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antibodies,
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Post ASH Seminar

Fueling Growth Through Our Platforms and Products

December 10, 2103

Live in New Orleans 12:30PM – 3:00PM CST

Via WebEx 7:30PM – 9:30PM CET



Forward Looking Statement

This presentation contains forward looking statements. The words “believe”, “expect”, “anticipate”, “intend” and “plan” and similar expressions identify forward looking statements. All statements other than statements of historical facts included in this presentation, including, without limitation, those regarding our financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to our products), are forward looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward looking statements. Such forward looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future. The important factors that could cause our actual results, performance or achievements to differ materially from those in the forward looking statements include, among others, risks associated with product discovery and development, uncertainties related to the outcome of clinical trials, slower than expected rates of patient recruitment, unforeseen safety issues resulting from the administration of our products in patients, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products obsolete, and other factors. Further, certain forward looking statements are based upon assumptions of future events which may not prove to be accurate. The forward looking statements in this document speak only as at the date of this presentation.

Agenda

12:30PM Welcome

Jan van de Winkel, PhD, *President & CEO*

12:40PM Ofatumumab: News from ASH

Ofatumumab

Prof. Peter Hillmen, MD, *Leeds Teaching Hospitals NHS Trust*

Nikolai Brun, MD, *VP, Medical Dept.*

Jan van de Winkel

Ofatumumab Q&A

Peter Hillmen

Jan van de Winkel

Nikolai Brun

1:25PM Daratumumab: The evolving Multiple Myeloma landscape

Daratumumab

Paul Richardson, MD, *Dana Farber Cancer Institute*

Jan van de Winkel

Daratumumab Q&A

Paul Richardson

Torben Plesner, MD, *Vejle Hospital*

Jan van de Winkel

Nikolai Brun

1:55PM World class antibody expertise

Advances in our proprietary technologies

Jan van de Winkel

Looking ahead: Milestones for 2014

Jan van de Winkel

Q&A

Jan van de Winkel

David Eatwell, *EVP & CFO*

2:30PM Refreshments

The Genmab Advantage

World Class Products and Technologies

- Focus on human antibodies to treat cancer
- Arzerra® on the market with growing sales and potential label expansions in the future
- Daratumumab development program building steam
- HuMax®-TF-ADC clinical study underway
- Robust pre-clinical pipeline
- Innovative proprietary technologies – DuoBody® and HexaBody™
- Blue chip partnerships
- Solidly on track to sustainable profitability

Achievements in 2013 Across All Business Areas



Ofatumumab



Daratumumab



Pipeline



Partnerships

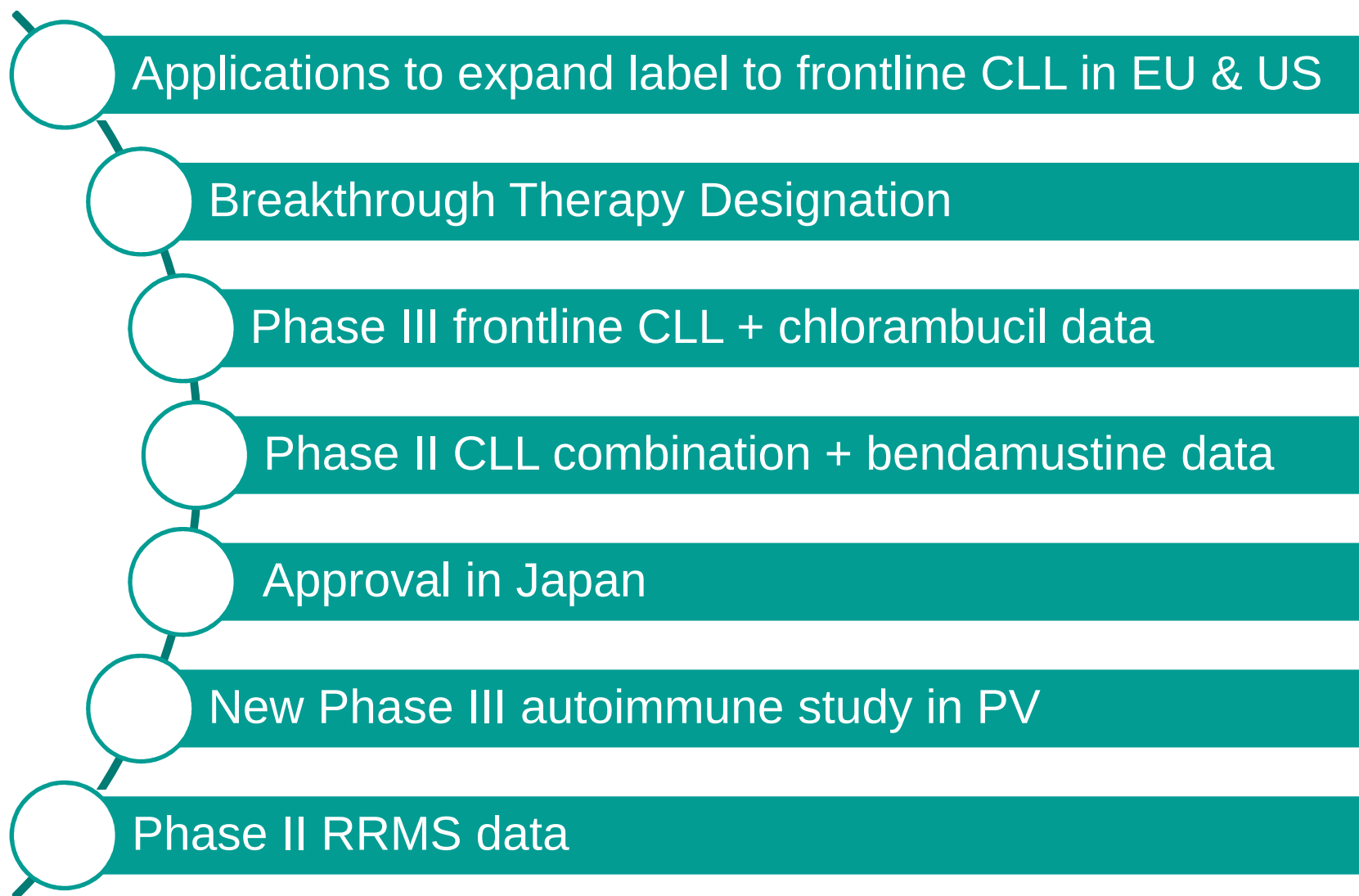


Technology

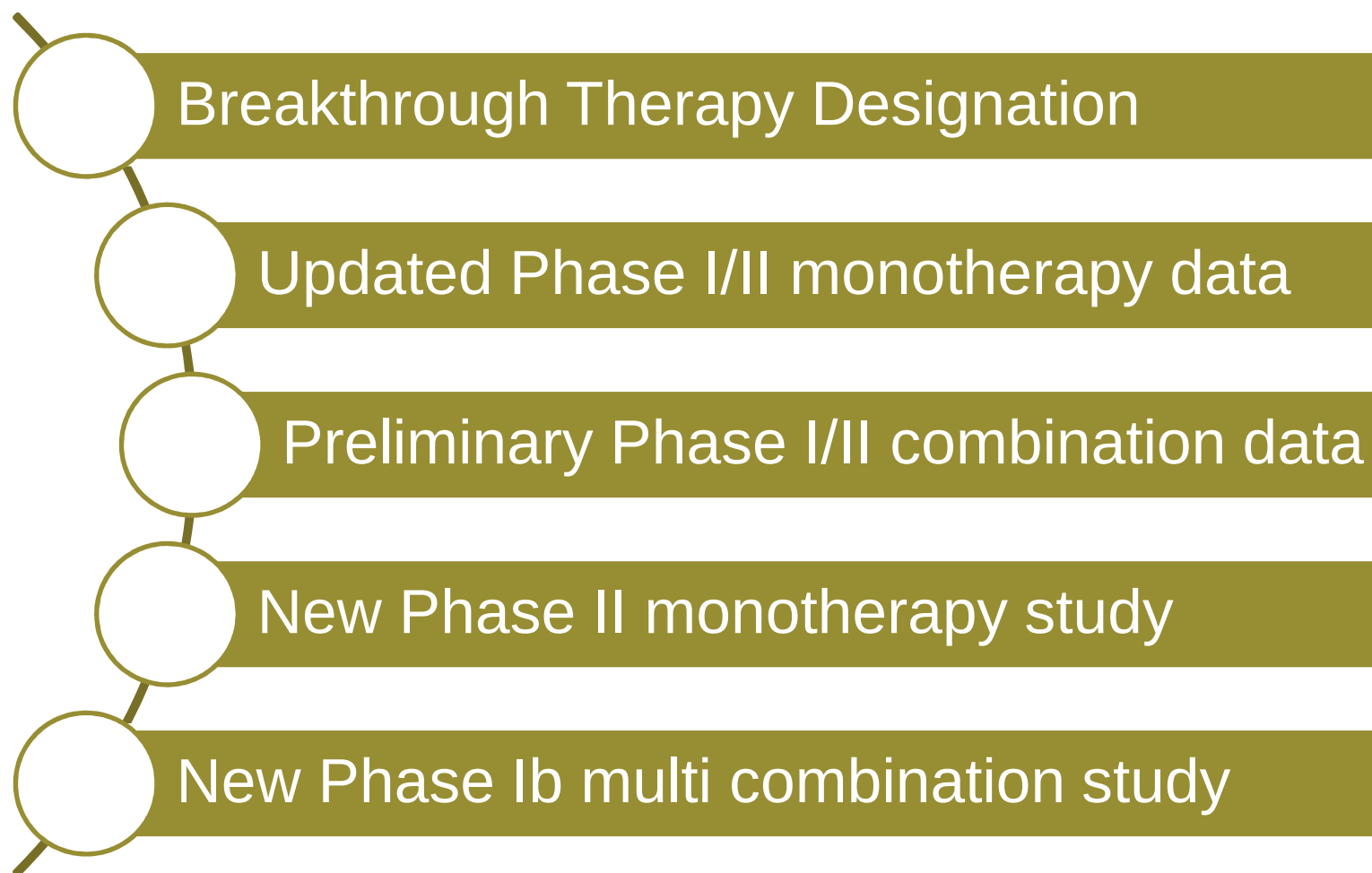


Finances

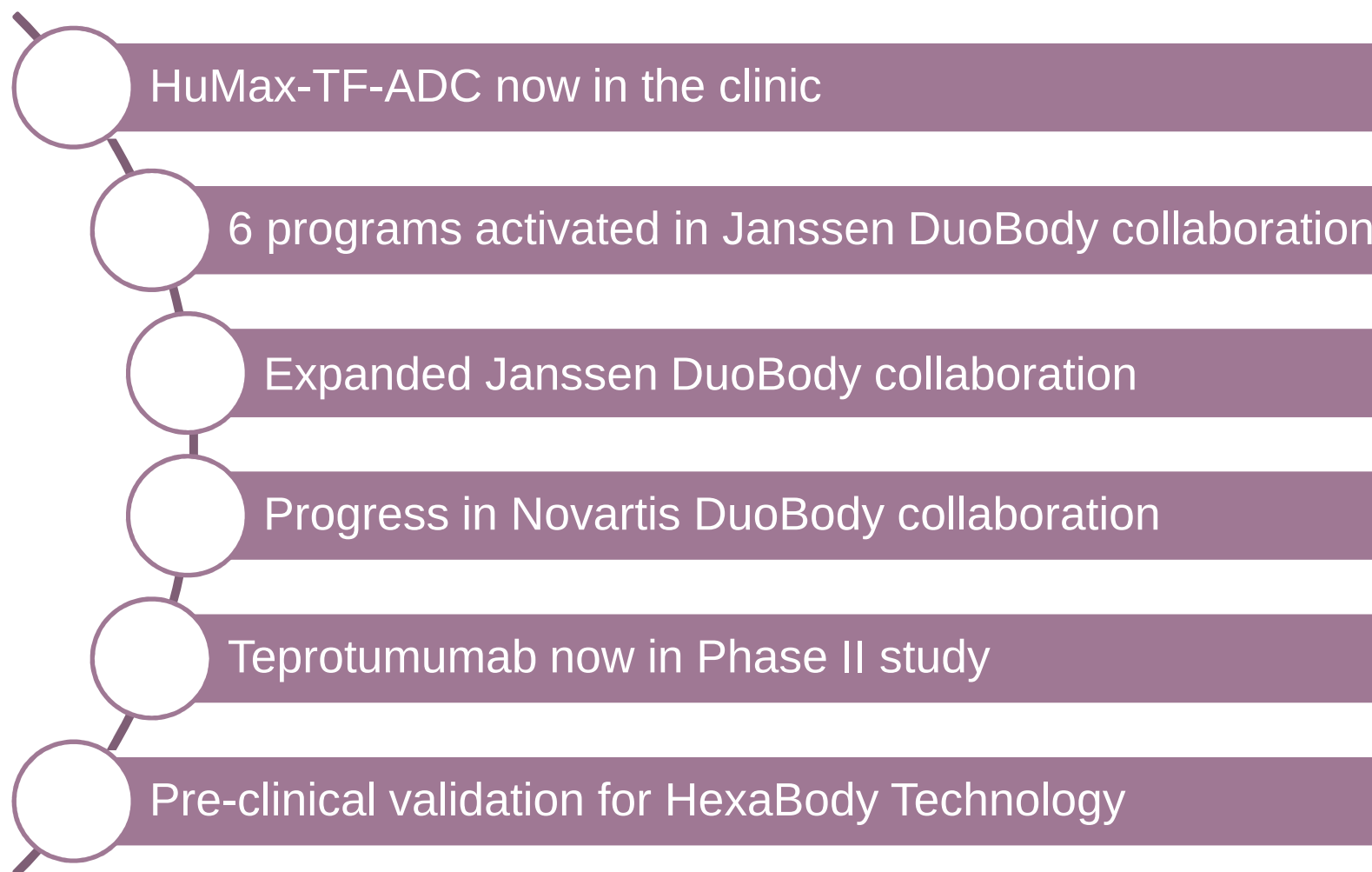
Maximizing the Value of Ofatumumab



Building on Strong Daratumumab Data



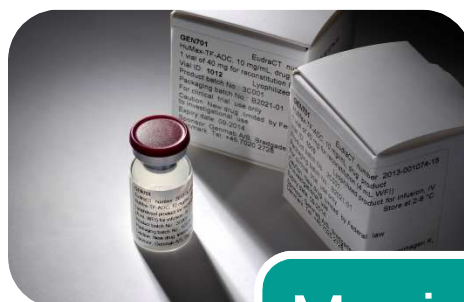
Advancing Our Pipeline and Technologies



2014 Promises to be an Exciting Year



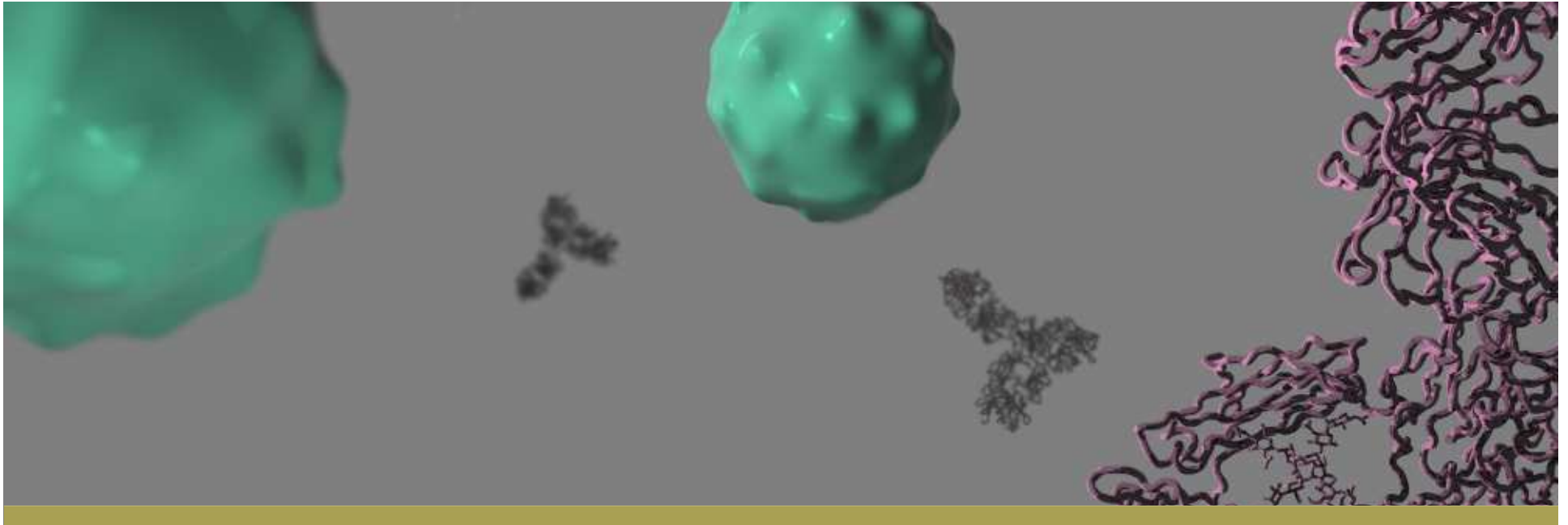
Four ofatumumab
Phase III readouts



Moving HuMax-TF-
ADC forward



Building on strong
daratumumab data



News from the Clinic

Ofatumumab

Presented by Prof. Peter Hillmen
Leeds Teaching Hospitals NHS Trust



Ofatumumab + Chlorambucil versus Chlorambucil alone in Patients with Untreated Chronic Lymphocytic Leukemia (CLL)

Results of the Phase III Study COMPLEMENT 1 (OMB110911)

Abstract #528,

*Session: 642. CLL: Therapy, excluding Transplantation: Chemoimmunotherapy Clinical Trials
Monday, December 9, 2013: 4:00 PM*

**Peter Hillmen, Tadeusz Robak, Ann Janssens, K. Govindbabu, Janusz Kloczko, Sebastian Grosicki, Jiri Mayer, Panagiotis Panagiotidis, Christian Lerchenmueller, Eva Kimby, Anna Schuh, Thomas Boyd, Marco Montillo, Astrid McKeown, Jodi L. Carey, Ira Gupta, Chai-Ni Chang, Steen Lisby, and Fritz Offner,
on behalf of the COMPLEMENT 1 Study Investigators**



COMPLEMENT 1: Rationale

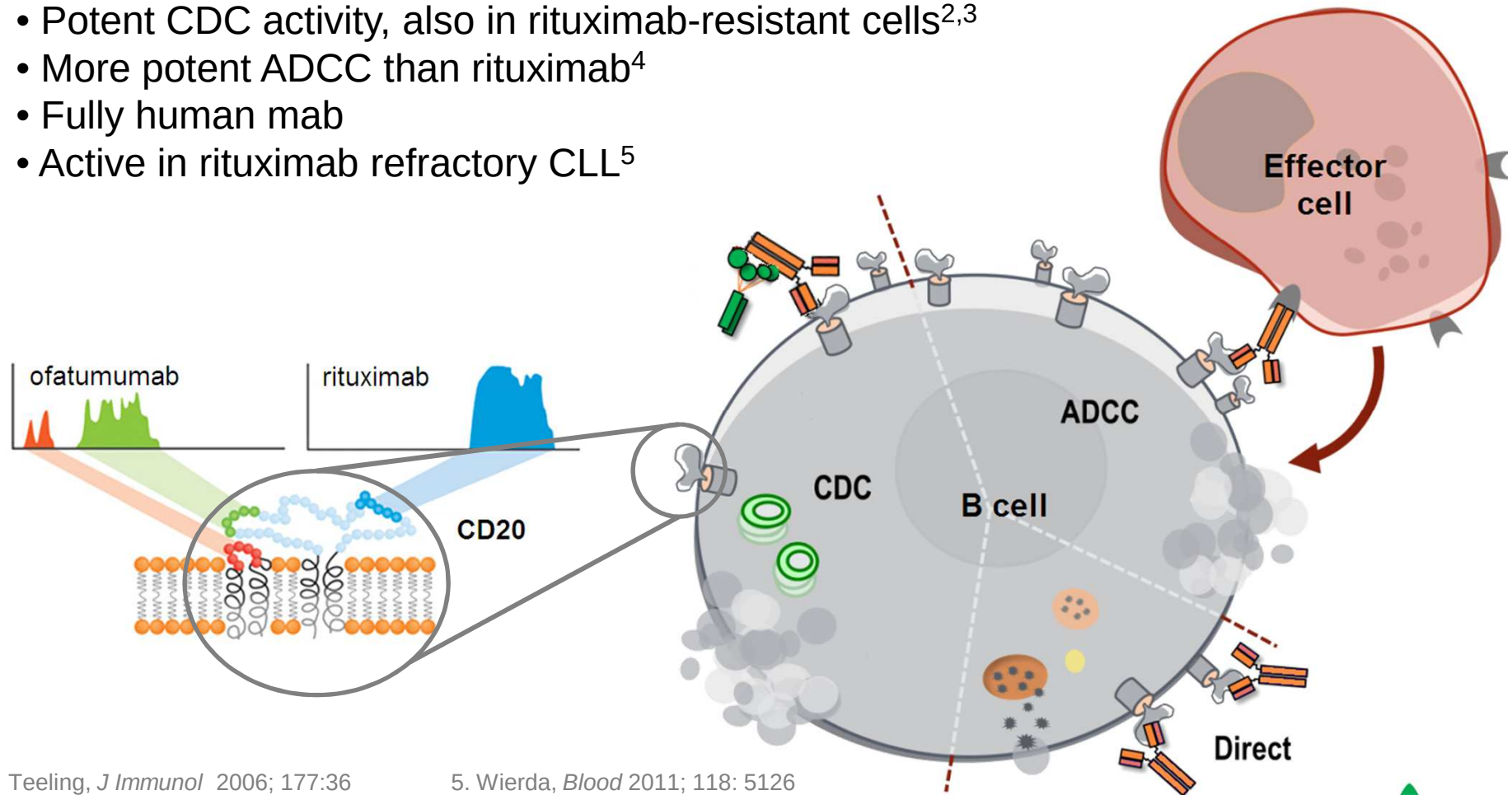
- Majority of CLL patients are elderly and have co-existing medical conditions^{1,2}
 - Limited treatment options and many are precluded from receiving FCR³
- Chlorambucil remains a valid treatment option for many of these patients with dose and duration of therapy being important^{3, 4, 5}
- Encouraging data with anti-CD20-mabs and chlorambucil showing superior efficacy than chlorambucil alone⁶
- Clinical experience with ofatumumab mono- or combination therapy in CLL (incl. 95% ORR 1L O+B)^{7, 8, 9}

1. Howlader, *SEER Cancer Statistics Review* 2013
2. Thurmes, *Leuk Lym* 2008 46:49
3. Zent, *Am Soc Clin Oncol* Ed. 2010:268
4. Woyach, *J Clin Oncol* 2012 31:440
5. Eichhorst, *Blood* 2009 114:3382

6. Hillmen, *Blood* 2010; 116:697
7. Wierda, *Blood* 2010, 116:Abstract 921
8. Wierda, *Blood* 2011, 117(24):6450
9. Offner, *IWCLL* 2013, Abstract 4.29

Ofatumumab: Mechanism of Action

- Membrane-proximal epitope encompassing small & large loop of CD20¹
- Potent CDC activity, also in rituximab-resistant cells^{2,3}
- More potent ADCC than rituximab⁴
- Fully human mab
- Active in rituximab refractory CLL⁵



1. Teeling, *J Immunol* 2006; 177:36

2. Teeling, *Blood* 2004; 104:1793

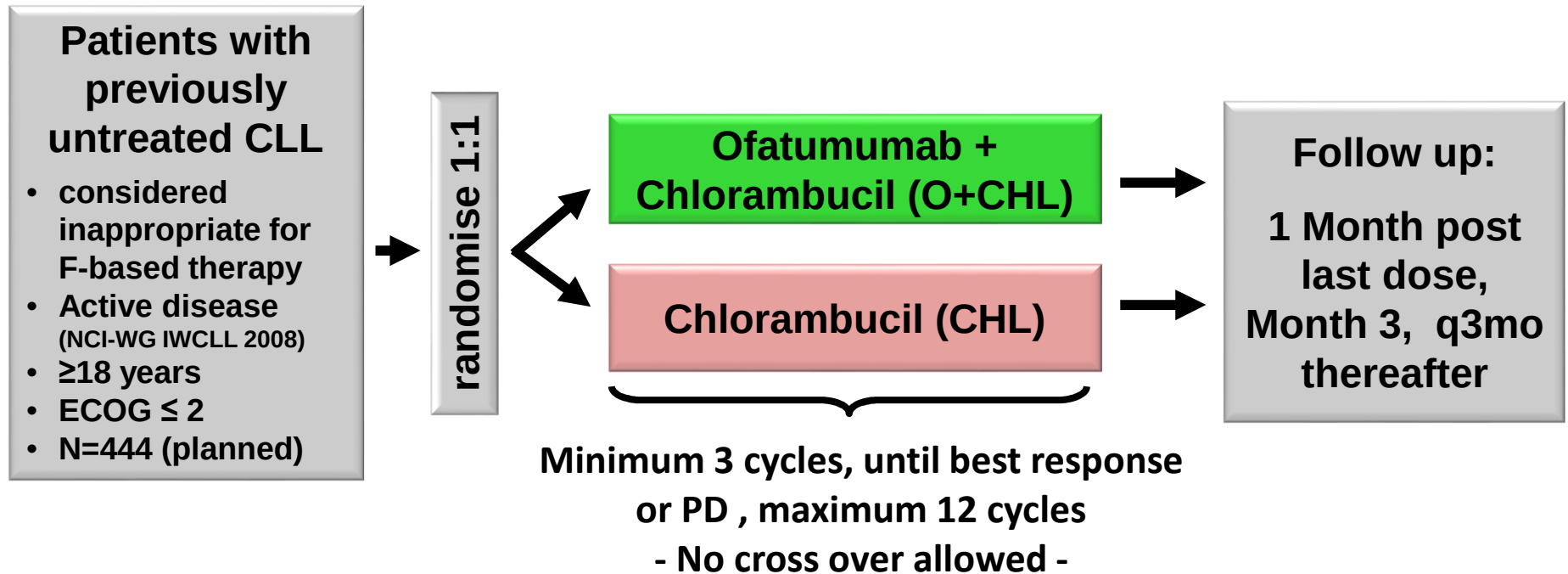
3. Barth, *Br J Haematol* 2012; 156:490

5. Wierda, *Blood* 2011; 118: 5126

4. Craig, ASH 2009 Abstract 1725

ADCC = antibody-dependent cell-mediated cytotoxicity; CDC = complement-dependent cytotoxicity; Epitope mapping image: www.pepscan.com/presto/products-services/epitope-mapping; Cell image :DAVA Oncology;

COMPLEMENT 1: Study Design



O: cycle 1 d1 300 mg, d8 1000 mg, Cycle 2-12 d1 1000 mg every 28 days

CHL: 10 mg/m² d1-7 every 28 days

Dose rationale: evidence of highest ORR and longest PFS with low toxicity compared to any other CHL monotherapy regimen

Baseline Patient Characteristics

	CHL (n=226)	O+CHL (n=221)
Age, Years, median (range)	70 (36-91)	69 (35-92)
≥ 65, %	69	69
≥ 75, %	28	25
Male, %	62	64
ECOG - 0,1, %	91	91
Comorbidities, median (range)	3 (0-10)	3 (0-10)
≥2, %	70	73
CrCl mL/min, median (min-max)	69 (21-209)	72 (26-172)
<70 mL/min, %	51	45
≥65 yrs or ≥2 comorbidities or CrCl <70 mL/min, %	87	87
CIRS, median (range)	8 (4-19)	9 (4-21)

CrCl = Creatinine Clearance, CIRS=Cumulative Illness Rating Scale,
ECOG=Eastern Cooperative Oncology Group Performance Status

Baseline Disease Characteristics

	CHL (n=226)	O+CHL (n=221)
B Symptoms, %	53	53
Rai – low/intermed/high, %	9/51/39	7/51/42
Binet – A/B/C, %	31/38/31	35/33/32
Chromosomal Aberration	(n=216)	(n=209)
17p-, %	8	5
11q-, %	11	19
+12, %	16	17
13q-, %	49	58
6q-, %	2	<1
No Aberration, %	37	26
IgVH Mutational Status	(n=203)	(n=201)
Unmutated (>98%), %	56	57
Beta-2-microglobulin	(n=217)	(n=214)
>3500 µg/L, %	78	71

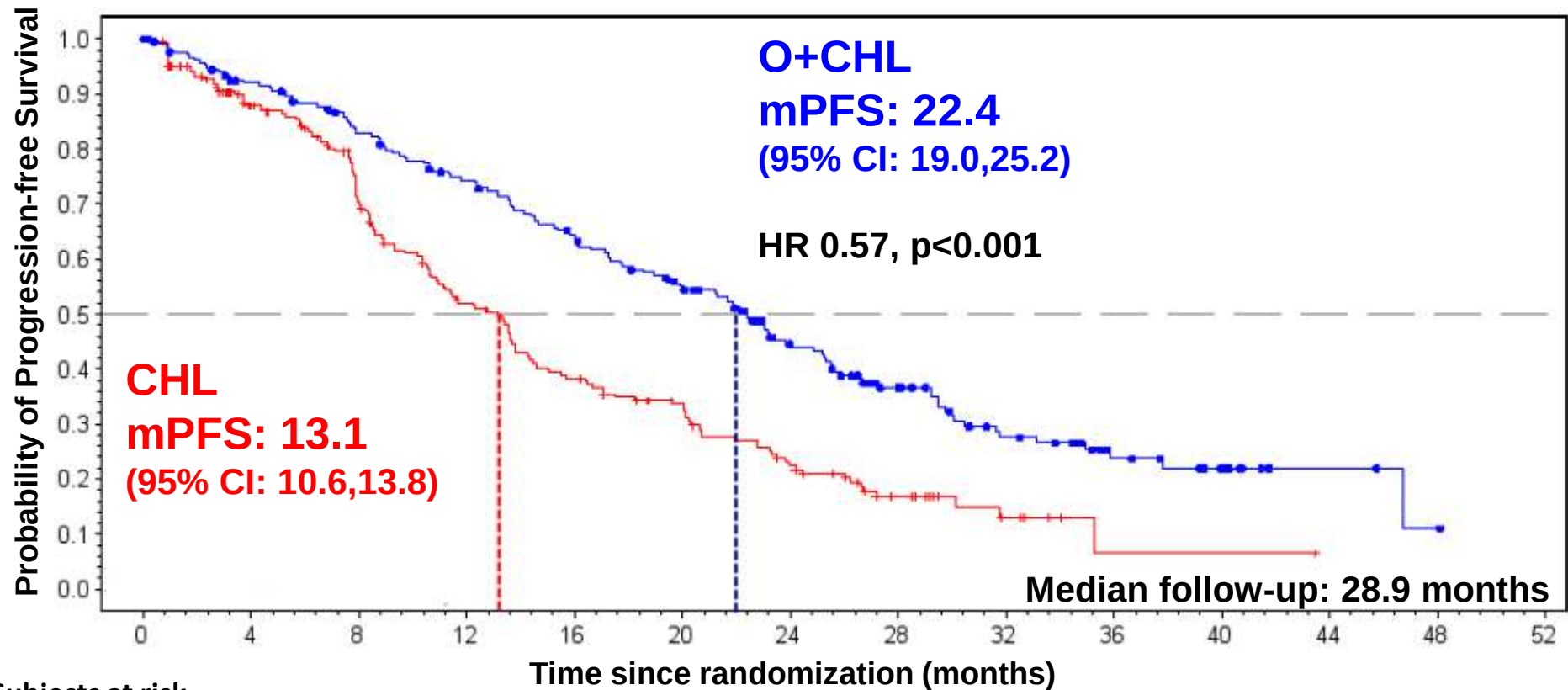


Study Treatment

	CHL (n=227)	O+CHL (n=217)
Number of cycles (mean), n	6.0	6.4
Number of cycles (median), n	6.0	6.0
Subject receiving at least 6 cycles of Ofatumumab	n/a	82%
CHL dose reductions	19%	19%

Progression-free Survival

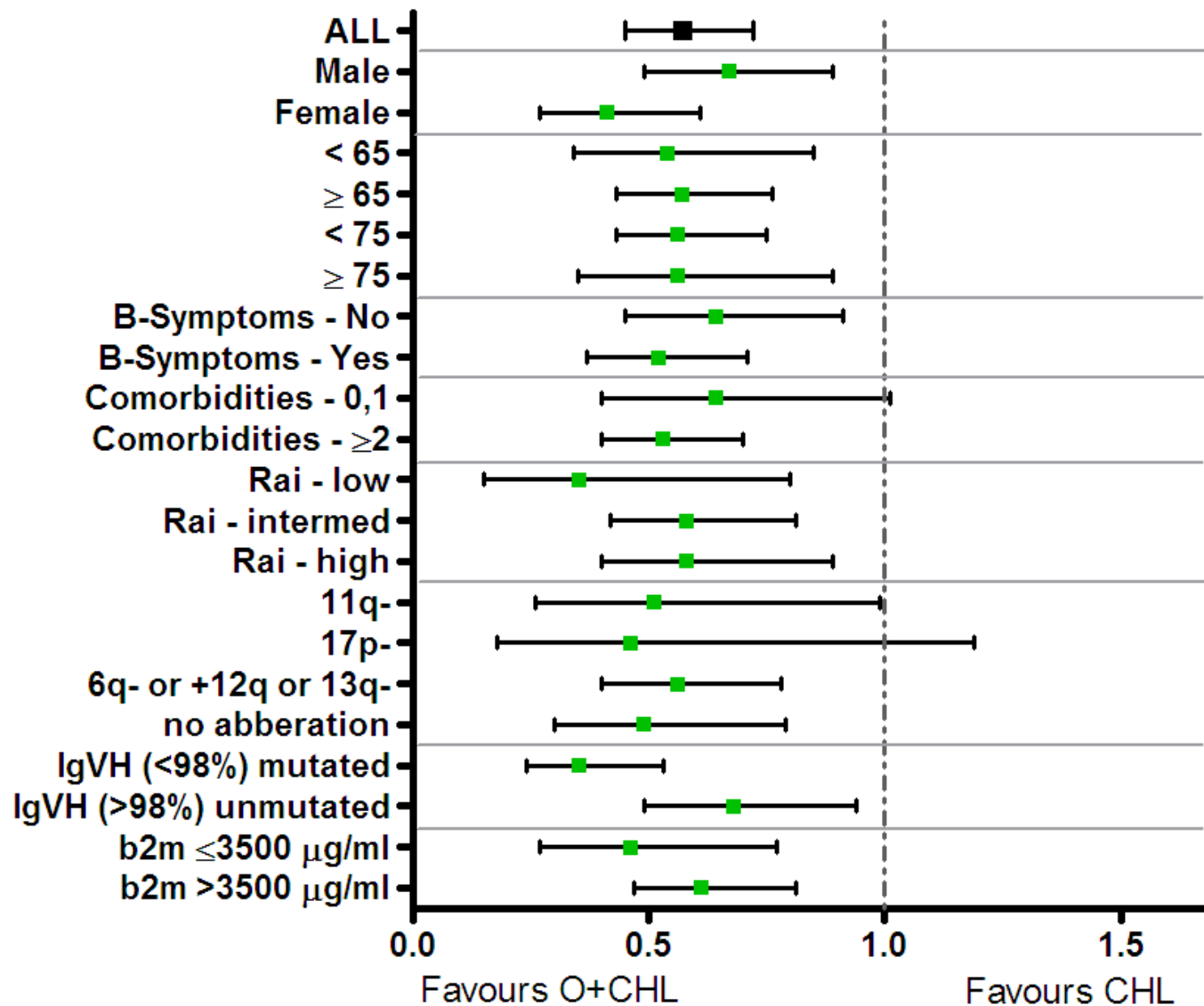
as assessed by an Independent Review Committee
(median [months])



Subjects at risk

C	226	173	130	92	67	52	33	17	6	1	1		
O+CHL	221	192	169	148	125	104	70	46	28	15	9	3	1

mPFS Subgroup Analysis



End-of-treatment Response

as assessed by an Independent Review Committee

	CHL (n=226)	O+CHL (n=221)
Overall Response Rate*, %	69	82
p-value	<0.001	
CR, %	1	14
PR, %	67	68
SD, %	23	12
PD, %	4	2
NE, %	3	3
Missing, %	<1	<1

*As per IWCLL 2008 criteria, CR includes CRi, PR includes nPR

Minimal Residual Disease

NEGATIVE MRD Assessment	CHL		O+CHL	
	N	MRD ^{neg} n (%)	N	MRD ^{neg} n (%)
All Subjects (irrespective of response or sample availability)	226	8 (4)	221	26 (12)
MRD^{neg} in PB or BM at 3M post treatment	226	4 (2)	221	19 (9)
MRD^{neg} in BM at 3M or MRD^{neg} at 6M in PB	226	5(2)	221	17 (8)
Subjects with IRC-assessed CR or CRi	3	0	32	12 (38)*
Subjects with IRC-assessed PR or nPR	152	7 (5)‡	150	14 (9)

*More than 50% of CR/CRi subject remained MRD negative in PB for >12 months, 4 subjects were MRD negative in BM (out of 8 BM samples)

‡ one subject with SD was MRD negative ; PB=peripheral blood, BM=bone marrow;
MRD Assessed by flow cytometry [Rawstron, Leukemia 2007 21:956], Protocol required MRD samples (PB and/or BM) from all pts with CR. Samples from pts with other responses if received were analysed. At least one MRD sample was available from n=315 subjects (55% from O+CHL arm); n=104 from BM (64% from O+CHL arm).

Time-to-Event Endpoints

[Months]	CHL (n=226)	O+CHL (n=221)
Time to Response*, median (95%CI)	1.9 (1.1, 1.9)	1.1 (1.0, 1.9)
HR, p-value	0.85,=0.084	
Duration of Response*, median (95%CI)	13.2 (10.8, 16.4)	22.1 (19.1, 24.6)
HR, p-value	0.56,<0.001	
Time to Next Therapy, median (95%CI)	24.7 (22.6, 29.1)	39.8 (34.7, 48.8)
HR, p-value	0.49,<0.001	

*Responders only

Overall Survival

	CHL (n=226)	O+CHL (n=221)
Overall survival (median), months	NR	NR
p-value	p=0.666	
Overall Survival 2 yrs , %	86.7	88.7
Overall Survival 3 yrs , %	83.2	85.1

Median follow-up: 28.9 months

Adverse Event Overview

(Reporting period: from first dose to 60 days after last dose¹⁾)

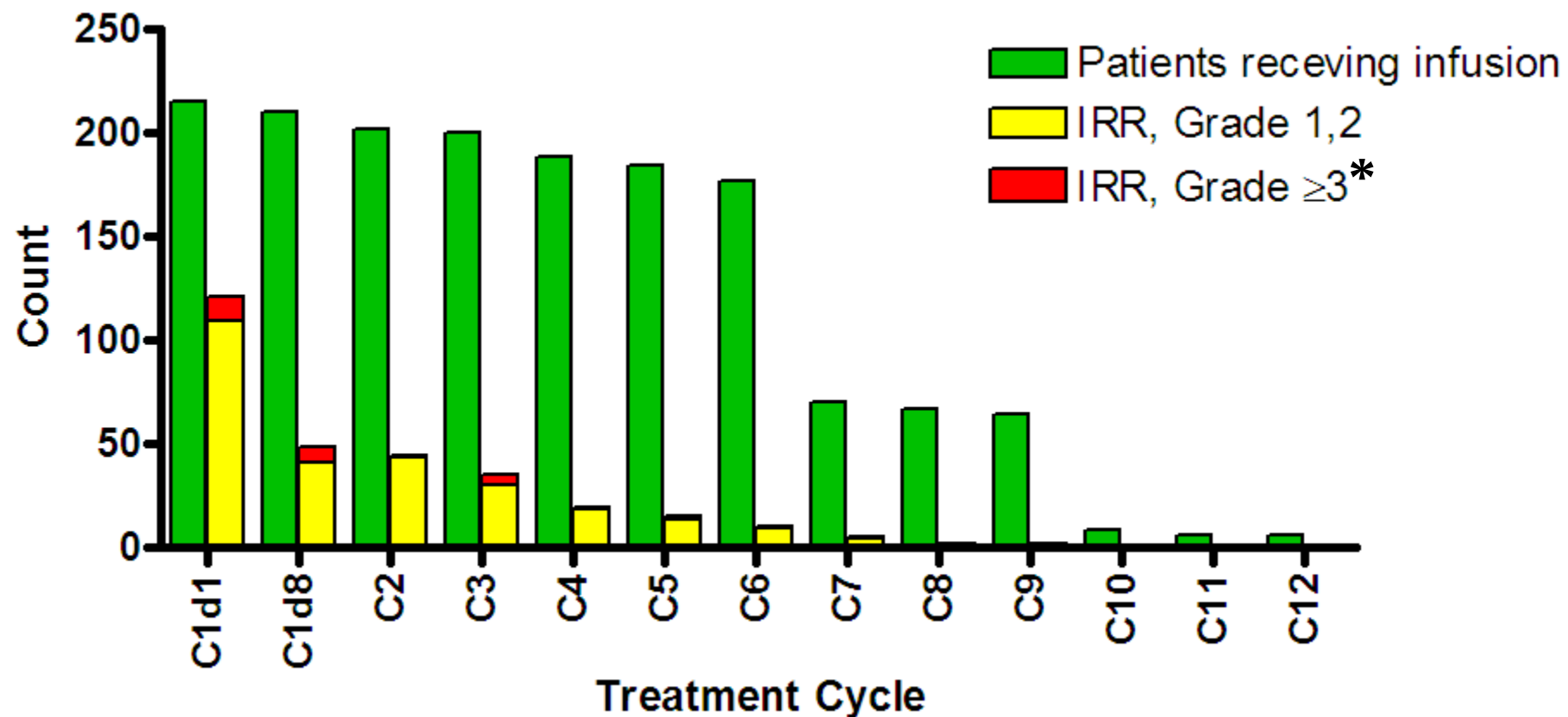
Patient with AE, %	CHL (n=227)	O+CHL (n=217) ²
AEs, any	87	94
AEs related to study treatment	65	84
AEs leading to WD of treatment	13	13
AEs ≥ Grade 3	43	50
Infusion-related Reactions (IRR)³	n/a	10
Neutropenia	14	26
Thrombocytopenia	10	5
Anemia	5	5
Infections	12	9
Death (includes death due to PD)	3	4

1. Data for treatment plus up to 60 days after last dose is reported to allow inclusion of any event that could be caused by the drug prior to its clearance.
2. Safety population is based on the actual treatment subject received, 3 subjects who did not receive any treatment were excluded, CHL population includes 2 subjects from the O+CHL arm who did not receive O
3. Defined as onset occurring after the start of infusion and within 24 hours of infusion end



COMPLEMENT 1

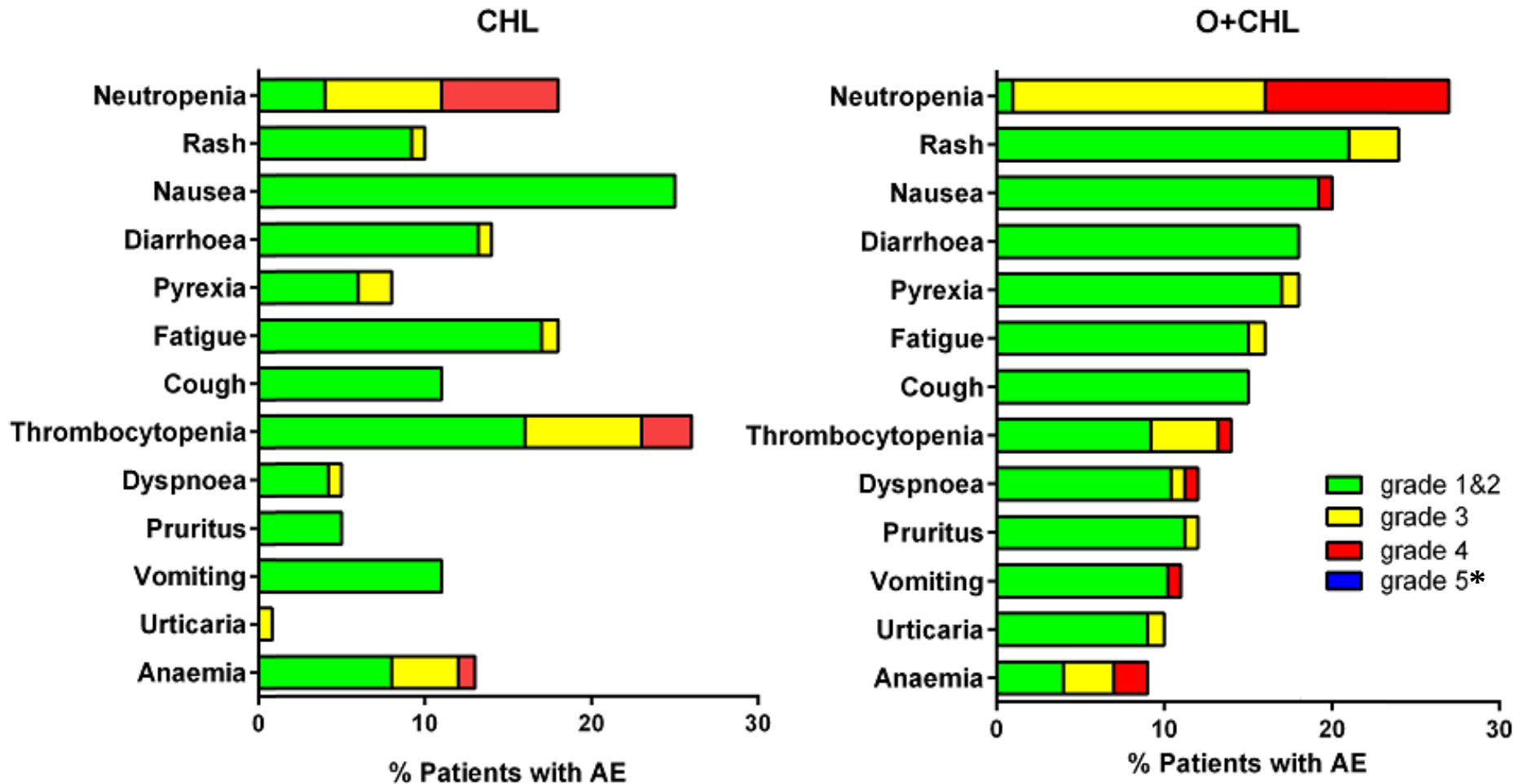
Infusion-related Reactions



* None of the events Grade ≥ 3 was a grade 5 event

Most Common AEs

(as reported by investigator; Cut-off: Any Grade occurring in $\geq 10\%$ of patients, reporting period: from first dose to 60 days after last dose)



*there were no grade 5 events in listed events

COMPLEMENT 1: Data Summary (1)

Addition of ofatumumab to chlorambucil is associated with:

- **Improved mPFS:** 71% improvement (22.4 vs 13.1 m)
- **Extended treatment-free period:** Additional 15 months (39.8 vs 24.7m)
- **Increased response:** ORR (82% vs 69%); CR rate (14% vs 1%)
- **Improved and durable MRD negativity:** 12% vs 4% in all subjects (irrespective of response or MRD sample available), for pts with CR: 38% vs 0%
- **Improved efficacy irrespective of age or fitness**

COMPLEMENT 1: Data Summary (2)

Safety observations were:

- **Tolerability irrespective of age or fitness:** >80% subjects completed at least 6 cycles, WD due to AE equal for O+CHL and CHL (13 vs 13%)
- **Mostly mild IRRs with diminishing frequency/severity:** 6% Gr ≥ 3 at first infusion, 3% or less subsequently
- **No additional infection risk** (Gr ≥ 3 : 9% O+CHL vs.12%), despite **increased neutropenia:** 26 vs.14% (Gr ≥ 3)
- **Improved thrombocytopenia:** 5 vs.10% (Gr ≥ 3)

Conclusions

COMPLEMENT 1: Ofatumumab added to chlorambucil in previously untreated patients with CLL who are considered inappropriate for fludarabine based therapy demonstrated:

- **Effective treatment with clinically meaningful improvements**
- **Side effect profile that is expected and manageable**
- **Suitable for an unfit patient population**

Acknowledgments

We would like to thank all the patients who participated in the study and the investigators from all study sites (listed alphabetical by country and last name) and their site staff for their contributions

Belgium: A. Delannoy, A. Jannsens, F. Offner, E. Van den Neste, A. Van Hoof; **Brazil:** V. Buccheri, M. Capra, N. Hamerschlag; **Canada:** M. Cheung; **Czech Republic:** T. Kozak, J. Mayer, L. Smolej; **Germany:** C. Beck, HG. Derigs, J. Duerig, M. Hallek, M. Hensel, E. Hoering, C. Lerchenmueller, A. Matzdorff, B. Schmidt, U. Soeling, H. Stauder; **Greece:** A. Anagnostopoulos, A. Kioumi, P. Panagiotidis; **India:** U. Agarwal, K. Govindbabu, M. Jain, V. Raina, R. Vinod, M. Sengar, B. Shah, Bhavin; **Ireland:** M. Cahill, G. Crotty, A. Hayat, B. Hennessy, D. O'Keeffe, E. Vandenberghe; **Italy:** F. Angelini, F. Ferrara, G. Gaidano, P. Galieni, PP. Ghia, AM. Gianni, M. Gobbi, M. Montillo, M. Musso, F. Pane, M. Pizzuti, R. Rizzi, G. Rossi, F. Zaja; **Netherlands:** GW Van Imhoff, MR. Schipperus; **Poland:** S. Grosicki, W. Homenda, J. Kloczko, K. Kuliczowski, T. Robak, K. Warzocha; **Russian Federation:** K. Abdulkadyrov, B. Afanasyev, L. Kovaleva, D. Osmanov, V. Ptushkin; **Spain:** ME. Abella Monreal, MA Canales Albendea, EM. González Barca, M. González Díaz, M. Granell Gorrochategui, J. Loscertales Pueyo; **Sweden:** M. Höglund, E. Kimby, B. Lauri; **United Kingdom:** K. Bowles, M. Dungarwalla, G. Follows, J. Gribben, E. Heartin, P. Hillmen, R. Jan-Mohamed, S. Jowitt, Simon, C. Knechtli, S. Marshall, D. Milligan, J. Neilson, R. Noble, D. Oscier, A. Pettitt, C. Pocock, S. Rule, A. Schuh, A. Stewart, J. Wallis; **United States:** H. Adler, E. Aly, S. Beeram, W. Berry, M. Boxer, T. Boyd, J. Davis II, N. DiBella, S. Fleischauer, S. Gregory, B. Hellerstedt, R. Hermann, M. Kosmo, K. McIntyre, M. McLaughlin, A. Melnyk Jr., D. Richards, A. Rodney, M. Savin, JS. Tolman, G. Wright;

GSK authors: A. McKeown, J. Carey, I. Gupta, CN. Chang; **Genmab authors:** Steen Lisby; **GSK Study Team:** A. McKeown, O. Wright, I. Dixon, CN. Chang, J. Carey, R. Jewell, T. Wiseman, C. Wang, A. Haiderali, I. Gupta

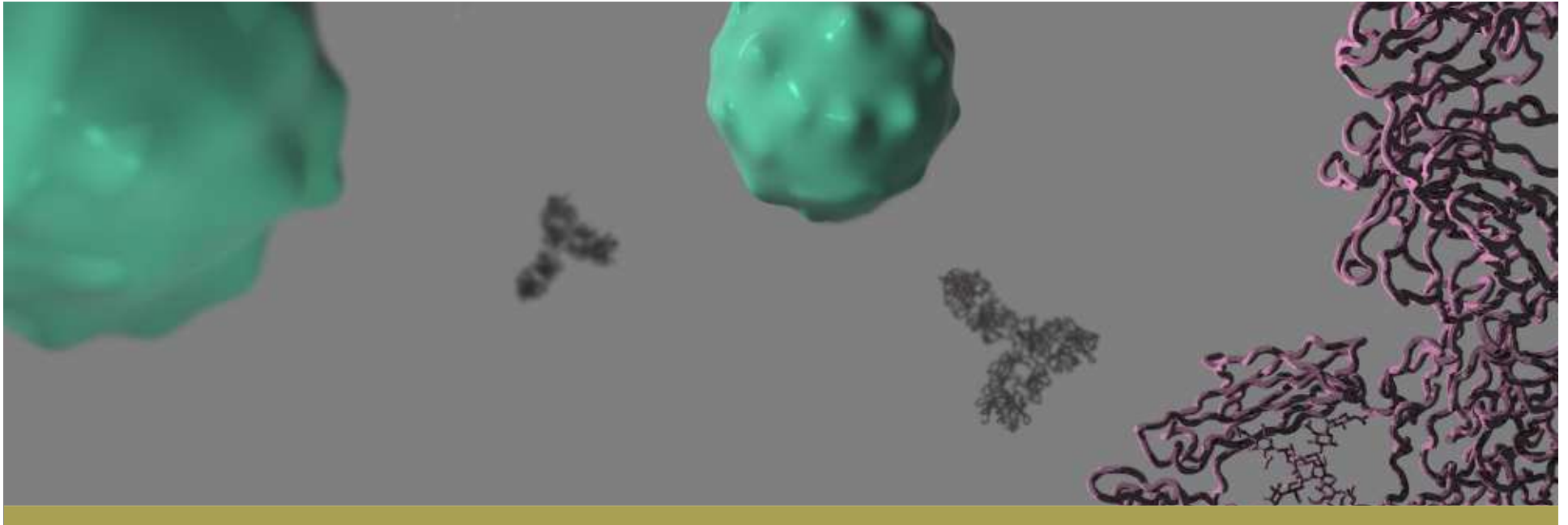
BACK-UP

Key Efficacy Results: Comparison of IRC and Investigator assessment

[Months]	CHL (n=226)	O+CHL (n=221)
IRC-assessed mPFS (95%CI)	13.1 (10.6, 13.8)	22.4 (19.0, 25.2)
HR, p-value	0.57, <0.001	
Investigator-assessed mPFS (95%CI)	14.8 (13.6, 16.8)	23.4 (21.0, 26.0)
HR, p-value	0.58, <0.001	
IRC-assessed Overall Response Rate*	69	82
p-value	<0.001	
CR Rate	1	14
INV-assessed Overall Response Rate*	81	88
p-value	.004	
CR Rate	21 [‡]	49 [‡]

*As per IWCLL 2008 criteria, CR includes CRi, PR includes nPR

‡ Discrepancy IRC vs Inv due to missing/incomplete BM, or >30% BM invasion



News from the Clinic

Ofatumumab

Presented by Nikolai C. Brun, MD, PhD

VP, Medical Department, Genmab





*Innovating
antibodies,
improving lives*

Ofatumumab and Bendamustine Combination Therapy in Patients With Untreated and Relapsed CLL - Results of Phase II Study OMB115991

Nikolai Constantin Brun

December 10, 2013



Background: Ofatumumab in Combination with Fludarabine and Cyclophosphamide¹ in Previously Untreated CLL

Ofatumumab (1000mg) + Fludarabine (25mg/m ²) + Cyclophosphamide (250mg/m ²) N=30	
Overall response rate (%)	73 (N=22)
Complete response (%)	50 (N=15)
Nodular partial response/ CR with incomplete bone marrow (%)	3 (N=1)
Partial response (%)	20 (N=6)
Median progression-free survival (months)	Not reached
Grade 3-4 neutropenia (%)	60
Grade 3-4 infections (%)	13
Grade 3-4 infusion reactions (%)	0
MRD negative in blood (%)	Not measured

¹Wierda et al. Blood 2011;117:6450-6458

Study 991 (Ofatumumab+ Bendamustine) Objectives

- The following objectives were evaluated in the two separate patient populations:
 - Primary objective: to evaluate the investigator-assessed overall response rate (ORR), according to the 2008 NCI-WG guidelines*, measured after 3 cycles, after 6 cycles, and after the last dose of study treatment
 - Secondary objectives included:
 - ORR with computed tomography (CT) scan assessment
 - Complete response (CR) rate with and without CT scan assessment
 - Progression-free survival (PFS)
 - Overall survival (OS)
 - Time to response, duration of response, time to progression and time to next therapy
 - Safety and tolerability**
 - Disease, prognostic, and biological marker correlation with clinical response

*Hallek M, Cheson BD, Catovsky D, et al. Blood 2008; 111:5446-5456

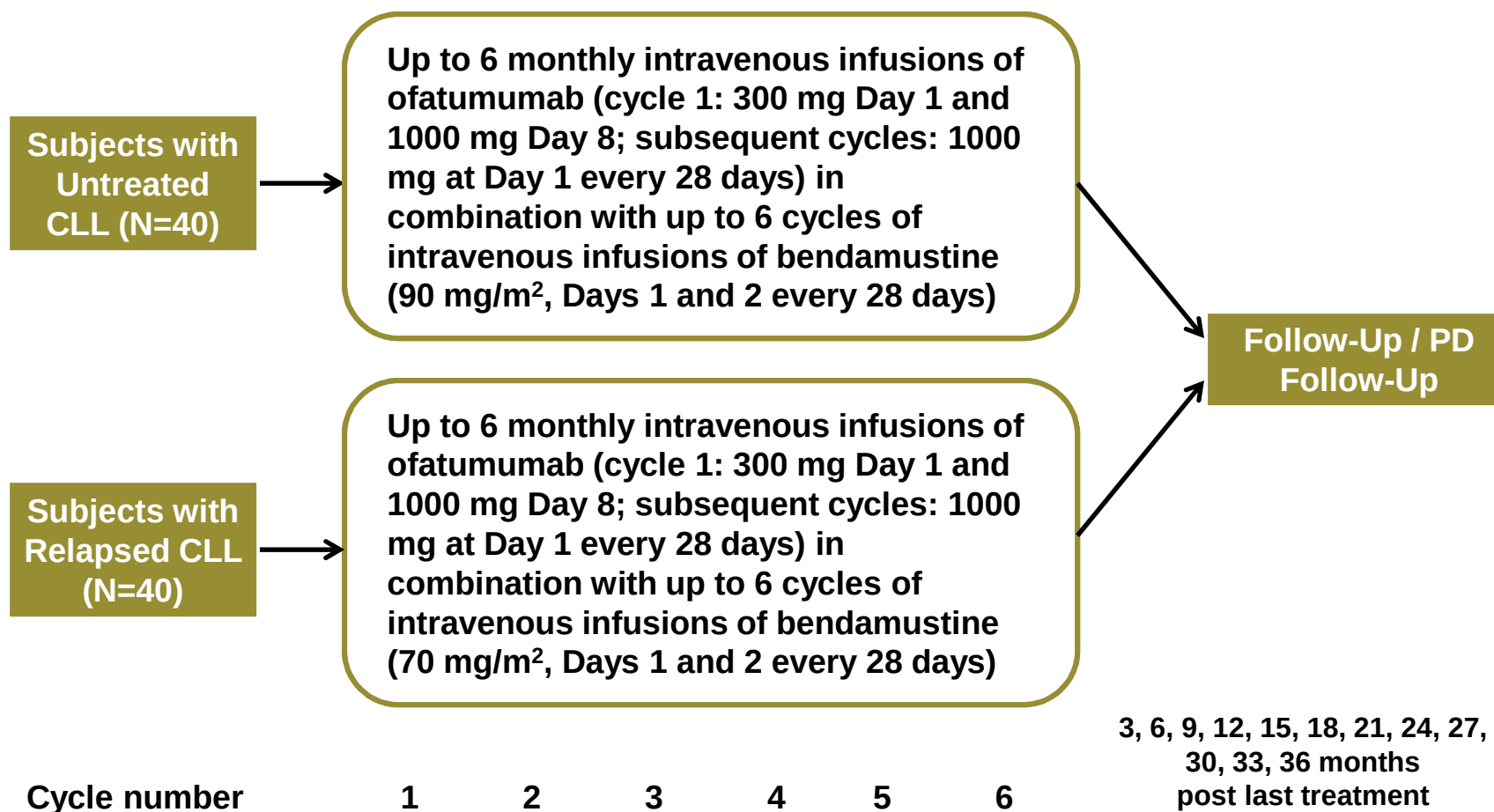
** AEs and SAEs were graded according to the National Cancer Institute's (NCI) Common Terminology for Adverse Events (CTCAE) version 4.0, with the exception of hematologic toxicities (platelets, hemoglobin, and ANC) which were graded according to the IWCLL Grading Scale for Hematological Toxicity.

Patient Population

- Inclusion criteria included previously untreated patients considered inappropriate for fludarabine-based therapy, or relapsed patients ≥ 18 years of age with CLL defined by a circulating B-lymphocyte count of $\geq 5,000/\mu\text{L}$, flow cytometry confirmation of immunophenotype with CD5, CD19, CD20, CD23, CD79b, and surface Ig, and patients who had an indication for treatment based on the 2008 National Cancer Institute-Sponsored Working Group (NCI-WG) guidelines**
- Exclusion criteria included refractory disease (in the relapsed population), defined as failing to achieve a complete or partial remission/response lasting at least 6 months to the most recent therapy, an Eastern Cooperative Oncology Group performance status of ≥ 3 , known CLL transformation, known central nervous system involvement of CLL, and known HIV-positivity

** Hallek M, Cheson BD, Catovsky D, et al. Blood 2008; 111:5446-5456

Study Design and Treatment – OMB115991



Results

Key Baseline Patient Characteristics	Previously Untreated CLL (n=44)	Relapsed CLL (n=53)
Median age, y (range)	62.5 (34-86)	68.0 (37-81)
Modified high-risk Rai Stage, %	32	57
Binet stage C, %	27	47
Median serum β_2 -microglobulin, mg/L	3.6	4.8
Median lymphocyte count, GI/L	67.6	50.0
17p Deletion, %	5	12
11q Deletion, %	18	29
Unmutated IGHV, %	66	72
ZAP70 positive, %	82	85
Completed all 6 treatment cycles, %	89	85
Median number of prior therapies (range)	-	1 (1-11)

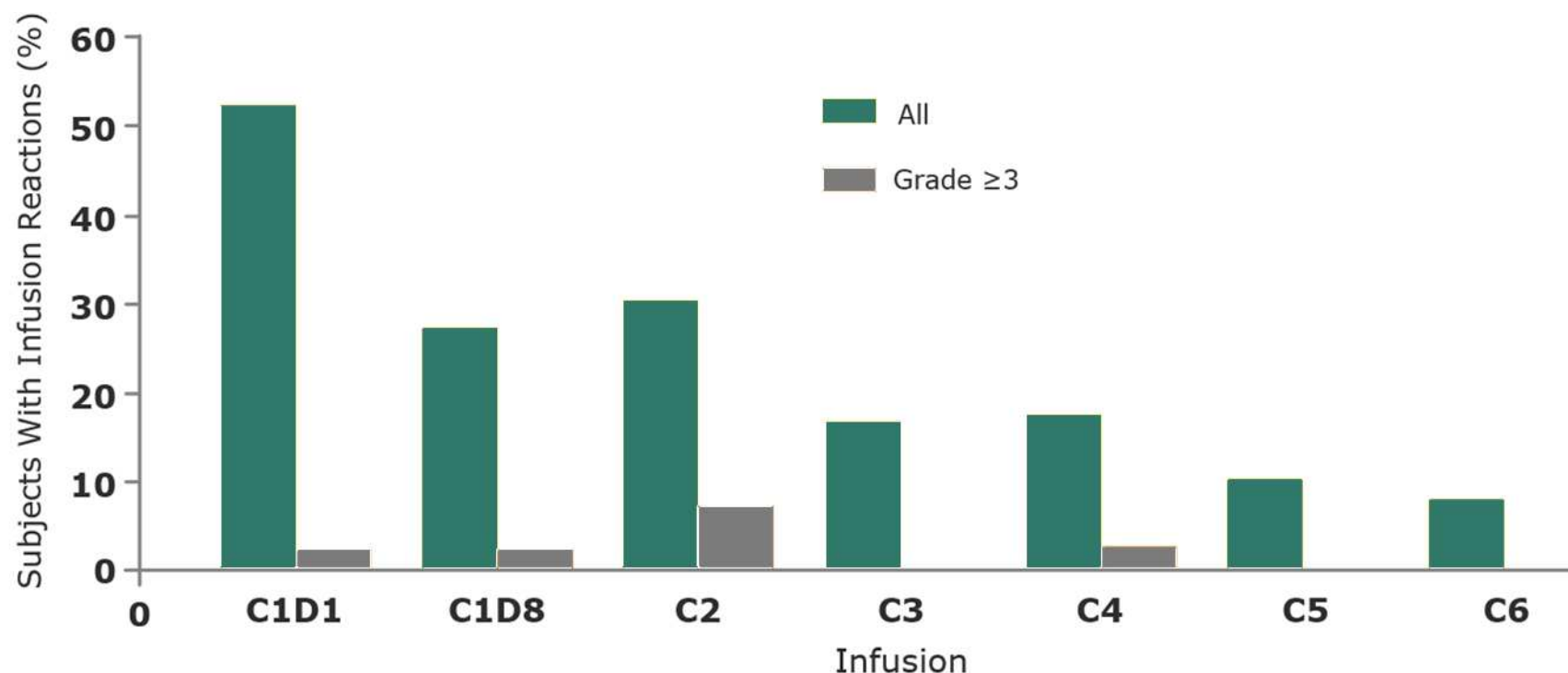
Safety: Previously Untreated Population

- Exposure: Most patients (89%) received all 6 cycles of study treatment; 2 patients (5%) received fewer than 3 cycles of therapy; 42 patients (95%) received between 3 and 6 cycles
- Adverse Events (AEs): Common ($\geq 5\%$) Grade ≥ 3 AEs occurring up to 60 days after last infusion are summarized below

Summary of Common ($\geq 5\%$) Grade 3, 4, or 5 AEs by Preferred Terms Up to 60 Days After Last Dosing (Previously Untreated Population)

Previously Untreated Population: Ofatumumab + Bendamustine 90 mg/m ² (N=44)	Grade 3	Grade 4	Grade 5
Any Event, n (%)	15 (34)	10 (23)	0
Neutropenia	7 (16)	9 (20)	0
Rash	2 (5)	0	0

Safety: Infusion Reactions by Infusion for Ofatumumab in Combination with Bendamustine (Previously Untreated Safety Population)



n	44	44	43	42	40	40	39
Count (All)	23	12	13	7	7	4	3
Percent (All)	52	27	30	17	18	10	8
Count (Grade ≥3)	1	1	3	0	1	0	0
Percent (Grade ≥3)	2	2	7	0	3	0	0

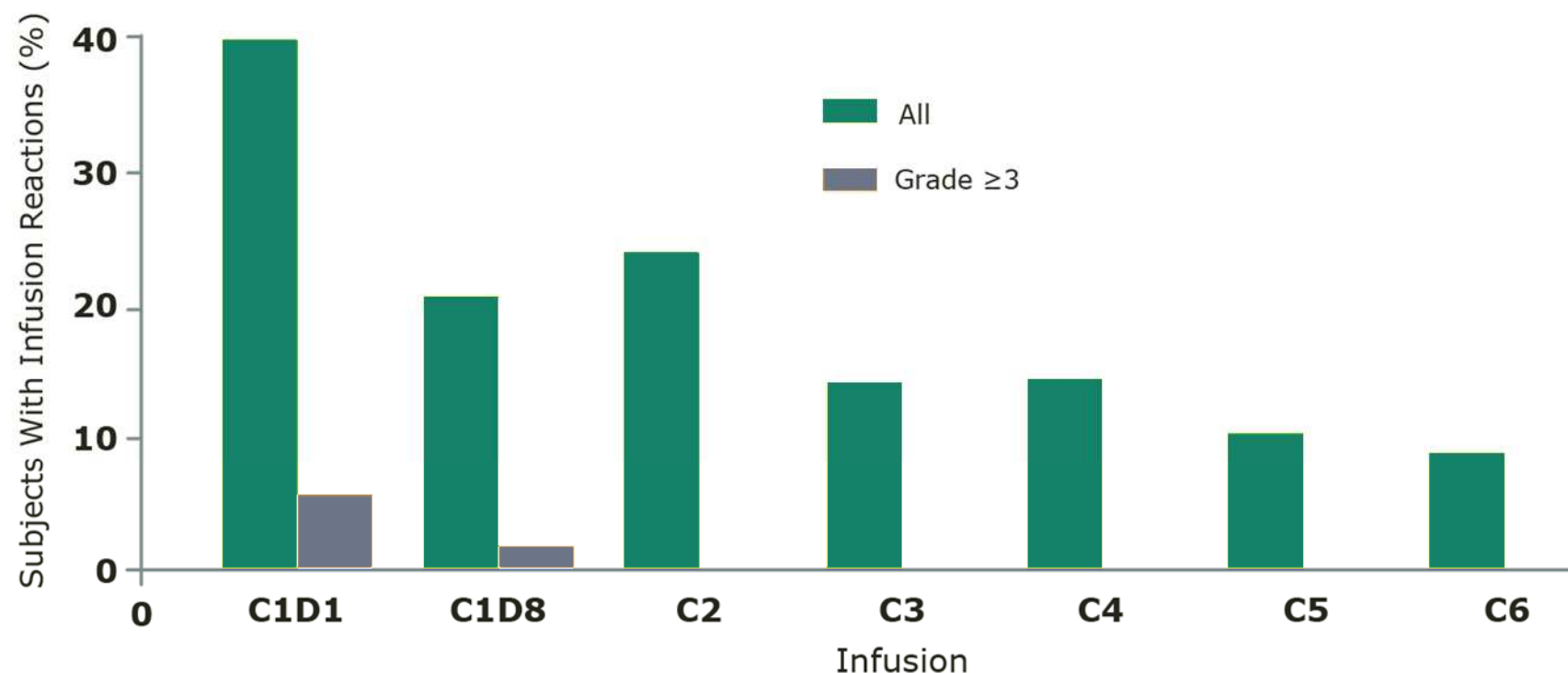
Safety: Relapsed Population

- Exposure: 85% of patients received all 6 cycles of study treatment; 4 patients (8%) received fewer than 3 cycles of therapy; 49 patients (92%) received between 3 and 6 cycles
- AEs: Common ($\geq 5\%$) Grade ≥ 3 AEs occurring up to 60 days after last infusion are summarized below

Summary of Common ($\geq 5\%$) Grade 3, 4, or 5 AEs by Preferred Terms Up to 60 Days After Last Dosing (Relapsed Population)

Relapsed Population: Ofatumumab + Bendamustine 70 mg/m ² (N=53)	Grade 3	Grade 4	Grade 5
Any Event, n (%)	17 (32)	18 (34)	3 (6)
Neutropenia	16 (30)	13 (25)	0
Febrile neutropenia	3 (6)	1 (2)	0
Thrombocytopenia	3 (6)	1 (2)	0

Safety: Infusion Reactions by Infusion for Ofatumumab in Combination with Bendamustine (Relapsed Population)



n	53	53	50	49	49	48	45
Count (All)	21	11	12	7	7	5	4
Percent (All)	40	21	24	14	14	10	9
Count (Grade ≥ 3)	3	1	0	0	0	0	0
Percent (Grade ≥ 3)	6	2	0	0	0	0	0

Efficacy: Previously Untreated Population

- 95% investigator-assessed ORR
 - 43% investigator-assessed CR rate
 - 56% minimal residual disease (MRD) negativity for the subjects who had an investigator-assessed CR and had MRD analysis performed
- With CT evaluation; 82% ORR and 27% CR rate
- Median time to response was 0.95 months
- As of the data cut-off (median duration on study was approximately 8.5 months), time-to-event endpoints of duration of response, PFS, time to progression, OS, and time to next anti-CLL therapy were not yet mature

Summary of Overall Response Rate as Assessed by the Investigator (Previously Untreated Population)

Ofatumumab + Bendamustine 90 mg/m ²	After 3 Cycles (N=42) ^a	After 6 Cycles (N=39) ^b	Overall Response After Last Dose (N=44)
Overall Response, n (%)			
Complete Response (CR)	15 (36)	19 (49)	19 (43)
Complete Response w/incomplete Bone Marrow (CRi)	0	2 (5)	2 (5)
Partial Response (PR)	23 (55)	13 (33)	17 (39)
Nodular Partial Response (nPR)	0	4 (10)	4 (9)
Stable Disease	3 (7)	0	1 (2)
Progressive Disease	0	0	0
Not Evaluable	0	0	0
Missing	1 (2)	1 (3)	1 (2)
Responder, n (%)			
Yes (CR + CRi + nPR + PR)	38 (90)	38 (97)	42 (95)
No	4 (10)	1 (3)	2 (5)
95% CI for (CR + CRi + nPR + PR) ^c	(77.38, 97.34)	(86.52, 99.94)	(84.53, 99.44)

^a N is the number of patients who completed study treatment at cycle 1, 2, and 3.

^b N is the number of patients who completed all 6 cycles of study treatment.

^c 95% exact binomial confidence interval (CI) for CR +CRi +nPR +PR.

Efficacy: Relapsed Population

- 74% investigator-assessed ORR
- 11% investigator-assessed CR
- No patients who had an investigator-assessed CR and had MRD analysis performed were MRD negative
- With CT evaluation, 70% ORR and 9% CR
- Median time to response was 0.95 months
- As of the data cut-off (median duration on study was approximately 8.7 months), median time-to-event endpoints of duration of response, PFS, time to progression, OS, and time to next anti-CLL therapy were either not reached, or were not interpretable due to immaturity of the data

Summary of Overall Response Rate as Assessed by the Investigator (Relapsed Population)

Ofatumumab + Bendamustine 70 mg/m ²	After 3 Cycles (N=49) ^a	After 6 Cycles (N=45) ^b	Overall Response After Last Dose (N=53)
Overall Response, n (%)			
Complete Response (CR)	11 (22)	6 (13)	6 (11)
Complete Response w/incomplete Bone Marrow (CRi)	1 (2)	2 (4)	2 (4)
Partial Response (PR)	30 (61)	21 (47)	23 (43)
Nodular Partial Response (nPR)	0	8 (18)	8 (15)
Stable Disease	7 (14)	0	5 (9)
Progressive Disease	0	7 (16)	8 (15)
Not Evaluable	0	0	0
Missing	0	1 (2)	1 (2)
Responder, n (%)			
Yes (CR + CRi + nPR + PR)	42 (86)	37 (82)	39 (74)
No	7 (14)	8 (18)	14 (26)
95% CI for (CR + CRi + nPR + PR) ^c	(72.76, 94.06)	(67.95, 92.00)	(59.67, 84.74)

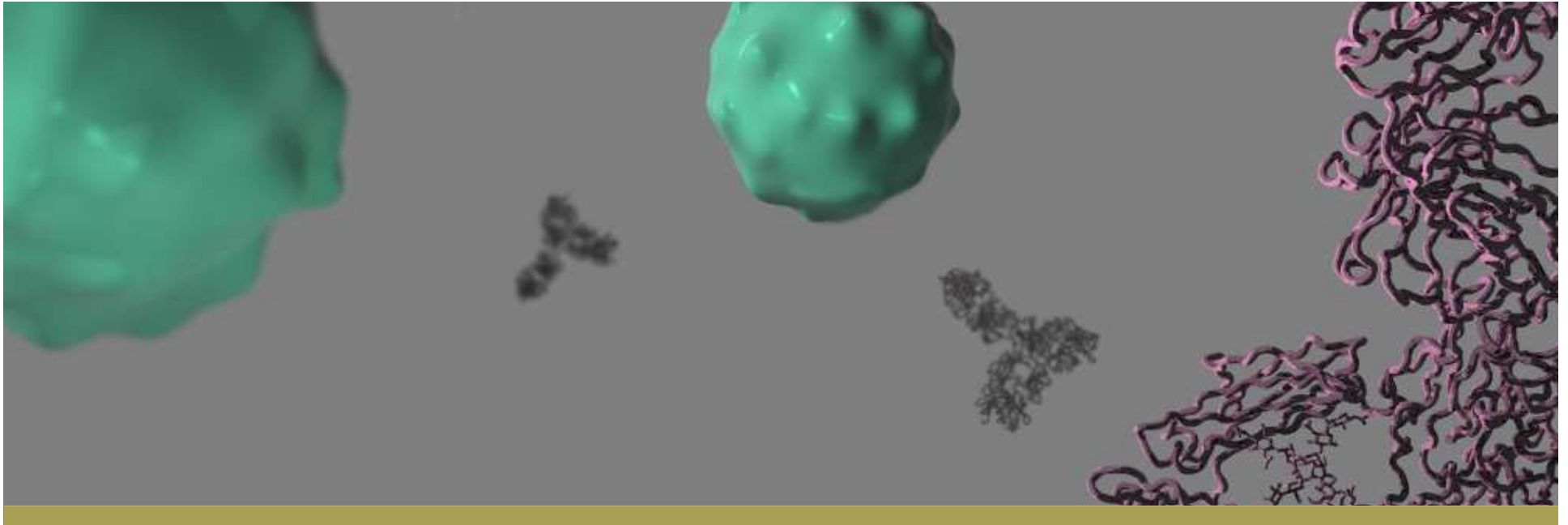
^a N is the number of patients who completed study treatment at cycle 1, 2, and 3.

^b N is the number of patients who completed all 6 cycles of study treatment.

^c 95% exact binomial confidence interval (CI) for CR +CRi +nPR +PR.

Conclusions

- Results of this Phase II, open-label, single-arm, multicenter study demonstrate that ofatumumab in combination with bendamustine shows high response rates and an acceptable safety profile for patients with either previously untreated CLL who are inappropriate for fludarabine-based therapy, or patients with relapsed CLL.
- Investigator-assessed ORR was 95% (CR rate 43%) in the previously untreated population and 74% (CR rate 11%) in the relapsed population. 56% of patients in the previously untreated population who had an investigator-assessed CR and had MRD analysis performed were MRD negative at the 3-month follow-up visit.
- The safety profile was acceptable with few AEs, mainly early infusion reactions.
- Longer follow-up is required to determine time-to-event endpoints such as PFS and OS.
- Ofatumumab/Bendamustine combination data look encouraging.

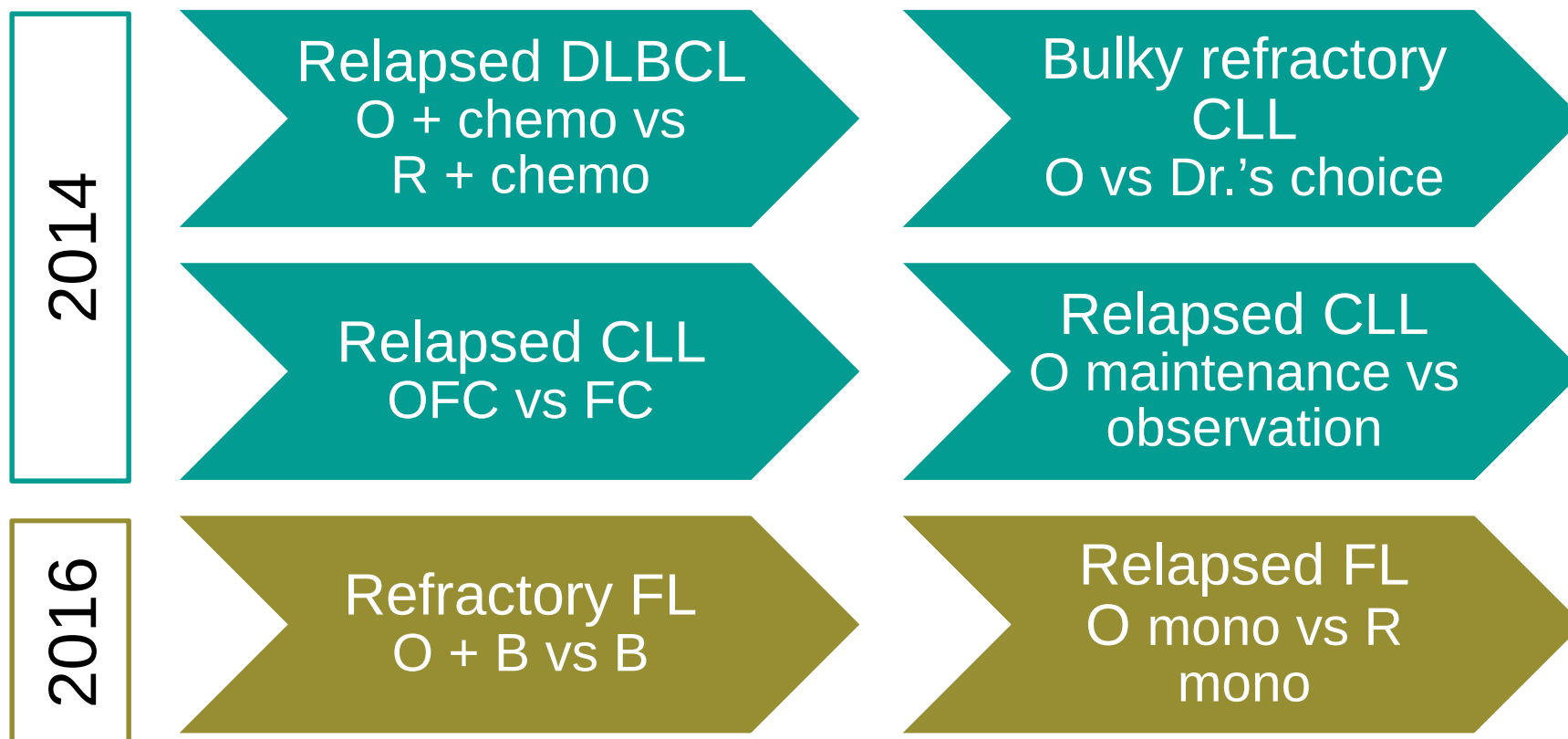


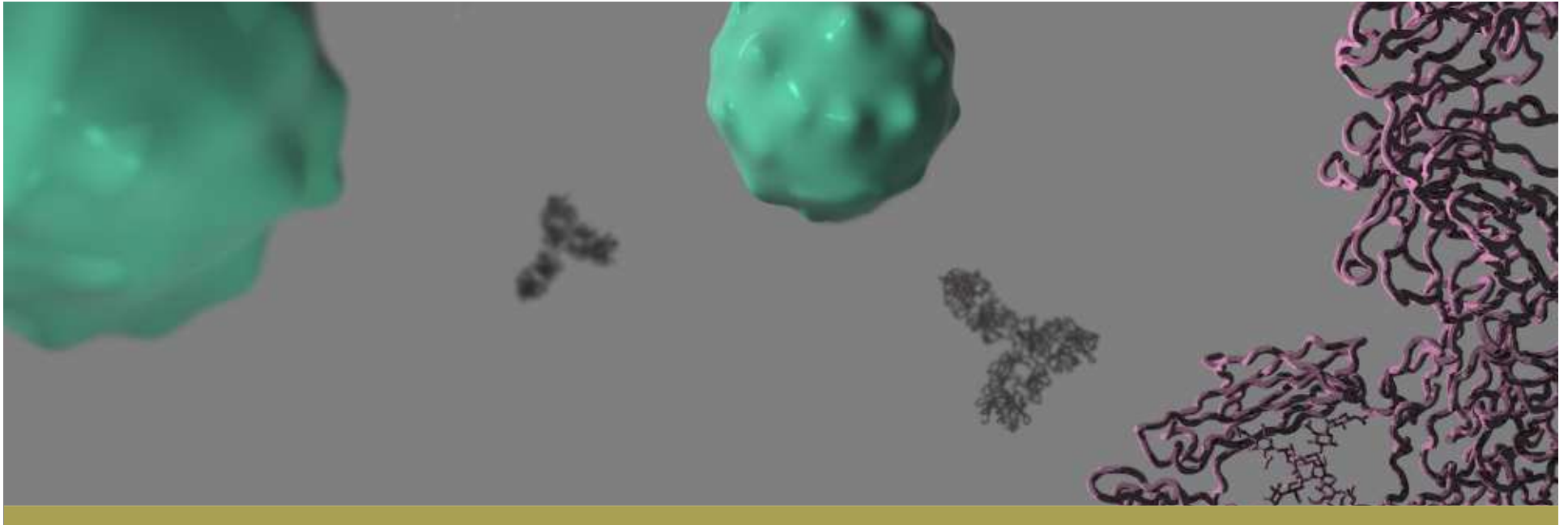
Ofatumumab

Jan van de Winkel
CEO, Genmab



4 Pivotal Study Readouts in 2014

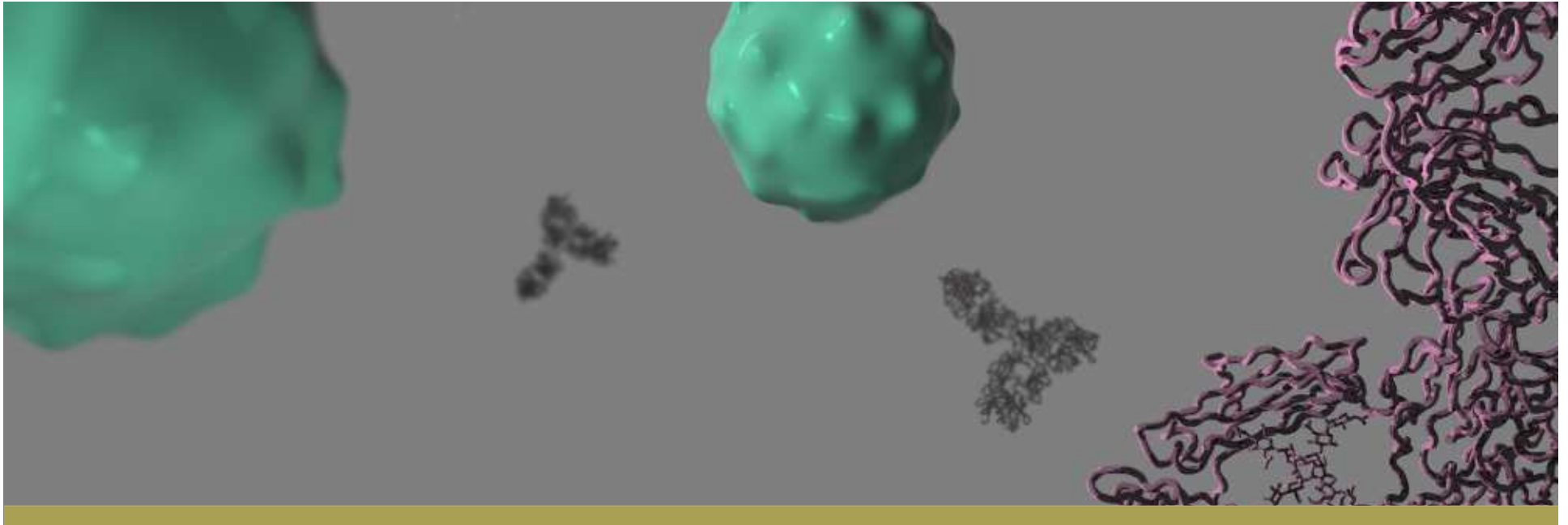




Ofatumumab Q&A

Peter Hillmen, *Leeds Teaching Hospitals NHS Trust*; Nikolai Brun & Jan van de Winkel, *Genmab*





News from the Clinic

Daratumumab

Presented by Dr. Paul Richardson
Dana Farber Cancer Institute



Preliminary Safety and Efficacy Data of Daratumumab in Combination with Lenalidomide and Dexamethasone in Relapsed or Refractory Multiple Myeloma

Plesner T^A, Arkenau T^B, Lokhorst H^C, Gimsing P^D, Krejcik J^A, Lemech C^B, Minnema MC^C, Lassen U^D, Cakana A^E, Brun N^F, Basse L^F, Palumbo A^G, Richardson PG^H on behalf of the GEN503 study group

^AVejle Hospital, Denmark; ^BSarah Cannon Research Institute, London, UK; ^CUniversity Medical Center Utrecht, Netherlands; ^DRigshospitalet, Copenhagen, Denmark; ^EJohnson & Johnson Pharmaceuticals, Research & Development, High Wycombe, UK; ^FGenmab A/S, Copenhagen, Denmark; ^GUniversity of Torino, Italy; ^HDana-Farber Cancer Institute, Boston, MA, USA

Background

- In the first-in-human dose-escalation study GEN501 of Daratumumab (DARA) as monotherapy in patients with relapsed or refractory multiple myeloma (MM) the safety profile was acceptable.
- In doses ≥ 4 mg/kg 42% of the patients (n=12) achieved a partial response and an additional 25% achieved a minimal response¹ according to modified IMWG guidelines¹.
- Targeting MM cells using a direct and indirect antitumor mechanism has shown to be effective².
- Combining DARA with lenalidomide (LEN) enhances NK cell-mediated killing of MM cell ex-vivo³ and is hypothesized to lead to a synergistically higher efficacy in the clinical setting.
- Here, we report the first experience from the ongoing GEN503 dose-escalation study combining DARA with LEN and low-dose dexamethasone (DEX).

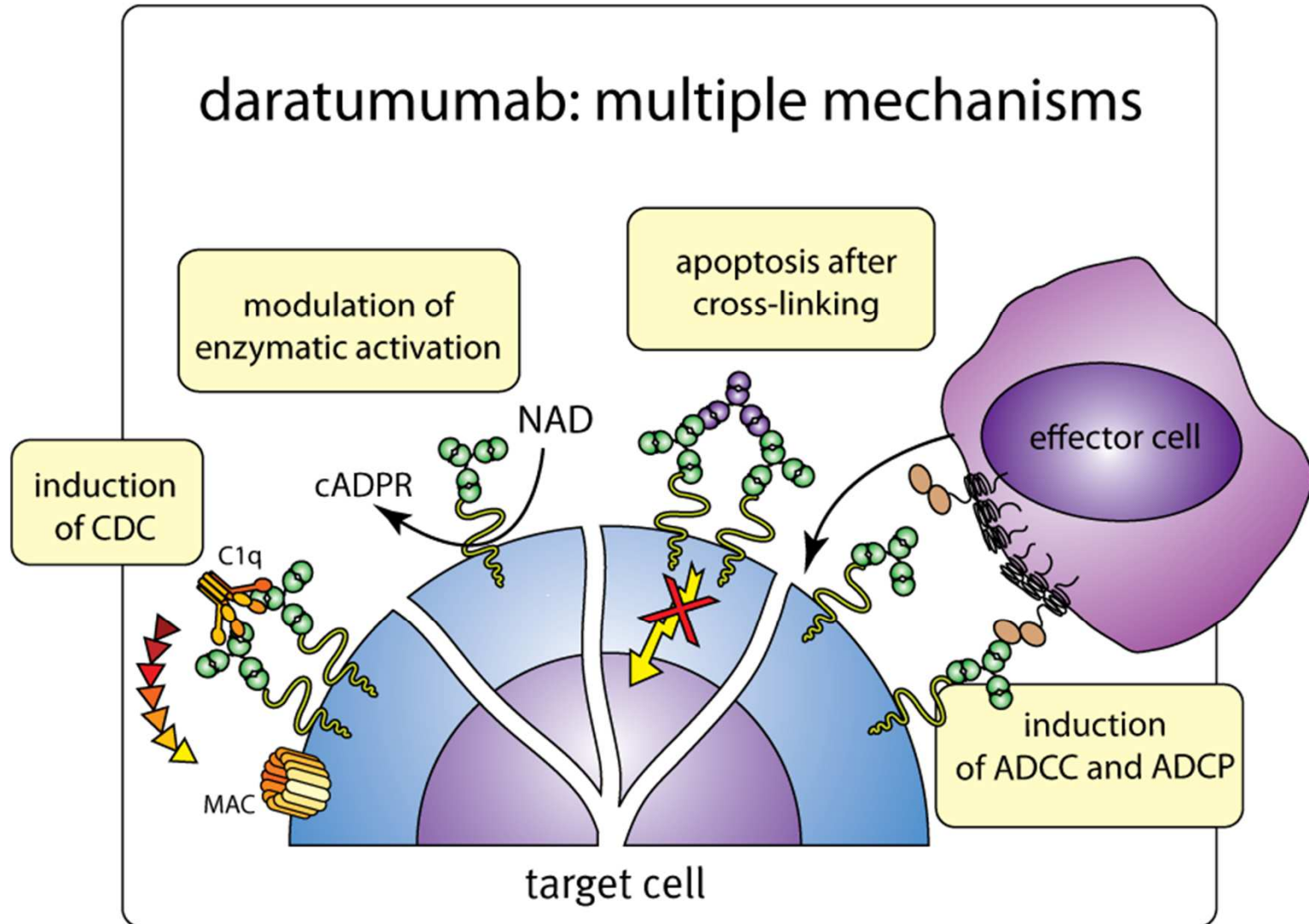
1: Rajkumar et al Blood 2011;117:4691-5

2: Lonial et al. J Clin Oncol 2010;28(15s)

3: van der Veer et al. Haematologica 2011;96(2):284-90

Daratumumab

A Human CD38 mAb with Broad-Spectrum Killing Activity



Study Design

- This is a phase I/II open-label multicenter study of DARA in combination with LEN and DEX including a classic 3 + 3 dose-escalation design. DARA is being administered in doses from 2, 4, 8 or 16 mg/kg weekly for 8 weeks, twice a month for 16 weeks and once a month until disease progression, unmanageable toxicity or up to maximum 24 months. LEN is being administered according to the label and DEX is being administered weekly.
- AEs are rated according to CTCAE version 4.0. DLTs are defined as non-hematological SAEs grade ≥ 3 not resolving within 6 hours, ADRs preventing infusion to be resumed or day 1 infusion of cycle 2 to be initiated, platelet count < 20.000 cells/uL, neutropenia grade 4 and neutropenic fever for more than 3 days. An IDMC evaluated all safety data for each dose cohort.
- Efficacy is evaluated by Genmab A/S and Janssen Biotech as best paraprotein response according to IMWG guidelines.
- Daratumumab plasma concentrations were measured by ELISA.
- Cut-off date for AEs, baseline characteristics, demography, and efficacy data was 19-Nov-2013 and for PK data 24-Sept-2013. The results are based on preliminary data before database lock.

Objectives

- The primary objective is to establish the safety profile.
- The secondary objectives are assessment of efficacy and pharmacokinetics.

In- and Exclusion Criteria

Inclusion Criteria

- Relapsed MM after receiving min 2 and max 4 prior lines of therapy and being eligible for LEN/DEX.
- Measureable serum M-component ≥ 1.0 g/dl and/or urine M-component ≥ 200 mg/24 hours.
- ≥ 18 years and with life expectancy ≥ 3 months.
- ECOG performance status of 0, 1 or 2.

Major exclusion criteria

- Previously received an allo-SCT or received an auto-SCT within 12 weeks before first DARA infusion.
- Have MM that is (primary) refractory to LEN, defined as not having a clinical response of at least MR for at least 2 months during the last treatment with LEN or MM that has never responded to any prior therapy with at least a PR for 3 months.

Baseline Characteristics and Demography

Characteristics	2 mg/kg (N=3)	4 mg/kg (N=3)	8 mg/kg (N=4)	16 mg/kg (N=2)	Total (N=12)
Gender, n					
Male/female	3/0	2/1	4/0	1/1	10/2
Age, years					
Median (range)	69 (48-71)	62 (61-65)	56 (49-69)	66 (56-76)	62 (48-76)
Prior lines of therapy					
Median (range)	4 (4-4)	3 (2-4)	4 (3-4)	3 (2-4)	4 (2-4)
LEN, refractory, n					
Refractory	0	1	1	0	2
Non refractory	1	1	1	0	3
LEN naïve	0	0	1	2	3
Not evaluable	2	1	1	0	4
Years since MM diagnosis					
Median (range)	4.0 (2.2-7.6)	2.1 (1.9-5.1)	3.2 (0.9-5.1)	5.5 (1.1-10.0)	3.2 (0.9-10.0)
Body weight, kg					
Median (range)	96 (84-97)	74 (72-83)	88 (79-105)	75.5 (72-79)	82 (72-105)
ECOG					
0	2	1	1	2	6
1	1	2	3	0	6
2	0	0	0	0	0

Number of Daratumumab Infusions

	2 mg/kg (N=3)	4 mg/kg (N=3)	8 mg/kg (N=4)	16 mg/kg (N=2)	Total (N=12)
Number of infusions					
Median (range)	21 (14-23)	18 (18-20)	12.5 (1-15)	5 (5-5)	14.5 (1-23)

Safety

- Safety data for 12 patients, including dose range from 2 mg/kg to 16 mg/kg were collected.
- No DLTs were reported in any of the dose cohorts.
- Four SAEs were reported, all assessed as unrelated to DARA.
- Seventeen AEs were $\geq$ grade 3 and 70% of these were hematological AEs of neutropenia, thrombocytopenia and anemia.
- One patient dosed 2 mg/kg was withdrawn by the sponsor due to recurrent grade 1 QT prolongation and hypokalemia. This patient had variation in baseline QTc values from 354-428 ms within 20 minutes.
- The most frequent AEs reported in >2 patients were neutropenia, gastrointestinal, musculoskeletal disorders and general disorders.
- 56% were assessed as related to treatment with DARA in combination with LEN/DEX, 2/3 of these being assessed as related to LEN/DEX.

Pharmacokinetics

The number of patients with evaluable PK is small (n=3 for 2 mg/kg; n=3 for 4 mg/kg and n=2 for 8 mg/kg). Following both the first dose and multiple repeated doses given on a weekly basis, the PK profile of DARA in combination with LEN and DEX is similar to DARA as monotherapy (GEN501 study) following the same dose schedule, suggesting that LEN and DEX do not affect the DARA PK profile. This is expected based on the known properties in terms of drug interaction potential for LEN and DEX.

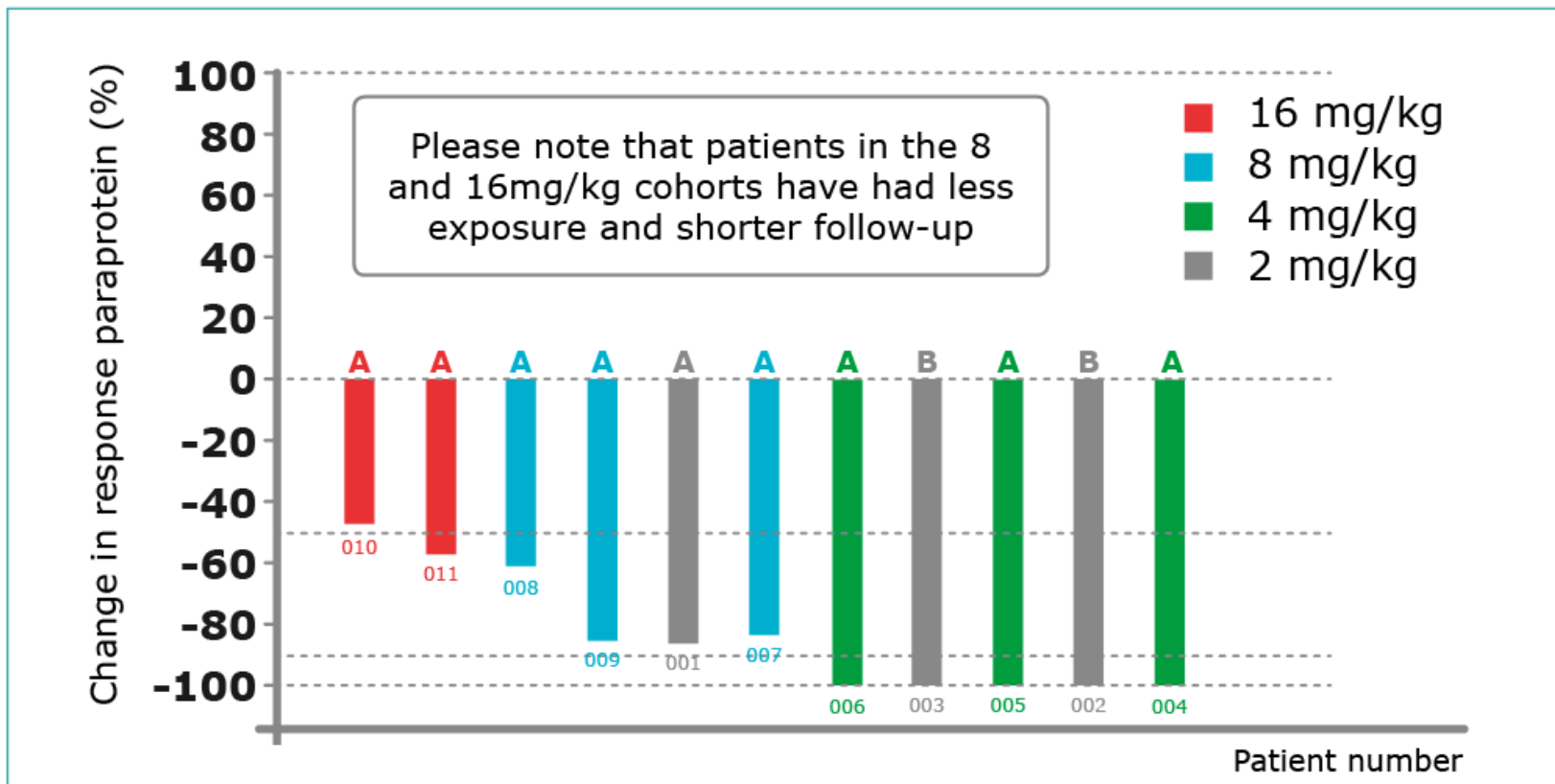
Incidence of Most Frequent AEs Reported in >2 Patients

% of patients	2 mg/kg (N=3)	4 mg/kg (N=3)	8 mg/kg (N=4)	16 mg/kg (N=2)	Total (N=12)
Neutropenia	100	33	25	0	42
Diarrhoea	33	100	25	0	42
Constipation	100	33	0	0	33
Nausea	33	67	25	0	33
Fatigue	100	0	25	0	33
Bone pain	33	33	25	0	25
Muscle spasms	33	67	0	0	25
Anaemia	33	67	0	0	25
Insomnia	0	67	25	0	25
Pyrexia	33	33	25	0	25

Efficacy

- Efficacy data for 11 patients have been collected. The best response in paraprotein indicates that all patients had a marked decrease in paraprotein.
- Time to achieving PR was median 4.1 weeks (2.0-4.3).
- Eight of 11 patients have achieved PR or better and two patients have achieved MR.

Best Change in Response Paraprotein (%)



The best change in response paraprotein evaluated according to IMWG 2011.

A: serum M-protein, B: urine-M-protein

Time to Response (Weeks)

	2 mg/kg Pt no 1/2/3	4 mg/kg Pt no 4/5/6	8 mg/kg Pt no 7/8/9	16 mg/kg Pt no 10/11	Total ^A (n=8) Median (range)
Time to response ≥ PR, weeks	4.1/2.1/4.1	4.3/2.0/2.1	4.0/ N/A /4.3	N/A	4.1 (2.0-4.3)

Time to response is defined as time from date of first dose till the first date at which the response (≥PR) was noted.

^A: only patients achieving PR or better

Response Rate (Number of Patients)

	2 mg/kg (N=3)	4 mg/kg (N=3)	8 mg/kg (N=3)	16 mg/kg (N=2)	Total (N=11)
CR	1	2	0	0	3
VGPR	1	1	0	0	2
PR	1	0	2	0	3
MR	0	0	1	1	2
SD	0	0	0	1	1
PD	0	0	0	0	0

Response rates evaluated in 11 patients according to IMWG 2011 guidelines.

CR: complete response, VGPR: very good partial response, PR: partial response; MR: minimal response, SD: stable disease, PD: progressive disease.

Conclusion

- DARA in doses up to and including 16 mg/kg in combination with LEN and DEX has been well tolerated.
- DARA in combination with LEN and DEX in relapsed or refractory MM patients provides a marked reduction in M-protein corresponding to 8 of 11 patients achieving PR or better.
- The MTD has not yet been reached.
- The DARA PK profile is not affected by LEN and DEX.
- Preliminary evidence of safety and antitumor activity suggests that further clinical development of DARA in combination with LEN and DEX is merited.

Acknowledgments

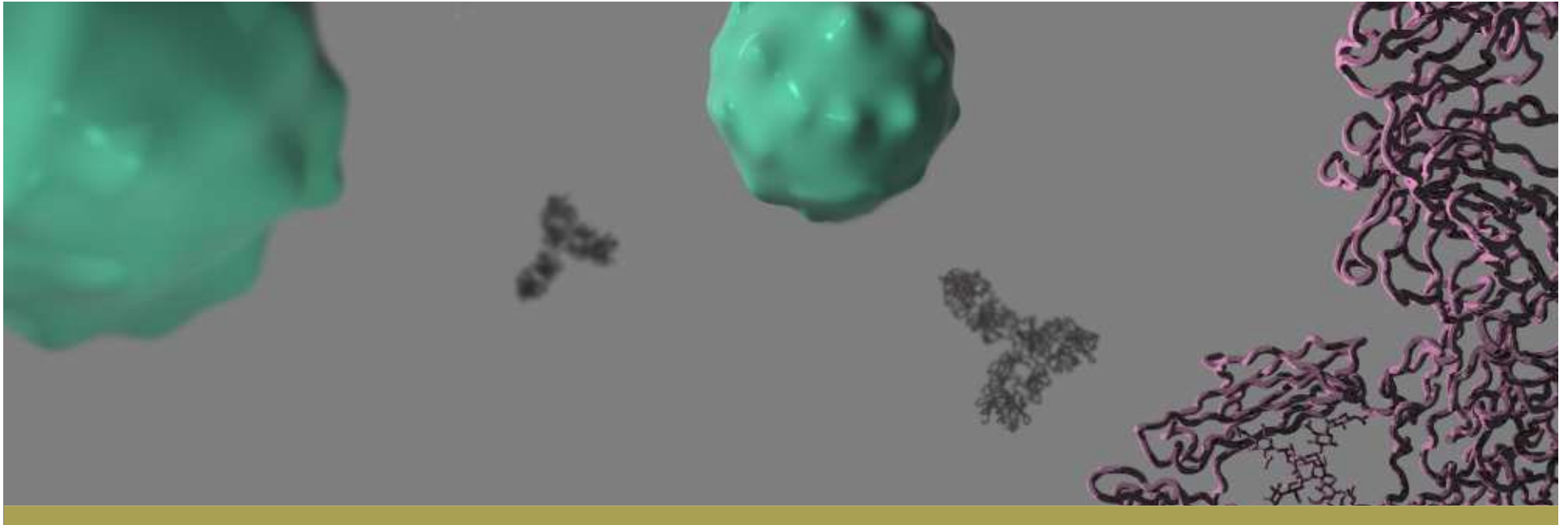
Special thanks to investigators, sub-investigators, research staff and patients and their families at the collaborating centers: Vejle Hospital, Denmark; Sarah Cannon Research Institute, UK; University Medical Center Utrecht, Netherlands; Rigshospitalet, Copenhagen, Denmark; University of Torino, Italy; Dana-Farber Cancer Institute, Boston MA, USA.

The study is supported by Genmab A/S and Janssen Biotech.

Disclosures

Plesner, Lokhorst, Palumbo and Richardson: Consultancy. Arkenau, Gimsing, Krejcik, Lemech, Minnema and Lassen: No relevant conflicts of interest to disclose. Cakana, Brun and Basse: Employment.

Abstract #1986 presented at the American Society of Hematology (ASH) 55th Annual Meeting and Exposition, New Orleans, LA, USA; December 7-10, 2013.



Daratumumab

Jan van de Winkel
CEO, Genmab



Extensive Daratumumab Development Plans in Multiple Myeloma

Smoldering

- New studies planned

Front line (transplant & non-transplant)

- Ph Ib multi combo

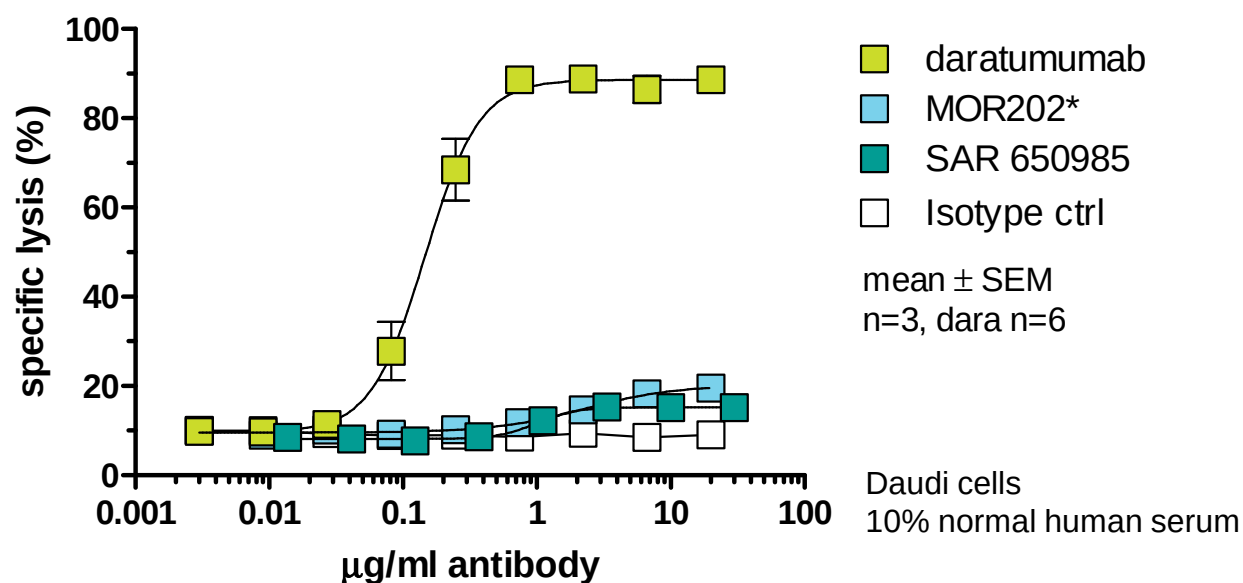
Relapsed

- Ph I/II len/dex combo

Relapsed- Refractory

- Ph I/II & Ph II single agent

Daratumumab Induces Superior CDC



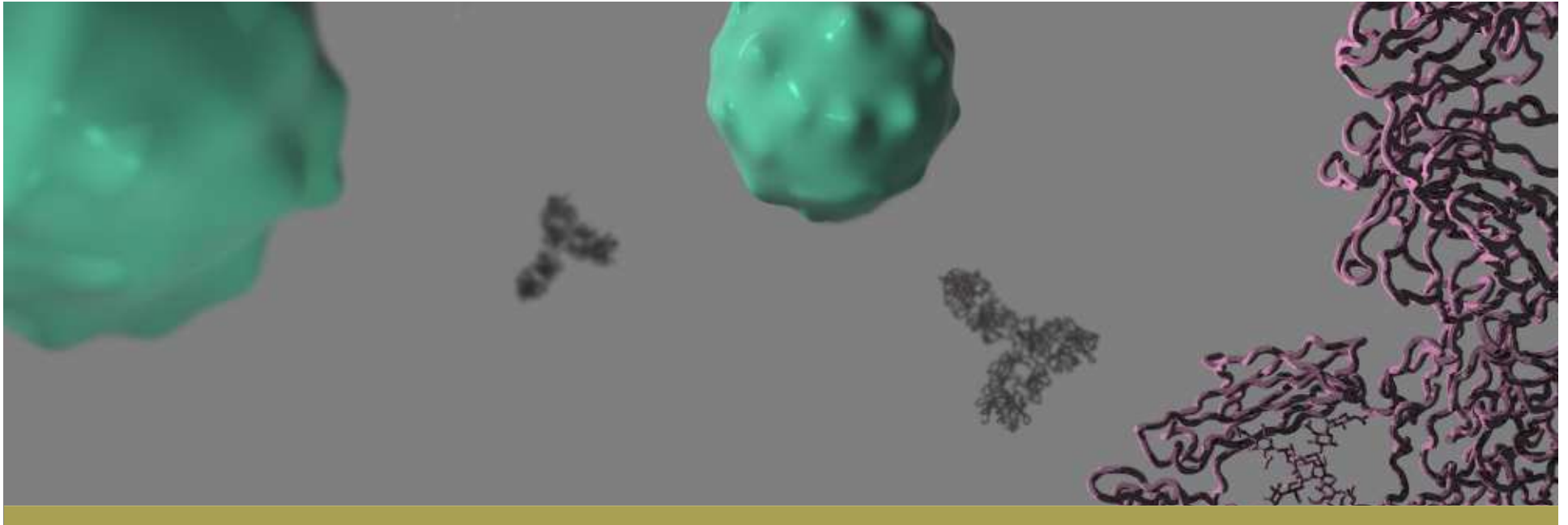
	Daratumumab (Genmab)	MOR202* ¹ (MorphoSys)	SAR 650984 ^{1, 2} (Sanofi-Aventis)
EC50 (µg/mL)	0.15	2.3	1.0
Maximum killing (%)	90	20	15

*MOR202 clone MOR03087; ¹:surrogate mAb produced in HEK cells, generated using VH and VL sequences as published PCT patent applications WO2012/041800 (MOR03087) and WO2008/047242 (38SB19); ²:38SB19

CD38 Landscape – Direct in-house Comparison with Surrogates of MOR03087 and SAR 650984

		Daratumumab (Genmab)	MOR202 ¹ (MorphoSys)	SAR 650984 ^{1, 2} (Sanofi-Aventis)
	Origin	Human	Human	Humanized
	Development phase	Phase II	Phase I/IIa	Phase I
	Binding ³	+++	++	+++
Mechanism of Action	ADCC (max lysis) ³	++	++	++
	CDC (max lysis) ³	+++	+	+
	Phagocytosis ^{3, 4}	+++	++	nd
	Ecto-enzyme function	+	nd	++
	Direct PCD ^{5, 6}	-	-	++
	PCD after cross-linking ^{5, 6}	+++	+++	+++

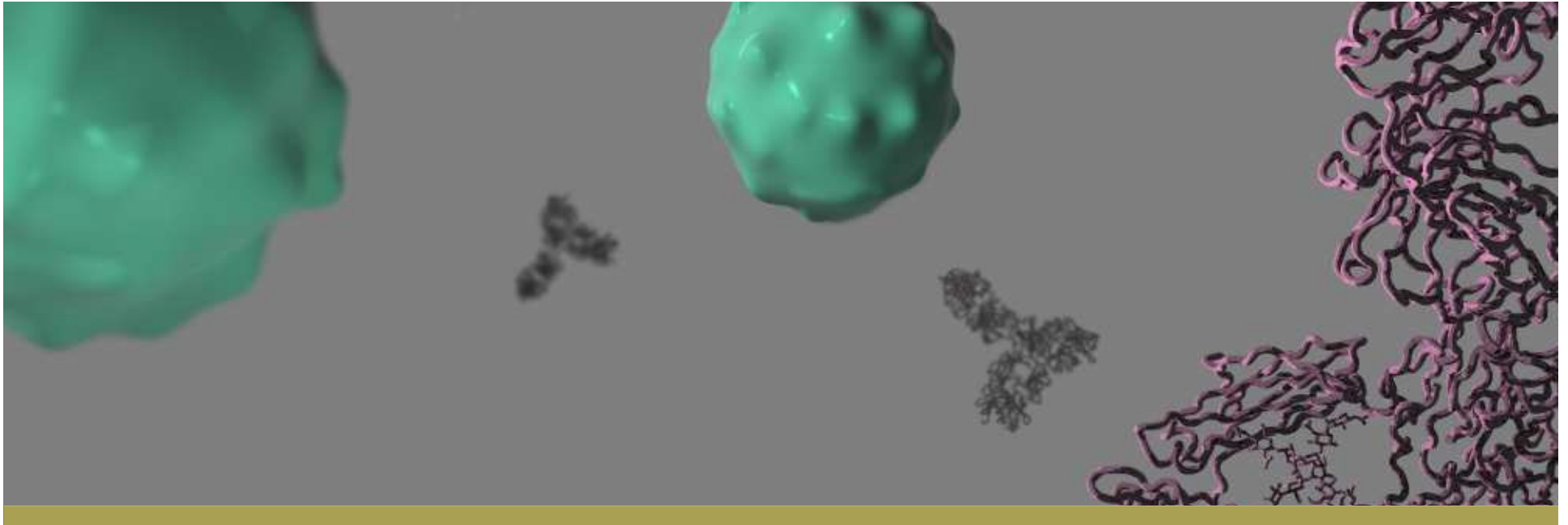
*MOR202 clone MOR03087; ¹:surrogate mAb produced in HEK cells, generated using VH and VL sequences as published in PCT patent applications WO2012/041800 (MOR03087) and WO2008/047242 (38SB19); ²:38SB19; ³:Daudi cells; ⁴:based on EC50 data, ⁵:Ramos cells ⁶: PCD: Programmed cell death, measured by Annexin V positivity and caspase-3 activation. nd = not determined



Daratumumab Q&A

Paul Richardson, *Dana Farber Cancer Institute*; Torben Plesner, *Vejle Hospital*; Nikolai Brun & Jan van de Winkel, *Genmab*





Advances in Proprietary Technologies

Jan van de Winkel
CEO, Genmab



Robust Technology & IND Engine to Produce Better Cancer Therapeutic Antibodies

UltiMAb® Platform

- Validated technology
 - 5 approved products
 - 29 in development
- Naked & potency-enhanced antibodies

DuoBody® Platform

- Genmab proprietary -

- Creates bispecific antibodies with ability to bind to 2 targets
- Potential in: cancer, infectious disease, autoimmune & CNS
- Collaborations with Novartis, Janssen, and KHK

Antibody-Drug Conjugates

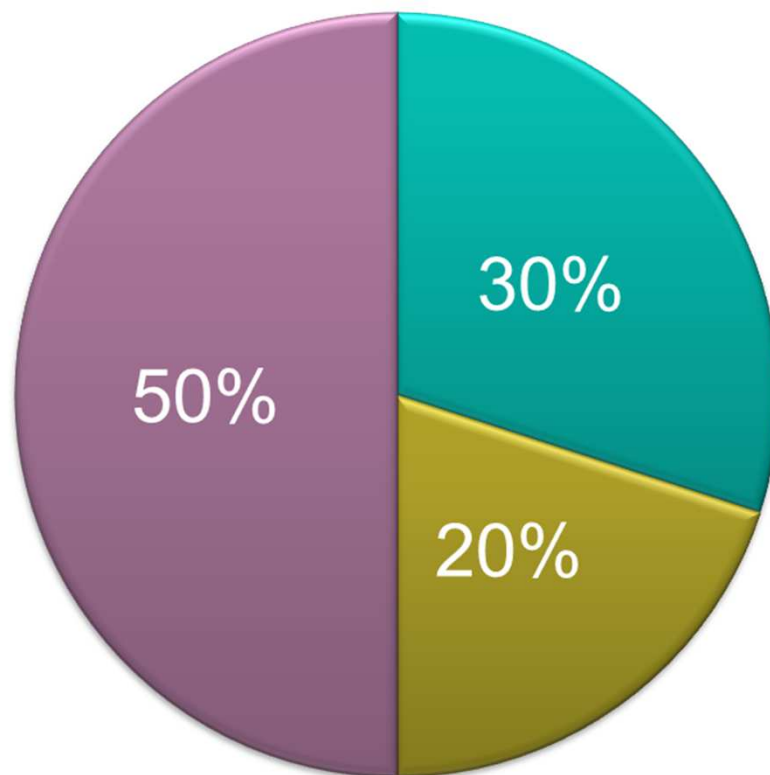
- Major new advancement in antibody technology
- Collaboration with Seattle Genetics
- Collaboration with ADC Therapeutics

HexaBody™ Platform

- Genmab proprietary -

- Enhances natural killing ability of antibodies
- Creates novel, differentiated products
- Potential in: cancer & infectious disease

Genmab's Innovative Pipeline



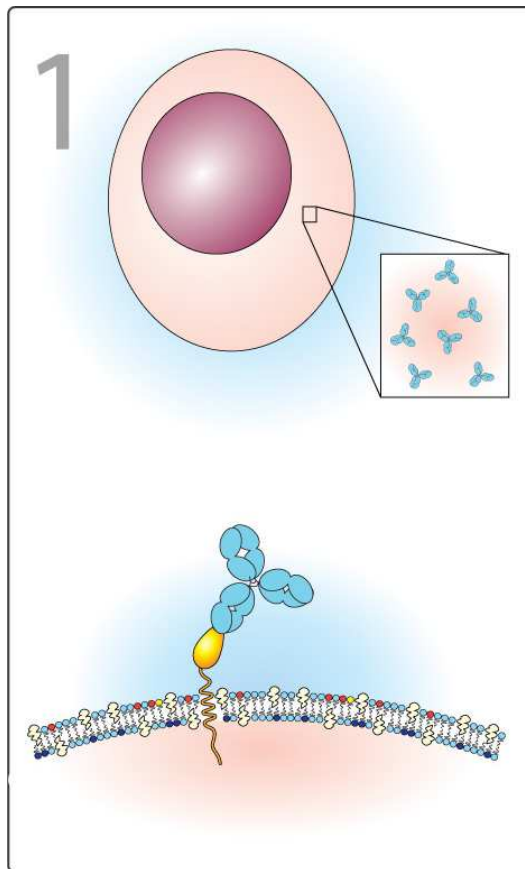
- Naked antibodies & HexaBody programs
- Antibody-drug conjugate programs
- DuoBody programs



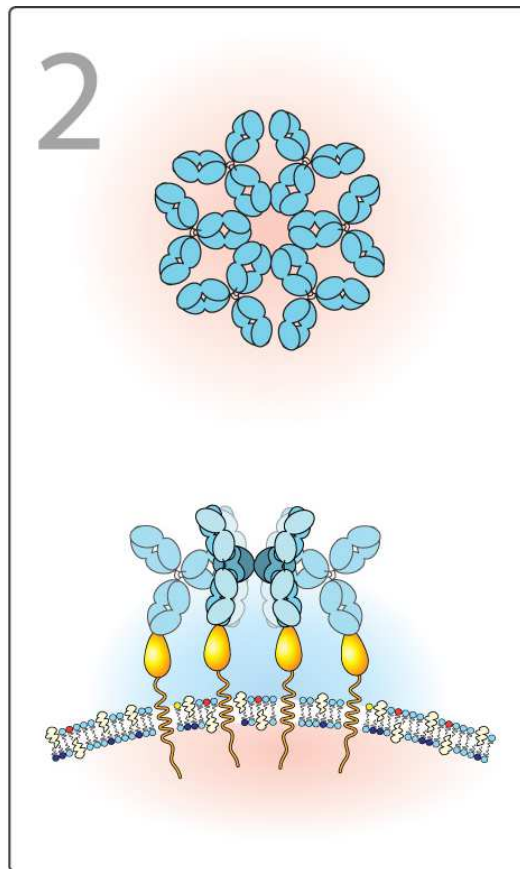
HexaBody™ Platform

Enforcing the Mechanism of Antibody Hexamer Formation

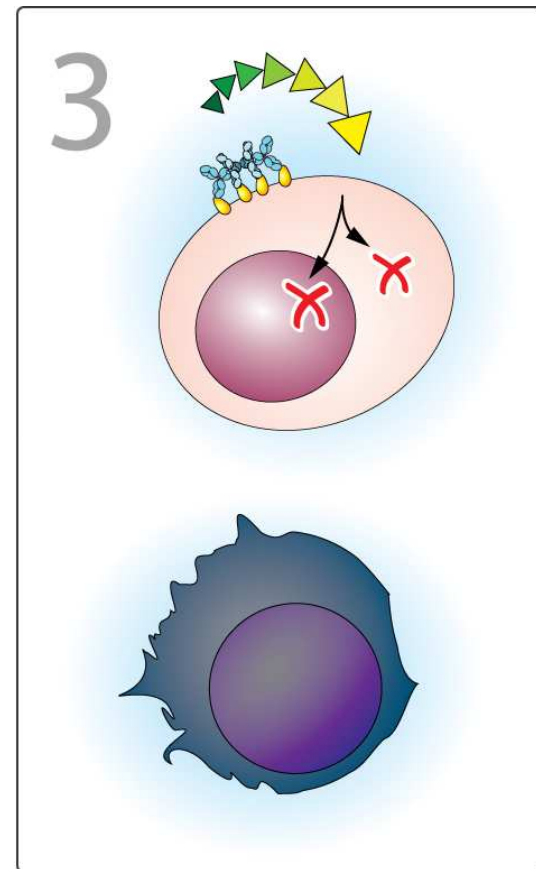
ANTIGEN BINDING



HEXAMER FORMATION
ON THE CELL SURFACE



RECRUITMENT OF EFFECTOR
MECHANISMS → CELL KILL



HexaBody – Proof of Concept

Enhanced CDC Applicable to Wide Range of Targets

- The HexaBody technology profoundly increased CDC activity of CD20, CD19, CD38 and CD52 antibodies

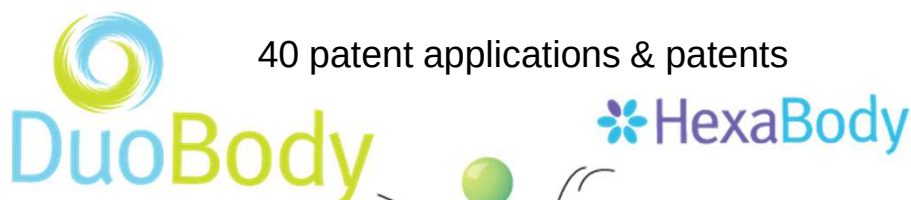
HexaBody - Proof of Concept

Enhanced Killing of Patient CLL Cells

- We could achieve similar effects using cancer cells obtained directly from CLL patients

Open Innovation

Networking Leads to Better Insights in Antibody Biology,
Accelerating the Creation of Innovative Antibody Formats



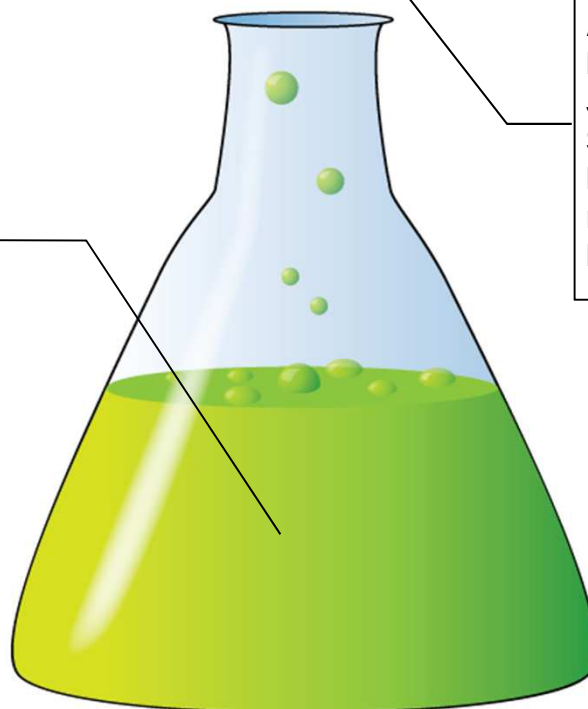
40 patent applications & patents

High quality scientific publications

Industry – University networking

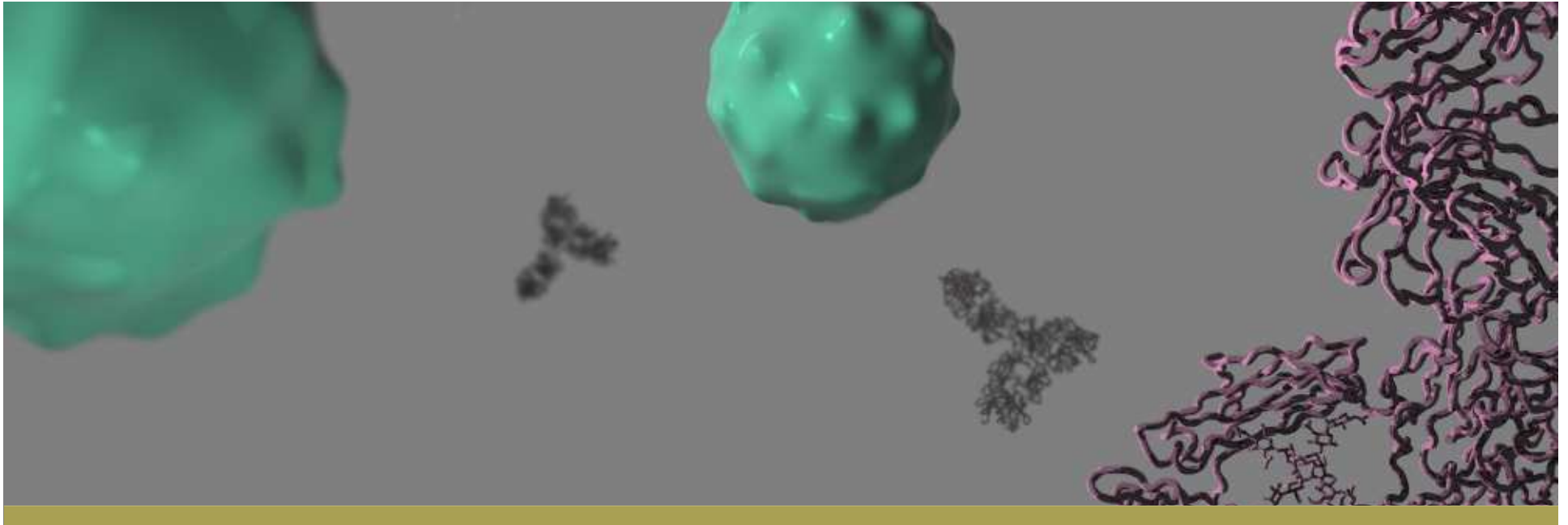
Sanquin
Genmab
Utrecht University
Maastricht University
Algonomics
The Scripps Research Institute
University of Virginia

Science 2007
Ann NY Acad Sci 2008
Nature Biotech. 2009
J. Immunol. 2011
Structure 2011
Mol. Immunol. 2011
mAbs 2012 /13
PNAS 2013



2014: Fueling Growth Through Our Platforms & Products

Priority	Milestone
Maximize value of ofatumumab	» Ph III relapsed CLL ofa + FC data » Ph III maintenance CLL data » Ph III bulky refractory CLL ofa vs physician's choice data » Ph III relapsed DLBCL; ofa + chemo vs RTX + chemo data » Update progress ofa sc autoimmune development
Expansion Arzerra	» CLL front line label expansion and launch » Launch & reimbursement in new countries
Fully exploit the potential of daratumumab	» Ph I/II MM monotherapy matured efficacy data » Ph I/II MM dara + Revlimid safety & efficacy data » Ph II MM monotherapy preliminary data » Ph Ib MM multi combo data » Start multiple new MM trials » Progress non-MM indications
Expand pipeline	» Progress Ph I HuMax-TF-ADC study » Report progress pre-clin. ADC, DuoBody & HexaBody projects
Next generation technologies	» Enter new DuoBody technology collaborations » Report progress DuoBody collaborations » Start HexaBody technology collaborations
Partnerships	» Report progress partnered programs » Enter new collaboration
Disciplined financial management	» Significant daratumumab milestones » No significant increase in cost base » Reduce cash burn



Q&A

Jan van de Winkel & David Eatwell, *Genmab*





Glædelig Jul og Godt Nytår
Holiday Greetings
Prettige Feestdagen

Copenhagen | Princeton | Utrecht

