
9 (2.6)*	25 (7.4)	9 (3.3)	17 (6.1)
2 (0.6)*	10 (2.9)	2 (0.7)	7 (2.5)
3 (0.9)*	14 (4.1)	2 (0.7)*	10 (3.6)
80 (23.1)	66 (19.4)	66 (23.8)	49 (17.7)
7 (2.0)	4 (1.2)	5 (1.8)	4 (1.4)
39 (11.3)	28 (8.2)	32 (11.6)	22 (7.9)
17 (4.9)*	0	15 (5.4)*	0
8 (2.3)*	22 (6.5)	5 (1.8)*	17 (6.1)
	55 (15.9) 119 (34.4) 138 (39.9) 5 (1.4)* 9 (2.6)* 2 (0.6)* 3 (0.9)* 80 (23.1) 7 (2.0) 39 (11.3) 17 (4.9)* 8 (2.3)*	$55 (15.9)$ $62 (18.2)$ $119 (34.4)$ $127 (37.4)$ $138 (39.9)$ $136 (40.0)$ $138 (39.9)$ $136 (40.0)$ $5 (1.4)^*$ $44 (12.9)$ $9 (2.6)^*$ $25 (7.4)$ $2 (0.6)^*$ $10 (2.9)$ $3 (0.9)^*$ $14 (4.1)$ $80 (23.1)$ $66 (19.4)$ $7 (2.0)$ $4 (1.2)$ $39 (11.3)$ $28 (8.2)$ $17 (4.9)^*$ 0 $8 (2.3)^*$ $22 (6.5)$	55 (15.9) 62 (18.2) 46 (16.6) 119 (34.4) 127 (37.4) 98 (35.4) 138 (39.9) 136 (40.0) 108 (39.0) 138 (39.9) 136 (40.0) 108 (39.0) 5 (1.4)* 44 (12.9) 3 (1.1)* 9 (2.6)* 25 (7.4) 9 (3.3) 2 (0.6)* 10 (2.9) 2 (0.7) 3 (0.9)* 14 (4.1) 2 (0.7)* 80 (23.1) 66 (19.4) 66 (23.8) 7 (2.0) 4 (1.2) 5 (1.8) 39 (11.3) 28 (8.2) 32 (11.6) 17 (4.9)* 0 15 (5.4)* 8 (2.3)* 22 (6.5) 5 (1.8)*

TEAE, treatment-emergent adverse event; D-VMP, daratumumab/bortezomib/melphalan/prednisone; VMP, bortezomib/melphalan/prednisone; AE, adverse event; IRR, infusion-related reaction.

*P<0.05.

^aStatistical testing conducted using Cochran-Mantel-Haenszel test.

^bIRRs related to daratumumab were reported in ALCYONE, whereas the VISTA study reported bortezomib-related IRRs. ^cDifferent criteria were used to report AEs in ALCYONE and VISTA.⁷ In ALCYONE, AEs that progressed initially from grade 3 or 4 to grade 5 were included in the proportion of grade 3/4 AEs reported.⁷ In VISTA, only TEAEs with the highest severity of grade 3 or 4 were reported.¹ ^dThe assessment of secondary primary malignancies was conducted at different follow-up time points.

Poster 3550: Comparative Efficacy and Safety of Daratumumab in Combination With Bortezomib, Melphalan, and Prednisone (D-VMP) in ALCYONE Versus Bortezomib, Melphalan, and Prednisone (VMP) in VISTA in Newly Diagnosed Multiple Myeloma (NDMM) Patients Using Propensity Score Matching (PSM)

CONCLUSIONS

- This PSM analysis demonstrates that ALCYONE D-VMP significantly improves efficacy compared to VISTA VMP
 - These findings confirm the observations of ALCYONE in which D-VMP demonstrated superiority versus VMP in terms of PFS and ORR, using a modified bortezomib dosing schedule in both treatment arms⁷
 - As reflected in the HRs, the improvement of efficacy is similar to what was demonstrated within the ALCYONE study⁷
- A recent matched adjusted treatment comparison of studies using a modified VMP dosing schedule versus the VISTA VMP regimen demonstrated similar efficacy and a potential reduction in the rates of peripheral neuropathy,¹⁶ supporting the use of the modified bortezomib dosing schedule for VMP
- Taken together, these findings suggest that the lower intensity VMP dosing schedule used in ALCYONE did not negatively impact the efficacy of D-VMP when compared to VMP as used in VISTA, while also mitigating incidence of peripheral neuropathy, a TEAE frequently associated with bortezomib

Poster 3550: Comparative Efficacy and Safety of Daratumumab in Combination With Bortezomib, Melphalan, and Prednisone (D-VMP) in ALCYONE Versus Bortezomib, Melphalan, and Prednisone (VMP) in VISTA in Newly Diagnosed Multiple Myeloma (NDMM) Patients Using Propensity Score Matching (PSM)

Poster 3551: A Matching-adjusted Indirect Treatment Comparison of Daratumumab- Bortezomib-Melphalan-Prednisone Versus Lenalidomide-Dexamethasone Continuous, Lenalidomide Dexamethasone 18 Months, and Melphalan-Prednisone-Thalidomide

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INTRODUCTION

- Indirect, naïve comparisons of FIRST and ALCYONE studies may introduce bias due to differences in study design and populations
- As no randomized controlled studies have directly compared D-VMP to other relevant treatment regimens in NDMM patients who are transplant ineligible, a network meta-analysis (NMA) was conducted to compare D-VMP against other available treatments; however, the reliability for comparing OS data was limited by the following factors¹¹:
 - At 16.5 months of follow-up, median OS was not reached in ALCYONE, and the immaturity of the ALCYONE OS data limited relative efficacy analyses
 - A comparison of the 4 MP trials that serve as a bridge to key approved comparators (Rd and MPT) investigated in FIRST indicated that although all 4 trials of MP showed similar median PFS (15.2-22.0 months), large differences in median OS were observed (31.0-43.1 months)
- To overcome the potential sources of bias faced in the NMA, an unanchored matching-adjusted indirect treatment comparison (MAIC) was conducted to assess relative OS and PFS differences between D-VMP and Rd continuous, Rd 18, and MPT in patients with NDMM who are transplant ineligible
 - An MAIC can be used to make indirect comparisons when no pairwise comparison is available
 - In an MAIC, individual patient characteristics from 1 study are weighted to match observed characteristics in the comparator treatment arm, allowing weighted outcomes to be determined

Poster 3551: A Matching-adjusted Indirect Treatment Comparison of Daratumumab- Bortezomib-Melphalan-Prednisone Versus Lenalidomide-Dexamethasone Continuous, Lenalidomide-Dexamethasone 18 Months, and Melphalan-Prednisone-Thalidomide

Naive Comparisons of OS Results were all in Favor of D-VMP Versus Comparator Treatments, and all OS Hrs for D-VMP were Improved After the MAIC

Table 2. Results of the Naïve Comparison and the MAIC of D-VMP Versus Rd Continuous/ Rd 18/MPT

	Naïve co	mparison	MAIC			
	OS	PFS	OS	PFS		
	HR (95% CI)	HR (95% CI)	HR (95% CI)	HR (95% CI)		
D-VMP versus	0.88 (0.62-1.27)	0.65 (0.50-0.83)	0.68 (0.44-1.06)	0.66 (0.50-0.87)		
Rd continuous	<i>P</i> = 0.51	<i>P</i> <0.001	<i>P</i> = 0.086	<i>P</i> = 0.003		
D-VMP versus Rd 18	0.78 (0.55-1.11)	0.66 (0.52-0.85)	0.60 (0.39-0.93)	0.69 (0.52-0.91)		
	<i>P</i> = 0.16	<i>P</i> = 0.001	<i>P</i> = 0.02	<i>P</i> = 0.008		
D-VMP versus MPT	0.68 (0.48-0.95)	0.63 (0.49-0.80)	0.53 (0.35-0.81)	0.64 (0.48-0.85)		
	<i>P</i> = 0.024	<i>P</i> <0.001	<i>P</i> = 0.003	<i>P</i> = 0.002		

Statistically significant results are shown in bold.

MAIC, matching-adjusted indirect treatment comparison; D-VMP, daratumumab plus bortezomib/melphalan/prednisone; Rd continuous, lenalidomide/dexamethasone given in 28-day cycles until disease progression; Rd 18, lenalidomide/dexamethasone given for 18 cycles; MPT, melphalan/prednisone/thalidomide; OS, overall survival; PFS, progression-free survival; HR, hazard ratio; CI, confidence interval.

Poster 3551: A Matching-adjusted Indirect Treatment Comparison of Daratumumab- Bortezomib-Melphalan-Prednisone Versus Lenalidomide-Dexamethasone Continuous, Lenalidomide-Dexamethasone 18 Months, and Melphalan-Prednisone-Thalidomide

CONCLUSIONS

- This MAIC analysis showed a significant OS benefit for D-VMP compared to Rd 18 and MPT and a trend favoring D-VMP versus Rd continuous in patients with NDMM who are transplant ineligible
- The results of the MAIC also suggest that D-VMP provides consistent and statistically significant PFS benefit relative to Rd continuous, Rd 18, and MPT in this patient population
- This analysis supports a previously conducted NMA,¹¹ which showed an improvement in PFS with D-VMP over a number of treatment regimens in the frontline setting
- One potential limitation is that OS results may be influenced by superior subsequent therapies available for patients treated in the more recent ALCYONE trial; however, this is unlikely as relatively few patients have experienced disease progression, and OS data remain immature at the time of this analysis

Poster 3551: A Matching-adjusted Indirect Treatment Comparison of Daratumumab- Bortezomib-Melphalan-Prednisone Versus Lenalidomide-Dexamethasone Continuous, Lenalidomide-Dexamethasone 18 Months, and Melphalan-Prednisone-Thalidomide

CASSIOPEIA (MM3006)

Presented by Dr. Meletios A. Dimopoulos, M.D., National and Kapodistrian University of Athens, School of Medicine



CASSIOPEIA: Method

- Phase III daratumumab + bortezomib, thalidomide, dexamethasone (D-VTD) vs VTD
- Frontline treatment for patients who are candidates for autologous stem cell transplant (ASCT)
- Sponsored by the French Intergroupe Francophone du Myelome (IFM) in collaboration with the Dutch-Belgian Cooperative Trial Group for Hematology Oncology (HOVON)
- 2 Part Study
 - Part 1: D-VTD vs VTD alone; 6 cycles; primary endpoint of stringent Complete Response
 - Part 2: All responders re-randomized to receive either maintenance treatment with dara [once per 8 weeks, 16 mg/kg] or observation only, primary endpoint of PFS
- 1,085 patients (intent to treat)

CASSIOPEIA: Topline Results

- Primary endpoint: stringent Complete Response (sCR) 100 days post-transplant
- First part of study met primary endpoint
 - 28.9% D-VTD
 - 20.3% VTD.
 - Odds ratio of 1.60 (95% CI: 1.21 2.12. p≤ 0.001)
- Safety profile consistent with known safety profile of VTD regimen used in patients receiving ASCT and the known safety profile for daratumumab

Daratumumab: **Deepening Responses in Relapsing / Refractory Multiple Myeloma & Additional Updates:** CASTOR (MMY3004), POLLUX (MMY3003), PAVO (MMY1004)

Presented by Dr. Nizar Bahlis, M.D. University of Calgary, Charbonneau Cancer Institute



CASTOR (MMY3004) & POLLUX (MMY3003)

Presented by Dr. Nizar Bahlis, M.D. University of Calgary, Charbonneau Cancer Institute



Poster 3270: Efficacy and Safety of Daratumumab, Bortezomib, and Dexamethasone (D-Vd) Versus Bortezomib and Dexamethasone (Vd) in First Relapse Patients With Multiple Myeloma (MM): Update of CASTOR

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CASTOR Study Design



PO, orally; Vd, bortezomib/dexamethasone; D, daratumumab; Obs, observation; PFS, progression-free survival; TTP, time to disease progression; OS, overall survival; ORR, overall response rate; VGPR, very good partial response; CR, complete response; MRD, minimal residual disease.

Daratumumab-Vd Maintained Significant PFS and ORR Benefit



Deep and Durable Responses and Maintained MRD Neg

Table 2. Response and MRD-negative Rates Overall and in Patients With 1PL							
	ITT/Response-evaluable			1PL			
Response, ^a n (%)	D-Vd (n = 240)	Vd (n = 234)	P value	D-Vd (n = 119)	Vd (n = 109)	P value	
ORR	203 (85)	148 (63)	<0.0001	109 (92)	81 (74)	0.0007	
≥CR	72 (30)	23 (10)	<0.0001	51 (43)	16 (15)	<0.0001	
sCR	23 (10)	6 (3)		17 (14)	5 (5)		
CR	49 (20)	17 (7)		34 (29)	11 (10)		
≥VGPR	151 (63)	68 (29)	<0.0001	91 (77)	46 (42)	<0.0001	
VGPR	79 (33)	45 (19)		40 (34)	30 (28)		
PR	52 (22)	80 (34)		18 (15)	35 (32)		
MRD negativity (10⁻⁵) ^ь	(n = 251)	(n = 247)		(n = 122)	(n = 113)		
n (%)	35 (14)	4 (2)	<0.000001	24 (20)	3 (3)	0.000025	
Sustained MRD negativity (10⁻⁵), n (%)°	8 (3)	0		7 (6)	0		
MPD, minimal residual diseases IDL. Laries line of the result ITT integet to treat D.V.d. deptymental (developmental) (developmental) (developmental) (developmental)							

MRD, minimal residual disease; IPL, 1 prior line of therapy; ITT, intent-to-treat; D-Vd, daratumumab/bortezomib/dexamethasone; Vd, bortezomib/dexamethasone; ORR, overall response rate; CR, complete response; sCR, stringent complete response; VGPR, very good partial response; PR, partial response; MRD, minimal residual disease. ^aResponse-evaluable population.

^bITT population.

^cSustained MRD negativity for ≥12 months.

PFS 2





No New Safety Signals Identified

Table 3. Most Common (≥20% of Patients) and Grade 3/4 (≥5% of Patients) TEAEs							
	All g	rades	Grade 3/4				
TEAE, n (%)	D-Vd Vd (n = 243) (n = 237)		D-Vd (n = 243)	Vd (n = 237)			
Hematologic							
Thrombocytopenia	145 (60)	105 (44)	112 (46)	78 (33)			
Anemia	71 (29)	75 (32)	38 (16)	38 (16)			
Neutropenia	48 (20)	23 (10)	33 (14)	11 (5)			
Lymphopenia	32 (13)	9 (4)	24 (10)	6 (3)			
Nonhematologic							
Peripheral sensory neuropathy	121 (50)	90 (38)	11 (5)	16 (7)			
Upper respiratory tract infection	85 (35)	43 (18)	6 (3)	1 (0.4)			
Diarrhea	86 (35)	53 (22)	9 (4)	3 (1)			
Cough	71 (29)	30 (13)	0	0			
Constipation	54 (22)	38 (16)	0	2 (0.8)			
Fatigue	55 (23)	58 (25)	12 (5)	8 (3)			
Back pain	53 (22)	24 (10)	6 (3)	3 (1)			
Pneumonia	38 (16)	31 (13)	25 (10)	24 (10)			
Hypertension	24 (10)	8 (3)	16 (7)	2 (0.8)			

TEAE, treatment-emergent adverse event; D-Vd, daratumumab/bortezomib/dexamethasone; Vd, bortezomib/dexamethasone.

CONCLUSIONS

- In this updated analysis with more than 3 years of median follow-up,
 D-Vd maintained significant PFS and ORR benefit in RRMM patients
- The greatest benefit was observed in patients with 1PL
 - Patients with 1PL demonstrated longer PFS with D-Vd versus Vd regardless of prior treatment with lenalidomide (HR, 0.30) or bortezomib (HR, 0.22)
- Responses were deep and durable, and treatment with D-Vd allowed for higher rates of sustained MRD negativity versus Vd alone
- No new safety signals were reported with D-Vd with longer follow-up
- In conclusion, these data suggest that D-Vd should be administered to patients with RRMM after their first relapse, regardless of prior lenalidomide or bortezomib exposure

Poster 1996: Three-year Follow-up of the Phase 3 POLLUX Study of Daratumumab Plus Lenalidomide and Dexamethasone (D-Rd) Versus Lenalidomide and Dexamethasone (Rd) Alone in Relapsed or Refractory Multiple Myeloma (RRMM)

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POLLUX Study Design



Daratumumab-rd Significantly Prolonged PFS Compared to Rd Median PFS Reached at 44.5 Months



Daratumumab-Rd Produced Significantly Deeper Responses Including Sustained MRD Neg Compared to Rd



ORR, overall response rate; MRD, minimal residual disease; CR, complete response; VGPR, very good partial response; D-Rd, daratumumab/lenalidomide/dexamethasone; Rd, lenalidomide/dexamethasone; PR, partial response; sCR, stringent complete response. ^aP < 0.0001.

Daratumumab-Rd Significantly Prolonged Time to Next Therapy Compared to Rd



No New Safety Signals Identified

Table 2. Most Common Any-grade (≥25% of Patients) and Grade 3/4 (≥5% of Patients) TEAEs							
	Any	grade	Grad	e 3/4			
TEAE, n (%)	D-Rd (n = 283)	Rd (n = 281)	D-Rd (n = 283)	Rd (n = 281)			
Hematologic							
Neutropenia	179 (63)	135 (48)	157 (56)	117 (42)			
Anemia	111 (39)	114 (41)	50 (18)	60 (21)			
Thrombocytopenia	87 (31)	88 (31)	42 (15)	44 (16)			
Lymphopenia	19 (7)	17 (6)	16 (6)	12 (4)			
Febrile neutropenia	18 (6)	8 (3)	18 (6)	8 (3)			
Nonhematologic							
Diarrhea	165 (58)	105 (37)	28 (10)	11 (4)			
Upper respiratory tract infection	121 (43)	78 (28)	5 (2)	5 (2)			
Fatigue	110 (39)	87 (31)	19 (7)	12 (4)			
Cough	99 (35)	42 (15)	1 (0.4)	0			
Nasopharyngitis	96 (34)	59 (21)	0	0			
Constipation	93 (33)	76 (27)	3 (1)	2 (0.7)			
Muscle spasms	84 (30)	60 (21)	3 (1)	4 (1)			
Nausea	82 (29)	51 (18)	6 (2)	2 (0.7)			
Insomnia	76 (27)	63 (22)	6 (2)	4 (1)			
Pyrexia	73 (26)	40 (14)	9 (3)	7 (3)			
Back pain	71 (25)	57 (20)	8 (3)	5 (2)			
Pneumonia	71 (25)	46 (16)	43 (15)	28 (10)			
Cataract	54 (19)	33 (12)	17 (6)	12 (4)			
Hypokalemia	51 (18)	31 (11)	17 (6)	9 (3)			
Hypophosphatemia	20 (7)	14 (5)	14 (5)	8 (3)			

TEAE, treatment-emergent adverse event; D-Rd, daratumumab/lenalidomide/dexamethasone; Rd, lenalidomide/dexamethasone.

CONCLUSIONS

- After >3 years of median follow-up, D-Rd continued to provide a significant PFS benefit and higher rates of deeper responses versus Rd alone in patients with RRMM
 - Median PFS for D-Rd was reached (44.5 months)
 - D-Rd did not negatively impact outcomes of subsequent therapy
 - D-Rd achieved a 6-fold increase in the rate of MRD negativity versus Rd
 - D-Rd achieved a higher rate of sustained MRD negativity compared with Rd, suggesting that continued D-Rd treatment allows for maintenance of MRD-negative status
- No new safety signals were observed following a median of 34 months of D-Rd exposure
- These updated data continue to support the use of D-Rd in patients with RRMM after first relapse

Poster 3272: Evaluation of Sustained Minimal Residual Disease (MRD) Negativity in Relapsed/Refractory Multiple Myeloma (RRMM) Patients (Pts) Treated With Daratumumab in Combination With Lenalidomide Plus Dexamethasone (D-Rd) or Bortezomib Plus Dexamethasone (D-Vd): Analysis of POLLUX and CASTOR

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POLLUX and CASTOR Produce High and Sustainable MRD Neg.

Table 2. Rates of Sustained MRD-negativity Status								
		POLLUX			CASTOR			
Sustained MRD negativity (10⁻⁵), n (%)	D-Rd (n = 286)	Rd (n = 283)	P value ^a	D-Vd (n = 251)	Vd (n = 247)	<i>P</i> value ^a		
ITT								
Sustained ≥6 months ^ь	47 (16.4)	2 (0.7)	<0.0001	22 (8.8)	3 (1.2)	0.0001		
Sustained ≥12 months ^c	37 (12.9)	1(0.4)	<0.0001	8 (3.2)	0	0.0074		
≥CR, n	159	64		72	23			
Sustained ≥6 months ^ь	47 (29.6)	2 (3.1)	<0.0001	22 (30.6)	3 (13.0)	0.1115		
Sustained ≥12 months ^c	37 (23.3)	1 (1.6)	<0.0001	8 (11.1)	0	0.1922		

MRD, minimal residual disease; D-Rd, daratumumab/lenalidomide/dexamethasone; Rd, lenalidomide/dexamethasone; D-Vd, daratumumab/bortezomib/dexamethasone; Vd, bortezomib/dexamethasone; ITT, intent-to-treat; CR, complete response.

^aP value was calculated with the use of the Fisher exact test.

^bDefined as MRD negative and confirmed by ≥6 months apart without MRD positivity in between.

^cDefined as MRD negative and confirmed by ≥12 months apart without MRD positivity in between.

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MRD Negativity Leads to Prolonged PFS and OS



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CONCLUSIONS

- DARA-based combination regimens enable a significantly higher proportion of patients to achieve deep and durable responses of ≥CR and sustained MRD negativity at 10⁻⁵
 - It has been shown that DARA-treated patients with 1 prior line of therapy have shown a higher rate of sustained MRD negativity,¹⁸ and we anticipate a greater magnitude of benefit in patients after first relapse
- Based on the depth of response achieved and the disconnect between CR and long-term efficacy, assays that define the disease state with greater precision and sensitivity, compared with traditional methods, are needed¹⁹
- The ability to reach sustained MRD negativity is associated with prolonged PFS and OS
 - Pooled MRD and sustained MRD data from POLLUX and CASTOR confirmed the findings from the individual studies
- These findings suggest that achieving sustained MRD negativity should be a treatment goal for patients with RRMM

Poster 3272: Evaluation of Sustained Minimal Residual Disease (MRD) Negativity in Relapsed/Refractory Multiple Myeloma (RRMM) Patients (Pts) Treated With Daratumumab in Combination With Lenalidomide Plus Dexamethasone (D-Rd) or Bortezomib Plus Dexamethasone (D-Vd): Analysis of POLLUX and CASTOR

PAVO (MMY1004)

Presented by Dr. Nizar Bahlis, M.D. University of Calgary, Charbonneau Cancer Institute


Poster 1995: **Subcutaneous Daratumumab** in Patients With Relapsed or Refractory Multiple Myeloma: Part 2 Safety and Efficacy Update of the Open-label, Multicenter, Phase 1b Study (PAVO)

Ajai Chari,¹,* Maria-Victoria Mateos,² Niels W.C.J. van de Donk,³ Jonathan L. Kaufman,⁴ Philippe Moreau,⁵ Albert Oriol,⁶ Torben Plesner,⁷ Lotfi Benboubker,⁸ Hareth Nahi,⁹ Jie Tang,¹⁰ Peter Hellemans,¹¹ Brenda Tromp,¹¹ Pamela L. Clemens,¹² Andrew Farnsworth,¹³ Jesus San-Miguel,¹⁴ Saad Z. Usmani¹⁵

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PAVO Study Design



RRMM, relapsed or refractory multiple myeloma; MD, mix and deliver; DARA, daratumumab; rHuPH20, recombinant human hyaluronidase PH2O; SC, subcutaneous; C_{trough}, trough concentration; ORR, overall response rate; CR, complete response.

^aC_{trough} on Cycle 3 Day 1 in Group 1 supported dose selection for Group 2. The study evaluation team reviewed safety after Cycle 1 and pharmacokinetics after Cycle 3 Day 1 for each group.

Poster 1995: Subcutaneous Daratumumab in Patients With Relapsed or Refractory Multiple Myeloma: Part 2 Safety and Efficacy Update of the Open-label, Multicenter, Phase 1b Study (PAVO)

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Subcutaneous Daratumumab – Known Safety Profile – Fewer Infusion Related Reactions

IRRs

- The incidence and severity of IRRs were low with DARA SC
- Among the 25 patients receiving DARA SC, 4 (16%) patients reported IRRs
 - Patient 1: hypertension (grade 3), chills (grade 2), dyspnea (grade 2)
 - Patient 2: allergic rhinitis (grade 1)
 - Patient 3: sneezing (grade 1)
 - Patient 4: hypertension (grade 3)
- The majority of IRRs occurred on Day 1 of study treatment (83%), with 1 patient experiencing an IRR on Day 57 (17%)
- No discontinuations due to IRRs were observed

Injection-site Reactions

- Few injection-site TEAEs (investigator-reported) were observed with DARA SC
 - Induration, erythema, injection-site discoloration, and hematomas were observed (n = 1 each)
- Measurable erythema (24%) and measurable induration (4%) at the injection site were reversible within 1 hour
 - Erythema was measured for all injections regardless of attribution as a TEAE

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Response Rates in The DARA SC 1,800-mg Cohort Deepened with Longer Follow-up



Poster 1995: Subcutaneous Daratumumab in Patients With Relapsed or Refractory Multiple Myeloma: Part 2 Safety and Efficacy Update of the Open-label, Multicenter, Phase 1b Study (PAVO)

Cycle 3 Day 1 C_{trough} Following SC or IV Administration of Daratumumab



Poster 2006: Pharmacokinetics (PK) of Subcutaneous Daratumumab in Patients With Relapsed or Refractory (RR) Multiple Myeloma (MM): Primary Clinical Pharmacology Analysis of the Open-label, Multicenter, Phase 1b Study (PAVO)

CONCLUSIONS

- Daratumumab co-formulated with rHuPH20 (DARA SC) enables dosing over 3 to 5 minutes
- + DARA SC was well tolerated
 - The IRR rate with DARA SC was 16%
 - IRR rates for daratumumab 16 mg/kg IV range from 45% to 56% in RRMM^{10,12,13,17-19}
- High clinical response rates that continued to deepen with longer follow-up were observed with DARA SC
- Median PFS was 12.3 months in all-treated patients and 11.7 months in double-refractory patients
- A detailed pharmacokinetic analysis from Part 1 and Part 2 of the study are presented separately (Clemens et al, ASH 2018; Abstract #2006)
- These data informed the 4 ongoing phase 3 studies of DARA SC 1,800 mg
 - COLUMBA (DARA SC vs daratumumab IV; NCT03277105)
 - AQUILA (smoldering multiple myeloma, single-agent DARA SC; NCT03301220)
 - APOLLO (DARA SC + pomalidomide/dexamethasone; NCT03180736)
 - ANDROMEDA (amyloidosis, DARA SC + bortezomib/ cyclophosphamide/dexamethasone [CyBorD] vs CyBorD alone; NCT03201965)

Poster 1995: Subcutaneous Daratumumab in Patients With Relapsed or Refractory Multiple Myeloma: Part 2 Safety and Efficacy Update of the Open-label, Multicenter, Phase 1b Study (PAVO)

Daratumumab Q&A



DuoBody-CD3xCD20 & DuoHexaBody-CD37 Pre-Clinical Data

Dr. Kate Sasser, CVP Translational Research, Genmab





DuoHexaBody[™]-CD37

Novel Ab Format Targeting CD37, a Known Target for B Cell Malignancies

- Bispecific IgG1 with an E430G hexamerization-enhancing mutation in IgG Fc domain
- DuoHexaBody-CD37 targets two non-overlapping epitopes on CD37
- In pre-clinical settings DuoHexaBody-CD37 induces potent anti-tumor activity through superior complementdependent cytotoxicity (CDC) and potent antibody-dependent cellmediated cytotoxicity (ADCC)

target cell **CDC INDUCTION** DUAL EPITOPE TARGETING HEXAMERIZATION CLL/ BCL complement cascade CD37 ADCC INDUCTION effector cell

DuoBody Format HexaBody Format DuoHexaBody Format



DuoHexaBody-CD37 Targets B Cell Lymphomas



- DuoHexaBody-CD37 induced potent CDC across a broad panel of lymphoma cell lines expressing various levels of CD37 (Panel A).
- In whole blood, DuoHexaBody-CD37 depleted B cells, but not other leukocyte populations. B cells were the highest expressors of CD37 (Panel B)



DuoHexaBody-CD37

Anti-tumor Activity in NHL and CLL Xenograft Models



DuoHexaBody-CD37 was effective at inhibiting tumor growth in 3 different xenograft models at levels as low as 0.1 mg/kg

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DuoHexaBody-CD37

Treatment Results in Potent Tumor Cell Lysis in Variety of B Cell Malignancies - More Potent than CD20 Antibodies



Ex Vivo evaluation of tumor cell lysis following DuoHexabody-CD37 treatment (10 ug/ml)



Ex Vivo evaluation of tumor cell lysis in samples from patients previously treated with a CD20 antibody.



Summary for DuoHexaBody-CD37

- Novel antibody format engineered by Genmab → bispecific DuoHexaBody
- Demonstrates potent *in vitro* and *in vivo* B cell targeting
- Aiming for IND in 2019
- Posters presented at ASH meeting:
 - Abstract # 4170
 - Abstract # 4179





DuoBody®-CD3xCD20 (GEN3013)

CD3 ϵ on T cells

- on all T cell subtypes
- part of the T cell receptor
- crosslinking induces T cell activation

CD20 on B cells

- on pre-B cells to plasmablasts
- Expressed on a wide variety of B cell malignancies
- A validated therapeutic target





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DuoBody-CD3XCD20

T cell Activation and Cytotoxicity Across B Cell Tumor Lines



Genmab

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DuoBody-CD3XCD20

Subcutaneous & IV Formats Both Result in B Cell Depletion in Cynomolgus Monkeys





Summary DuoBody-CD3XCD20

- DuoBody-CD3XCD20 results in potent CD4 and CD8 T cell activation and tumor cell cytotoxicity in vitro
- DuoBody-CD3XCD20 reduces in vivo B cell tumor growth in multiple models
- In cynomolgus monkeys, both subcutaneous and IV delivered DuoBody-CD3XCD20 results in rapid and sustained B cell depletion in the periphery and the lymph nodes
- DuoBody-CD3XCD20 is being evaluated in FIH clinical trial (NCT 03625037)
- Poster abstract #1664

2019 & Beyond: An Exciting Future Founded on Innovation and Expertise

Dr. Jan van de Winkel President & CEO





An Exciting Future Founded on Innovation and Expertise Basic Immunological Principles → Technologies & differentiated Products



We are curious to understand basic immunological principles

We translate this to practical applications

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An Exciting Future Founded on Innovation and Expertise Platform Technology Suite \rightarrow Expanding Product Pipeline

Technology	Principle	Applications
DuoBody®	Bispecific antibodies	Dual targeting: - Recruitment (e.g. T cells) - Tumor heterogeneity
HexaBody®	Target-mediated enhanced hexamerization	Enhanced potency: - CDC - Target clustering, outside-in signaling, apoptosis
DuoHexaBody™	Bispecific antibodies with target- mediated enhanced hexamerization	Dual targeting + enhanced potency - CDC - Target clustering, outside-in signaling, apoptosis
HexElect™	Two co-dependent antibodies with target-mediated enhanced hexamerization	Dual targeting + enhanced potency & selectivity: - Co-dependent unlocking of potency - New target space, previously inaccessible



An Exciting Future Founded on Innovation and Expertise

Future Transformative Medicines in the Clinic





An Exciting Future Founded on Innovation and Expertise 2019 IND Candidates





DuoHexaBody-CD37

- Based on DuoBody & HexaBody platforms
- Potential in B cell malignancies



An Exciting Future Founded on Innovation and Expertise



2019 & Beyond: Key 2019 Priorities

Dr. Jan van de Winkel President & CEO





Key 2019 Priorities Building a Robust Differentiated Product Portfolio

Priority	\checkmark	Targeted Milestones
Maximize daratumumab progress		 » FDA decision on Phase III MAIA & CASSIOPEIA multiple myeloma (MM) submission » Phase III COLUMBA MM subcutaneous (SC) daratumumab efficacy analysis
Optimize ofatumumab value		» Phase III ASCLEPIOS I & II relapsing multiple sclerosis SC ofatumumab study completion and reporting
Maximize tisotumab vedotin progress		» Phase II tisotumab vedotin recurrent / metastatic cervical cancer study enrollment complete by mid year
Strengthen innovative product pipeline		 Phase II enapotamab vedotin expansion cohort efficacy analysis Phase I/II HexaBody-DR5/DR5 initial clinical data Phase I/II DuoBody-CD3xCD20 clinical data dose escalation cohorts File INDs or CTAs for 3 new products



On Track to Realize Our Vision:

By 2025, Our Own Product has Transformed Cancer Treatment and We Have a Pipeline of Knock-your-socks Off Antibodies



Q&A







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