Ublituximab

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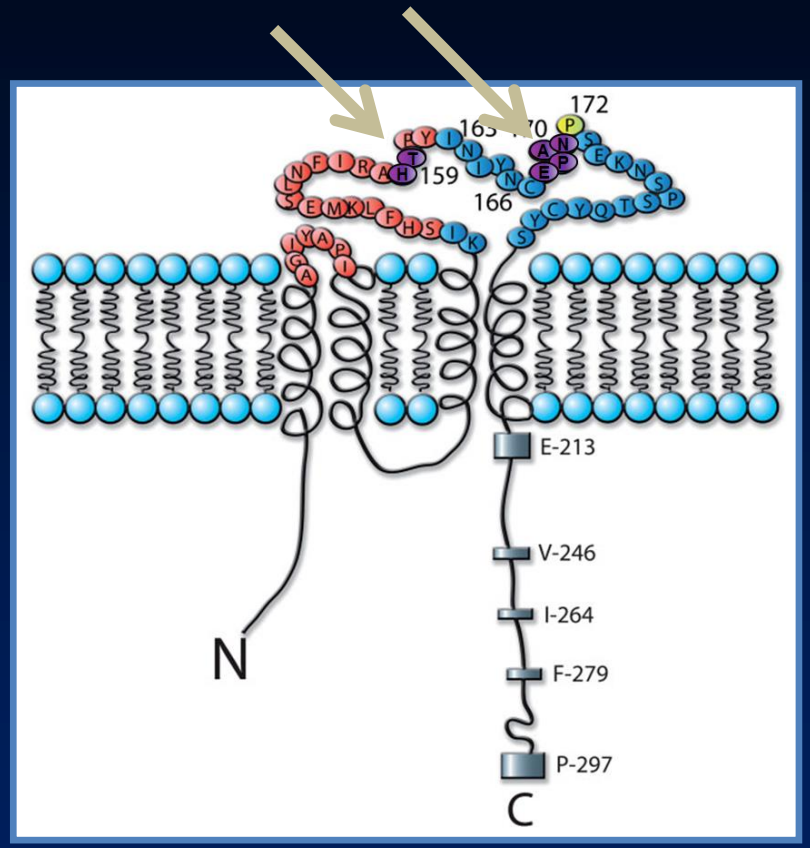
Ublituximab (TG-1101)

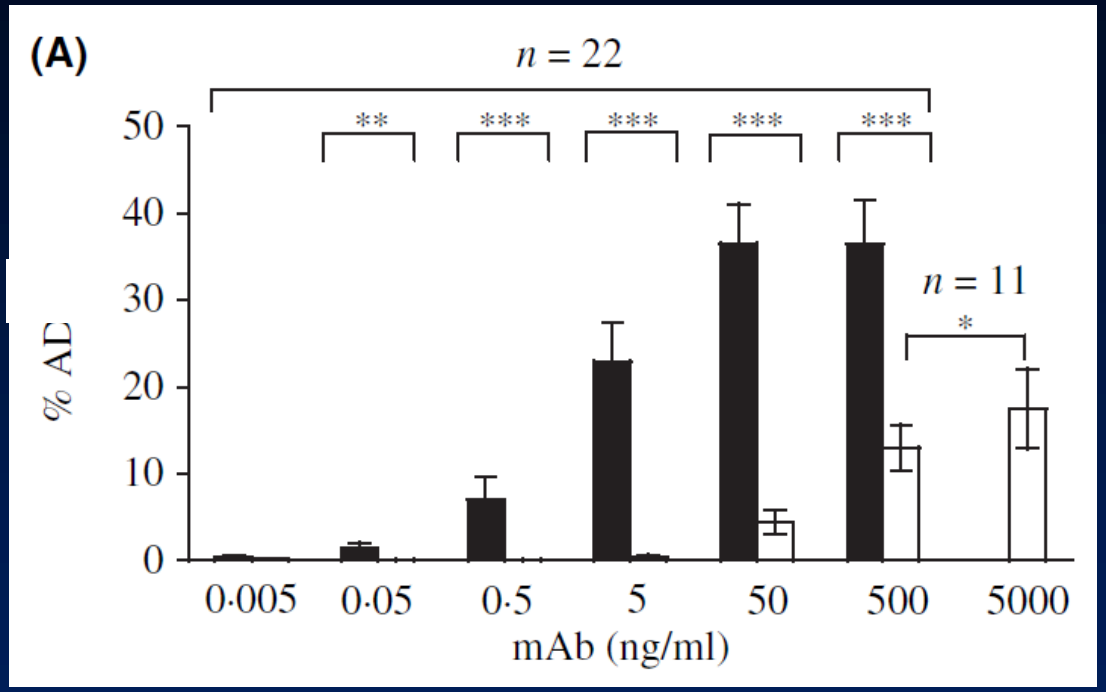
- Type 1 chimeric IgG1 mAb
- Unique binding sequence on CD20 Potential advantages over current standards of care:
  - Glycoengineered for enhanced ADCC
  - Activity in “low” CD20 expressing cell lines
- Single agent responses observed in rituximab refractory patients[1]



Source: Adapted from Ruuls et al 2008

[1]O’Connor et al, ASCO 2014

ADCC
Ublituximab vs Rituximab



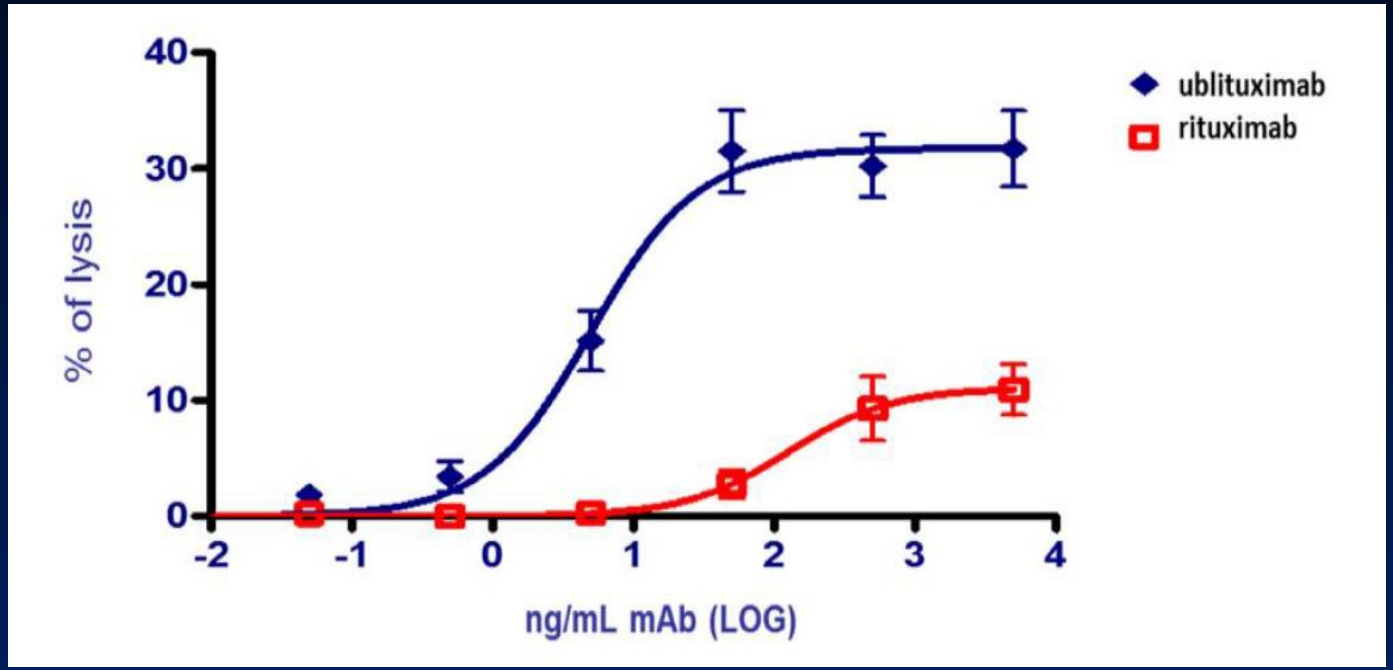
Black: UTX

White: RTX

- Rituximab (RTX) vs. Ublituximab (UTX) ability to induce ADCC in CLL patient donor cell lines

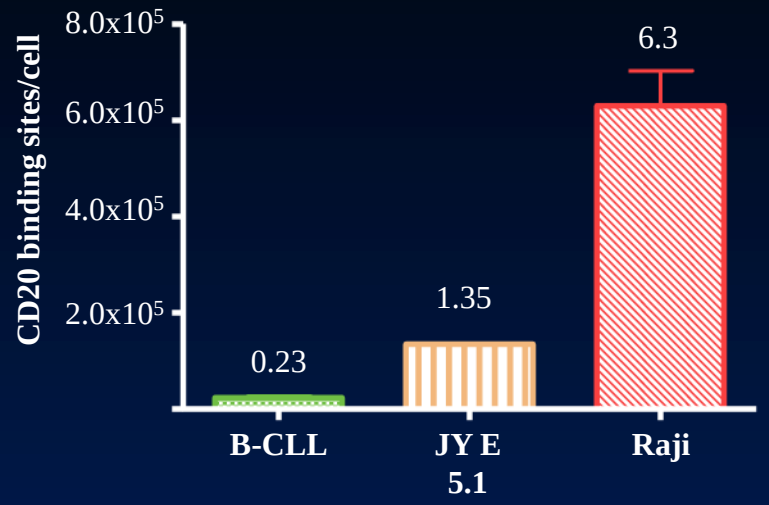
de Romeuf, et al. *Br J Haematol*. 2008;140:635-43;
Le Garff-Tavernier, et al. *Leukemia*. 2011;25:101-9.

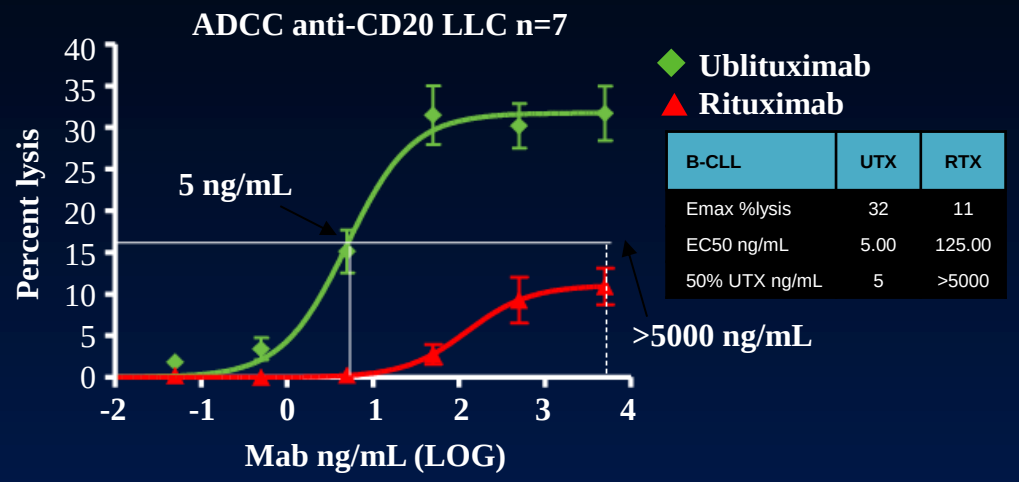
Enhanced ADCC Activity in Lysis Assays



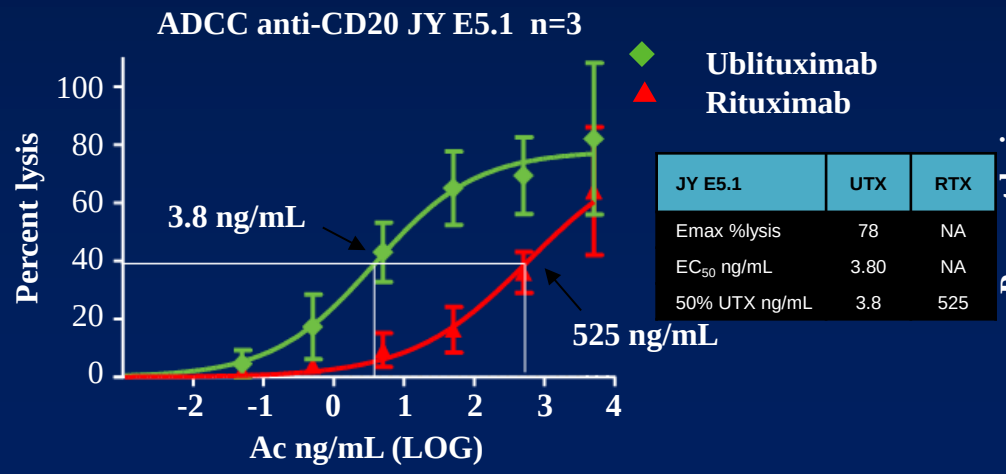
- Lysis of patient-derived CLL cells were tested in the presence of healthy donor NK cells at different concentrations of either UTX or RTX

Superior ADCC Induction Irrespective of CD20 Expression Levels

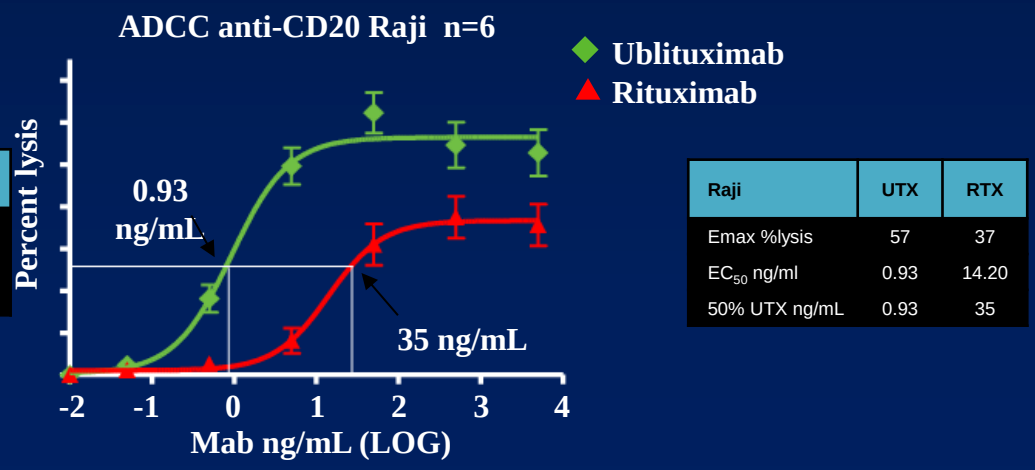




B-CLL	UTX	RTX
Emax %lysis	32	11
EC50 ng/mL	5.00	125.00
50% UTX ng/mL	5	>5000



JY E5.1	UTX	RTX
Emax %lysis	78	NA
EC_{50} ng/mL	3.80	NA
50% UTX ng/mL	3.8	525



Raji	UTX	RTX
Emax %lysis	57	37
EC_{50} ng/ml	0.93	14.20
50% UTX ng/mL	0.93	35

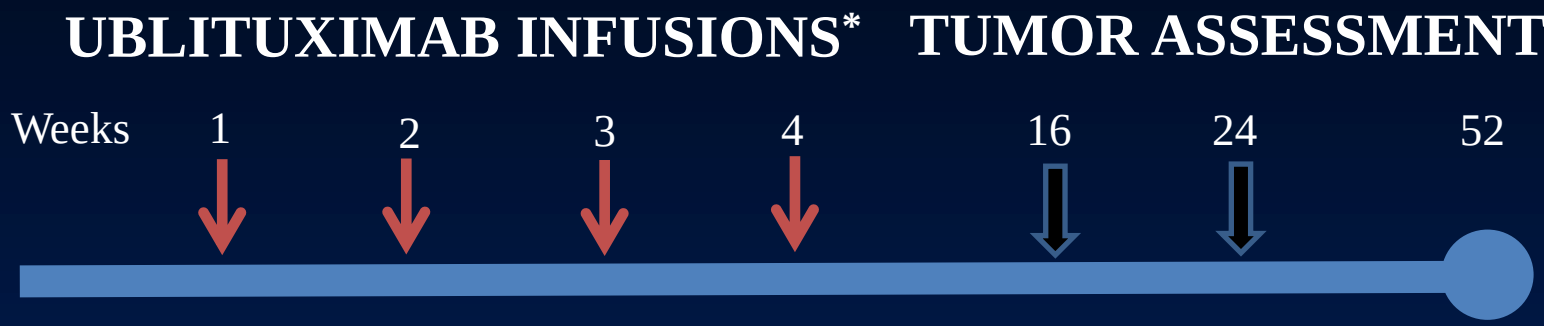
A Phase 1 Study of LFB-R603, A Novel Anti-CD20 Antibody, In Patients with Relapsed Chronic Lymphocytic Leukemia (CLL)

Guillaume Cartron[1], Bruno Cazin[2], Bertrand Coiffier[3], Stephane Lepretre[4], Pierre Feugier[5] , Therese Aurran[6], Guylene Chartier[7], Alain Sadoun[7], Vincent Ribrag[8]

[1]Hôpital Saint Eloi, Montpellier, France; [2]Hôpital C. Huriez, Lille, France; [3]Centre Hospitalier Lyon-Sud, Pierre-Benite, Lyon, France; [4]Centre Henri Becquerel, Rouen, France; [5]Hôpital Brabois, Vandoeuvre Les Nancy, France; [6]Institut Paoli-Calmettes, Marseille, France; [7]LFB Biotechnologies, Les Ulis, France; [8]Institut Gustave Roussy, Villejuif, France

Presented at the 52nd Annual American Society of Hematology Meeting; Orlando, FL; December 2010. Abstract 2447.

Ublituximab Phase 1 Trial in CLL: Treatment Schedule



*Doses of UTX ranged from 5 – 450 mg. There were 5 sequential cohorts (standard 3+3). The total dose per cohort was: (A) 75 mg; (B) 200 mg; (C) 510 mg; (D) 1050 mg; (E) 1650 mg.

- Key inclusion criteria
  - **Relapsed or refractory CLL, after ≥1 prior course of fludarabine**
  - **Circulating lymphocytes expressing CD20, CD5-CD19 and CD23**
- Key exclusion criteria
  - **Prior treatment with an anti-CD20 monoclonal antibody < 6 months before enrolment**
- Primary objectives: safety

Catron G, et al. ASH 2010. Abstract 2447.

Ublituximab Monotherapy in CLL: Baseline Characteristics

Median age, years (range)	62 (43 – 76)	
Male/Female, n	17/4	
ECOG PS 0/1, n	12/9	
Prior therapy regimens, median (range)	3 (1 – 6)	
Time from diagnosis to inclusion, years (range)	8.33 (2.5-14)	
Disease status at inclusion, relapsed/refractory, n	20/1	
Response to last anticancer regimen, n	CR, 7; PR, 10; NR, 3, UNK, 1	
Prior exposure to rituximab, %	57	
FISH results, n	Normal	9
	11q-	7
	13q-	9
	17p-	3
Lymph node enlargement, %	100	
Bulky adenopathy (>5cm), %	38	
SDP, mm^3 (range)	3427 (182-22164)	

Catron G, et al. 2010. Abstract 2447.

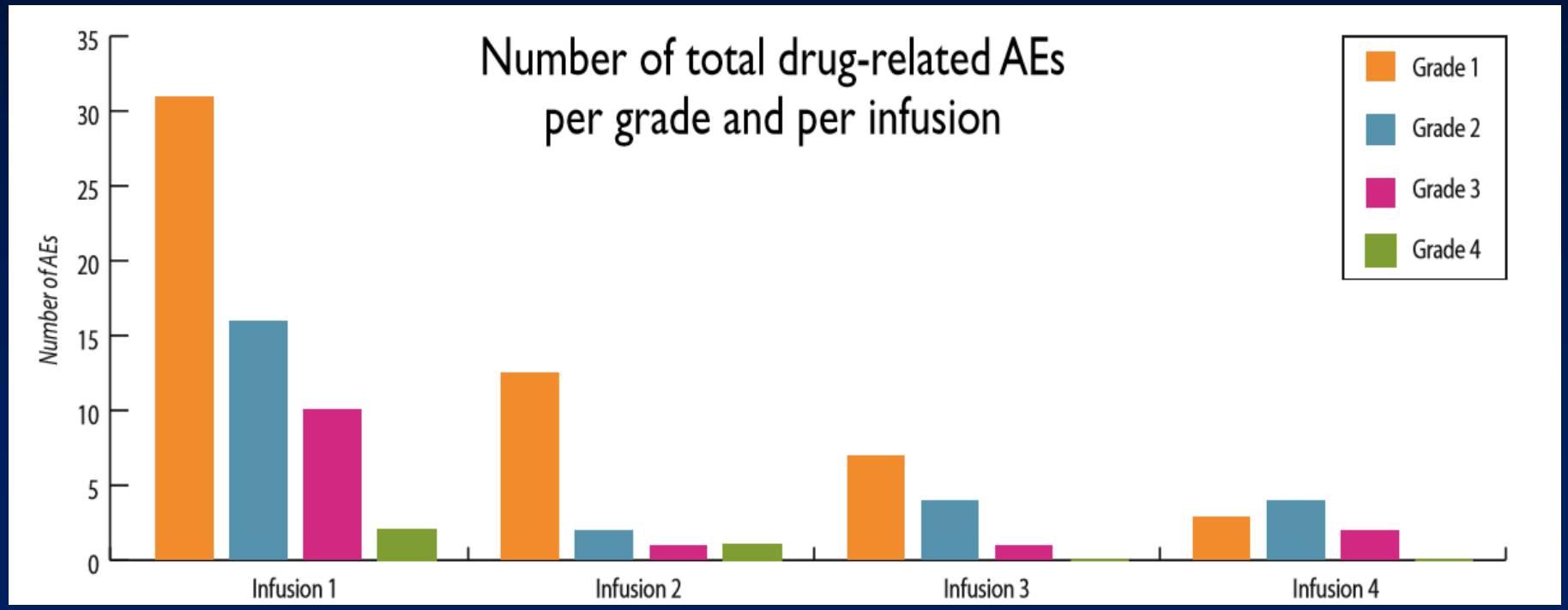
Ublituximab Monotherapy in CLL: Treatment-related Toxicity

Treatment-related AE	All Grades		Grade 3/4	
	N	%	N	%
TOTAL	113	**100**	23	**61.9**
Pyrexia	18	**61.9**	0	**NA**
Infusion related reaction*	12	**52.4**	3	**14.3**
Infection	12	**28.6**	5	**14.3**
Headache	11	**33.3**	0	**NA**
Neutropenia	10	**38.1**	7	**28.6**
Chills	6	**23.8**	0	**NA**
Thrombocytopenia	6	**23.8**	1	**4.8**
Hepatic cytolysis	4	**19**	3	**14.3**
Nausea	4	**14.3**	0	**NA**
Abdominal pain	3	**9.5**	0	**NA**
Asthenia	2	**9.5**	0	**NA**
Pancytopenia	2	**9.5**	2	**9.5**
Anemia	2	**9.5**	0	**NA**
Gamma glutamyltransferase increase	2	**9.5**	0	**NA**
Anal abscess	2	**4.8**	0	**NA**

Catron G, et al. ASH 2010. Abstract 2447.

Ublituximab Monotherapy in CLL: Infusion Reactions

- All patients received 4 infusions
- 34% of the total AEs occurred after the first infusion
- 41% of the total AEs occurred <48 hours after the ublituximab infusion



Catron G, et al. ASH. Abstract 2447.

Ublituximab Monotherapy in CLL: NCI-WG Responses

Cohort, n	A	B	C	D	E	TOTAL
Patients: Evaluable	6:5	3:2	3:3	3:3	6:5	21:18
CR	0	0	0	0	0	0
PR at week 16	1	2	1	0	1	5
PR at week 24	1	0	1	0	1	3
SD/PD	2/2	0/0	2/0	1/2	2/2	7/6

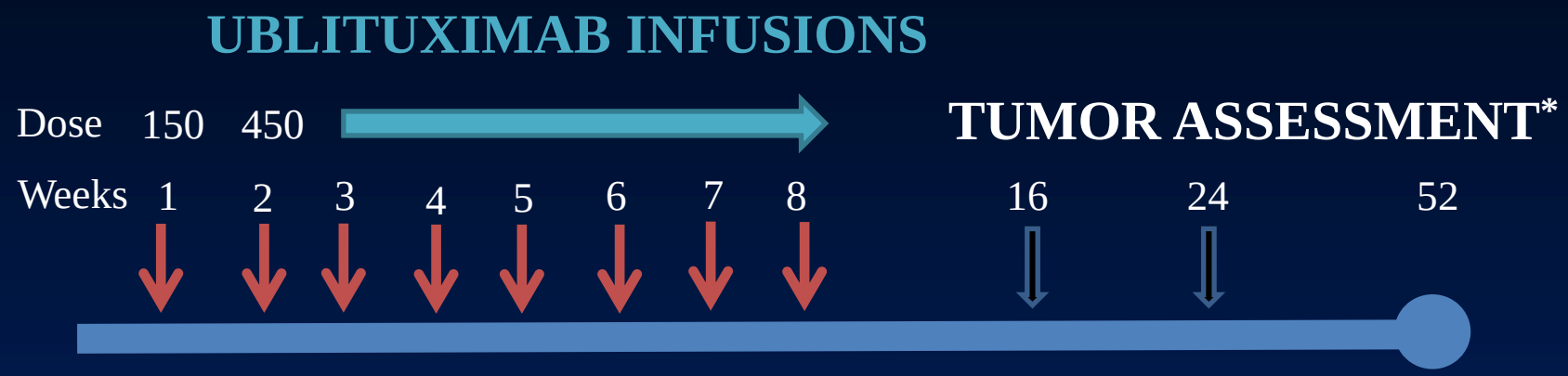
Catron G, et al. Presented at the 52nd Annual American Society of Hematology Meeting; Orlando, FL; December 2010. Abstract 2447.

Final Results of A Multicenter Phase 1b Single Agent Study With The Novel Anti-CD20 Monoclonal Antibody Ublituximab (TG-1101) In Patients With Relapsed Chronic Lymphocytic Leukemia (CLL)

Bruno Cazin[1], Stéphane Leprêtre[2], Bertrand Coiffier[3], Thérèse Aurran[4], Guillaume Cartron[5], Pierre Feugier[6],Oana Brehar[2], Alain Sadoun[7], Peter Sportelli[8], Hari Miskin[8],and Vincent Ribrag[9]

Presented at the 18th Congress of the European Hematology Association (EHA); Stockholm, Sweden; June 2013.
Abstract P111.
Also presented at the 53rd ASH Annual Meeting and Exposition, December 10-13, 2011. Abstract 2862.

Ublituximab Phase 1 Trial in CLL: Treatment Schedule



*Response assessment was conducted at Week 16, with a confirmatory assessment conducted at Week 24 for responders.

- Primary objectives: safety
- Secondary objectives: PK, immunogenicity, descriptive statistics of laboratory values, efficacy
- Exploratory: biomarkers, correlation of FCγRIIIA polymorphisms to response

Cazin B, et al. EHA 2014. Abstract P111.

Ublituximab Monotherapy in Relapsed CLL: Demographics

Median age, years (range)	69.5 (62 – 77)	
Male/Female, n	10/2	
ECOG PS 0/1, n	6/6	
Prior therapy regimens, median (range)	3 (1 – 8)	
Time from diagnosis to inclusion, years (range)	10.4 (4-23.6)	
Response to last anticancer regimen, n	CR, 3; PR, 6; SD, 2, PD, 1	
Prior exposure to rituximab, %	58	
FISH results, n	Normal	0
	11q-	2
	13q-	4
	17p-	2
	Trisomy 12	4
Bulky adenopathy (>5cm), %	33	
FCγRIIIA polymorphism, n	F/F	5
	F/V	4
	V/V	3

Cazin B, et al. Presented at the 18th Congress of the European Hematology Association (EHA); Stockholm, Sweden; June 2014. Abstract P111.

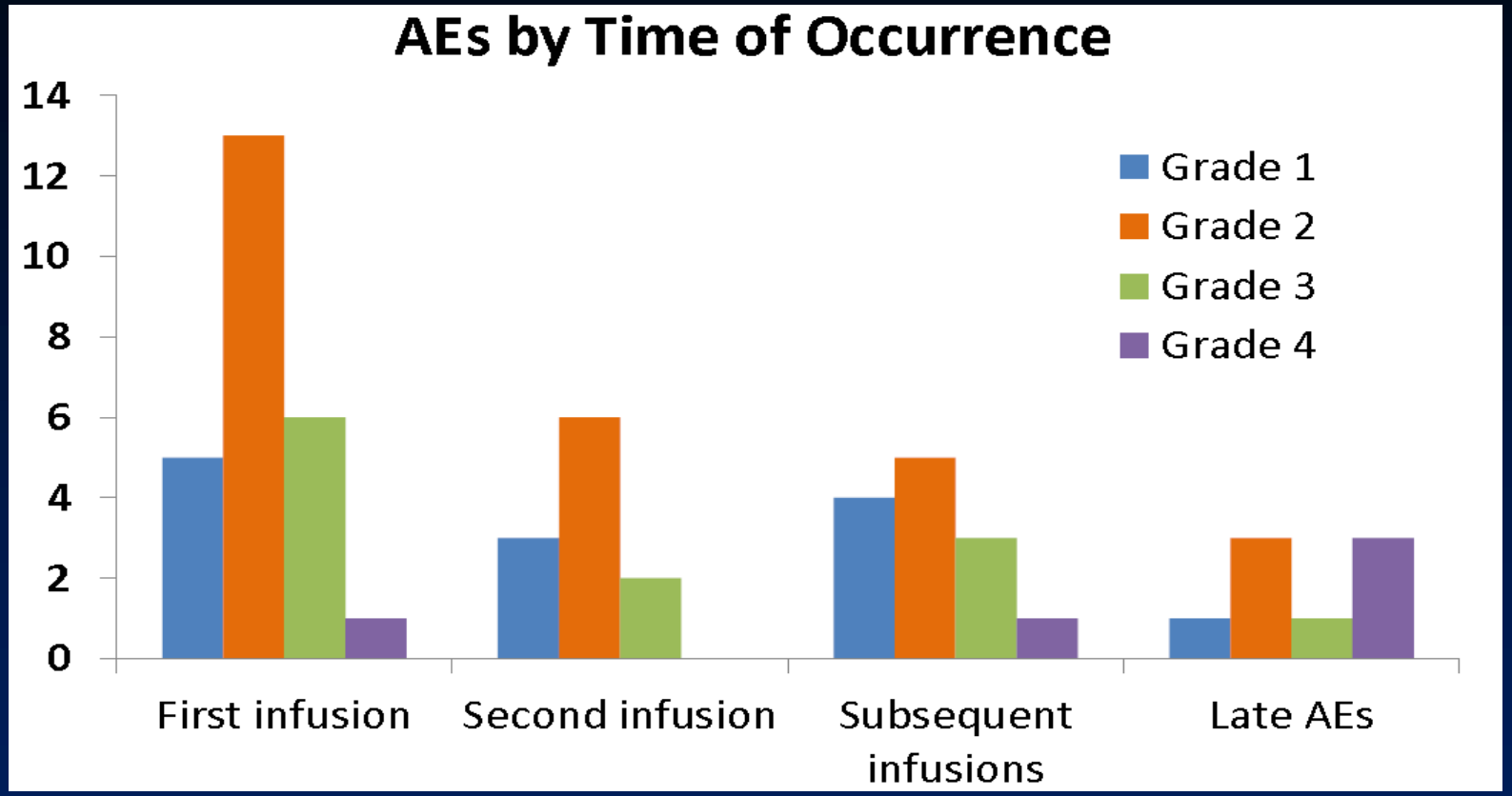
Ublituximab Monotherapy in Relapsed CLL: Treatment-related Toxicity

Treatment-related AE	All Grades		Grade 3/4	
	N	n (%)	N	n (%)
Any drug-related AEs	57	**12 (100)**	17	**10 (83.3)**
Infusion related reaction*	11	**9 (75)**	4	**4 (33.3)**
Neutropenia	10	**7 (58.3)**	9	**7 (58.3)**
Pyrexia	6	**6 (50)**		
Thrombocytopenia	5	**5 (41.7)**		
Chills	2	**2 (16.7)**		
Increased AST/ALT	2	**2 (16.7)**	2	**2 (16.7)**
Asthenia	2	**2 (16.7)**		
Headache	2	**1 (8.3)**		
Febrile neutropenia	1	**1 (8.3)**	1	**1 (8.3)**
Pancytopenia	1	**1 (8.3)**	1	**1 (8.3)**
Bronchitis	1	**1 (8.3)**		
Herpes zoster	1	**1 (8.3)**		
Infection (non specified)	1	**1 (8.3)**		
Other	12	**7 (58.3)**		

- 11 patients received all 8 infusions without dose reduction
- No drug-related mortality, and no on-study deaths

Cazin B, et al. Presented at the 18th Congress of the European Hematology Association (EHA); Stockholm, Sweden; June 2014. Abstract P111.

Ublituximab Monotherapy in Relapsed CLL: Infusion Related Reactions

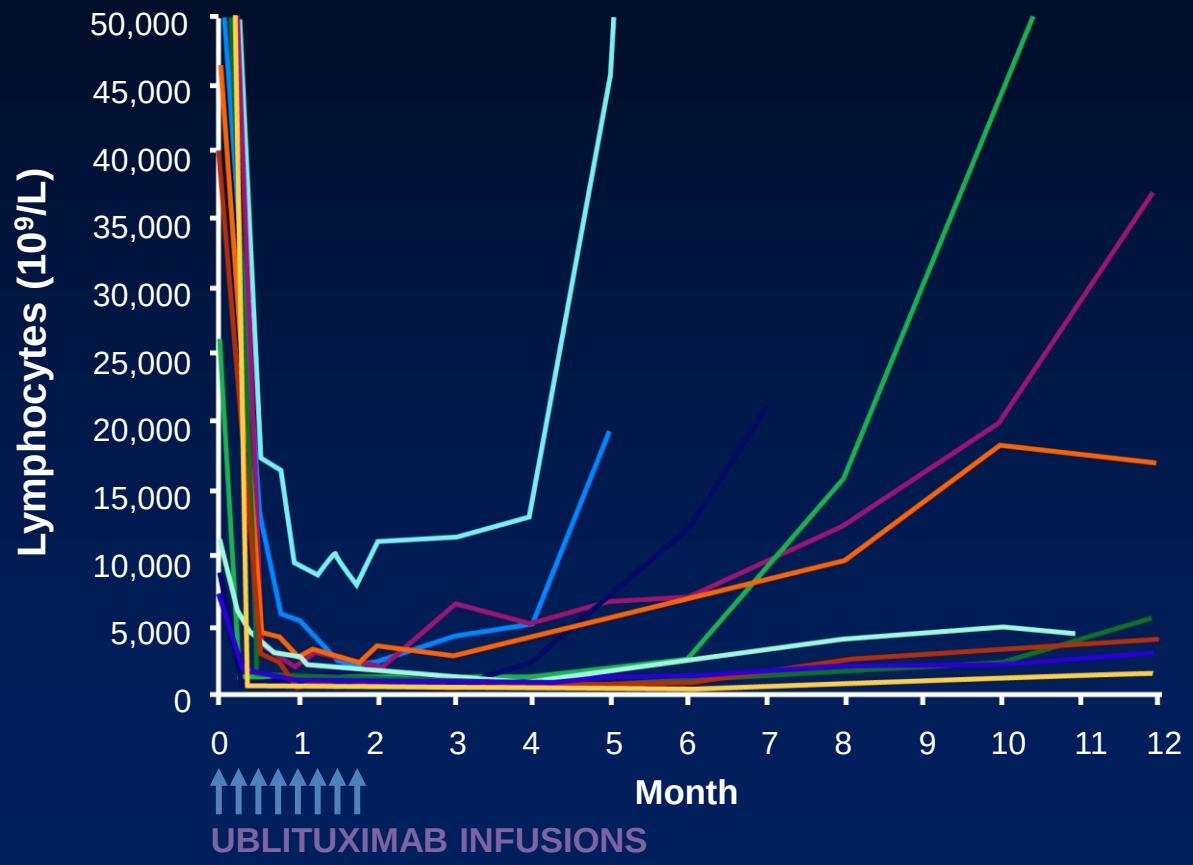


- Fever, chills, arterial hypotension, and tachycardia most common manifestations
- All recovered without sequelae through infusion rate management and/or symptomatic treatment with or without corticosteroids

Cazin B, et al. Presented at the 18th Congress of the European Hematology Association (EHA); Stockholm, Sweden; June 2014. Abstract P111.

Ublituximab Monotherapy in Relapsed CLL: Efficacy Results

Patients	**12**
Evaluable	**11**
CR	**0**
PR at Month 4 (week 16)	**7** ***(63.6%)***
SD at Month 4 (week 16)	**4**
PD at Month 4 (week 16)	**0**
PR at Month 6 (week 24)	**5** ***(45.5%)***



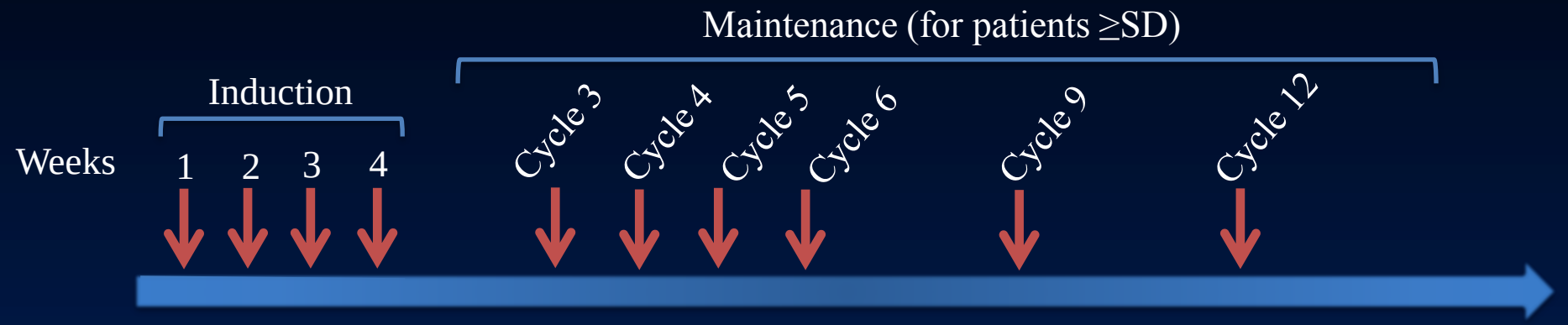
Cazin B, et al. (EHA); Stockholm, Sweden; June 2014. Abstract P111.

A Phase I Trial of Ublituximab (TG-1101), A Novel Anti-CD20 mAb in B-Cell Lymphoma Patients with Prior Exposure to Rituximab

Owen A. O'Connor[1], Changchun Deng[1], Jennifer E. Amengual[1], Mazen Y. Khalil[2], Marshall T. Schreeder[3], Daruka Mahadevan[4], Petros Nikolinakos[5], Ahmed Sawas[1], Jasmine M. Zain[1], Molly Patterson[1], Amber Moon[2], Kathy Cutter[3], Emily K. Pauli[3], Marnie Brotherton[4], Jamie Hodgson[5], Christen N. Cooper[5], Michelle A. Mackenzie[6], Peter Sportelli[7], Hari P. Miskin[7], and Charles M. Farber[6]

Presented at the 19th Congress of the European Hematology Association (EHA); Milan, Italy; June 2014. Abstract 444.

Ublituximab in RR B-Cell Malignancies: Treatment Schedule



Induction: UTX administered weekly x 4 in Cycle 1 (Cycle 28 days)
Maintenance: monthly infusions for patients with ≥SD starting Cycle 3; and infusions every 3 months starting Cycle 6

- Primary objective: Safety and MTD
- Secondary objectives: ORR (CR+PR), PK, and PFS
- Phase 1 cohort design: 3 + 3 dose escalation

Cohort 1	Cohort 2	Cohort 3	Cohort 4
450 mg	600 mg	900 mg	1200 mg

- **Cohort expansion: NHL (900 mg and 1200 mg); CLL (600 mg and 900 mg)**

Induction NHL: UTX weekly x 4 in Cycle 1 (Cycle 28 days); Induction CLL: UTX Days 1, 8, 15 of Cycles 1 and 2
Maintenance: monthly infusions for patients with ≥SD starting Cycle 3; and infusions every 3 months starting Cycle 6

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O'Connor O, et al; EHA 2014. Abstract 444.

Ublituximab in RR B-Cell Malignancies: Demographics

Parameter	
Evaluable for safety, n	35
Evlauable for efficacy, n*	30
Male:Female, n	17:18
Median age, years (range)	66 (45-88)

Type of Lymphoma		
Indolent NHL, n	Follicular	12
	MZL	8
CLL/SLL	CLL	8
Aggressive NHL	MCL	5
	DLBCL	2

Parameter	iNHL	aNHL	CLL	TOTAL
ECOG 0/1/2 (n)	9 / 11 / 0	2 / 4 / 1	2 / 5 / 1	13 / 20 / 2
Median Prior Therapies: n (range)	3 (1-6)	2 (1-9)	3 (1-6)	3 (1-9)
> 4 Prior Therapies: n (%)	7 (35)	2 (29)	3 (38)	12 (34)
> 2 Prior Rituximab Regimens: n (%)	15 (75)	5 (71)	5 (63)	25 (71)
Refractory to Prior Treatment: n (%)	11 (55)	2 (29)	2 (25)	15 (43)
Refractory to Prior Rituximab: n (%)	12 (60)	2 (29)	1 (13)	15 (43)

*5 pts not evaluable: 4 patients off study prior to first efficacy assessment (2 for non-related AE, 1 for SAE, 1 withdrew consent), 1 too early to evaluate

O'Connor O, et al. Presented at the 19th European Hematology Association; Milan, Italy; June 2014. Abstract 444.

Safety: Single-agent Ublituximab

At Least Possibly Related AE's (in > 5% patients)

All Patients (n=35)		
AE	All Grades, n (%)	Grade 3/4 n (%)
Infusion reaction*	10 (29%)	0
Fatigue	5 (14%)	1 (3%)
Diarrhea	4 (11%)	0
Pain (general)	4 (11%)	0
Dysgeusia	3 (9%)	0
Bilirubin Increase	2 (6%)	0
Pruritus	2 (6%)	0

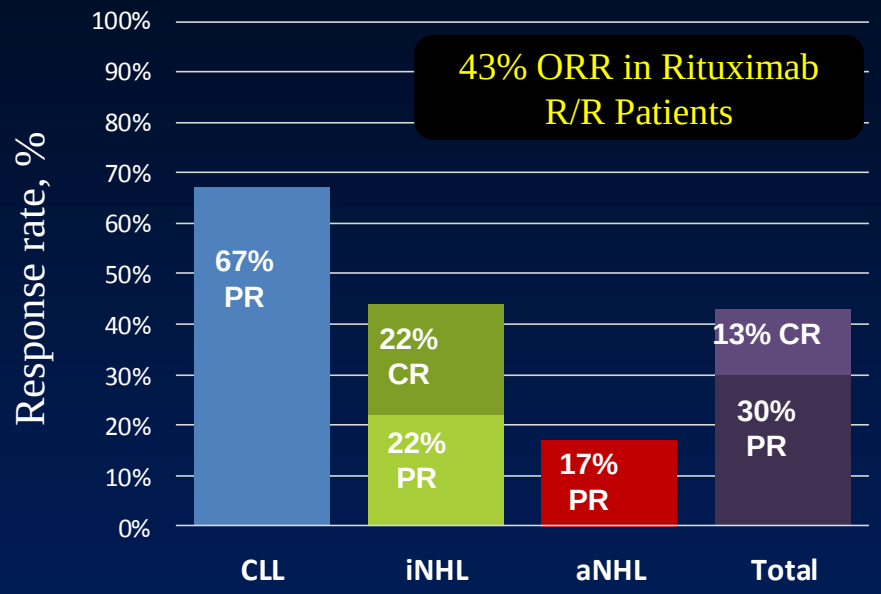
*IRR also includes chills, itching, dyspnea, throat irritation

Laboratory Abnormality (at least possibly related)

AE	CLL (n=8)		NHL (n=27)	
	Grade 1/2, n	Grade 3/4, n	Grade 1/2, n	Grade 3/4, n
Neutropenia	1	3	0	0
Thrombocytopenia	1	1	0	0
Anemia	0	0	0	1

O'Connor O, et al. Presented at the 19th European Hematology Association; Milan, Italy; June 2014. Abstract 444.

Efficacy of Single Agent Ublituximab
Overall Response by Lymphoma Subtype

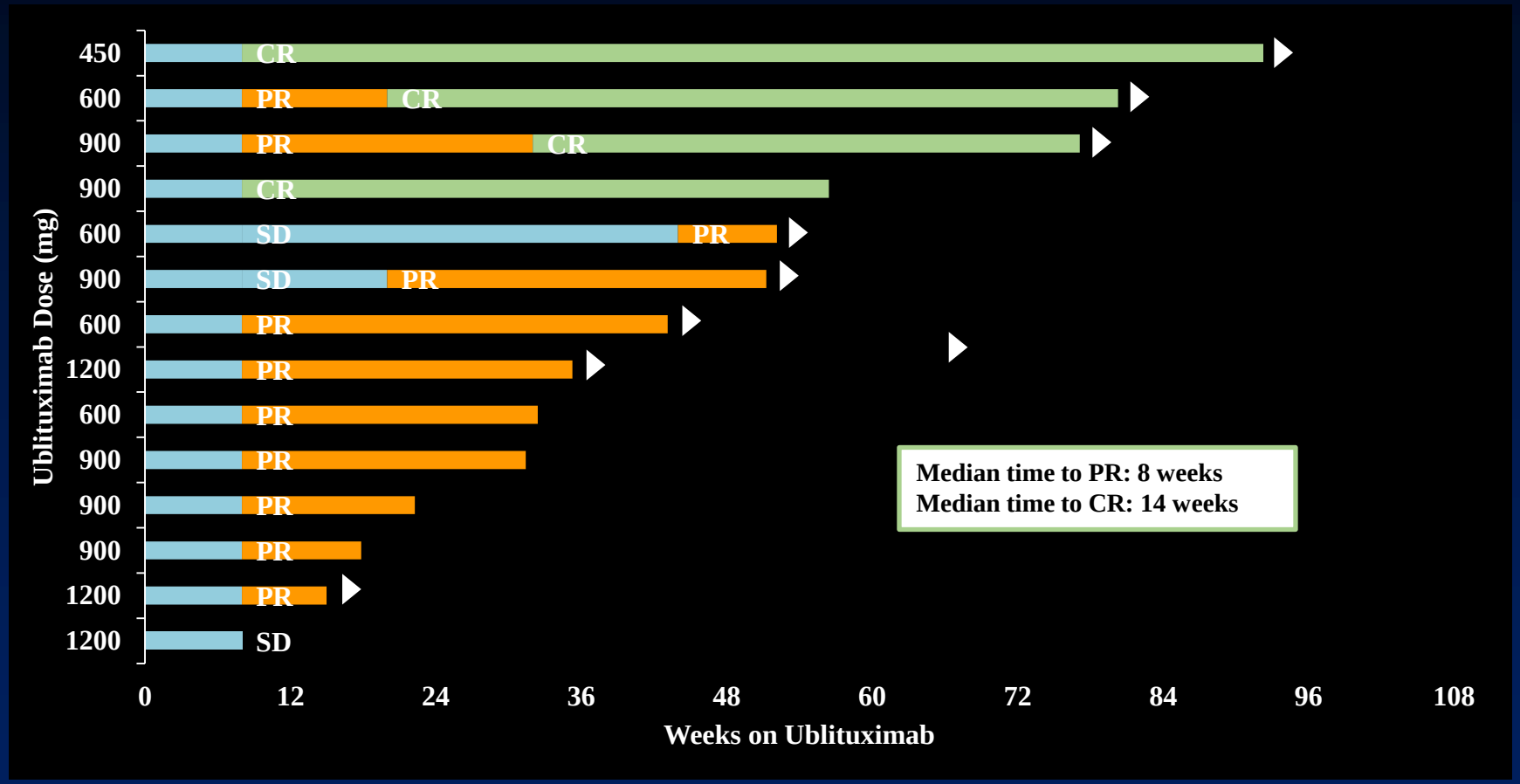


Type	n	CR n (%)	PR n (%)	ORR n (%)
CLL	6	-	4 (67)	4 (67)
FL	12	2 (17)	2 (17)	4 (33)
MZL	6	2 (33)	2 (33)	4 (67)
MCL	5	-	-	-
DLBCL	1	-	1 (100)	1 (100)
Total	30	4 (13)	9 (30)	13 (43)

- 43% ORR in rituximab relapsed and refractory patients
- Durable responses: patients in response 2+ years on single agent UTX
- UTX maintenance infusions have improved responses over time

O'Connor O, et al. Presented at the 19th European Hematology Association; Milan, Italy; June 2014. Abstract 444.

Evolving Responses During Maintenance Ublituximab

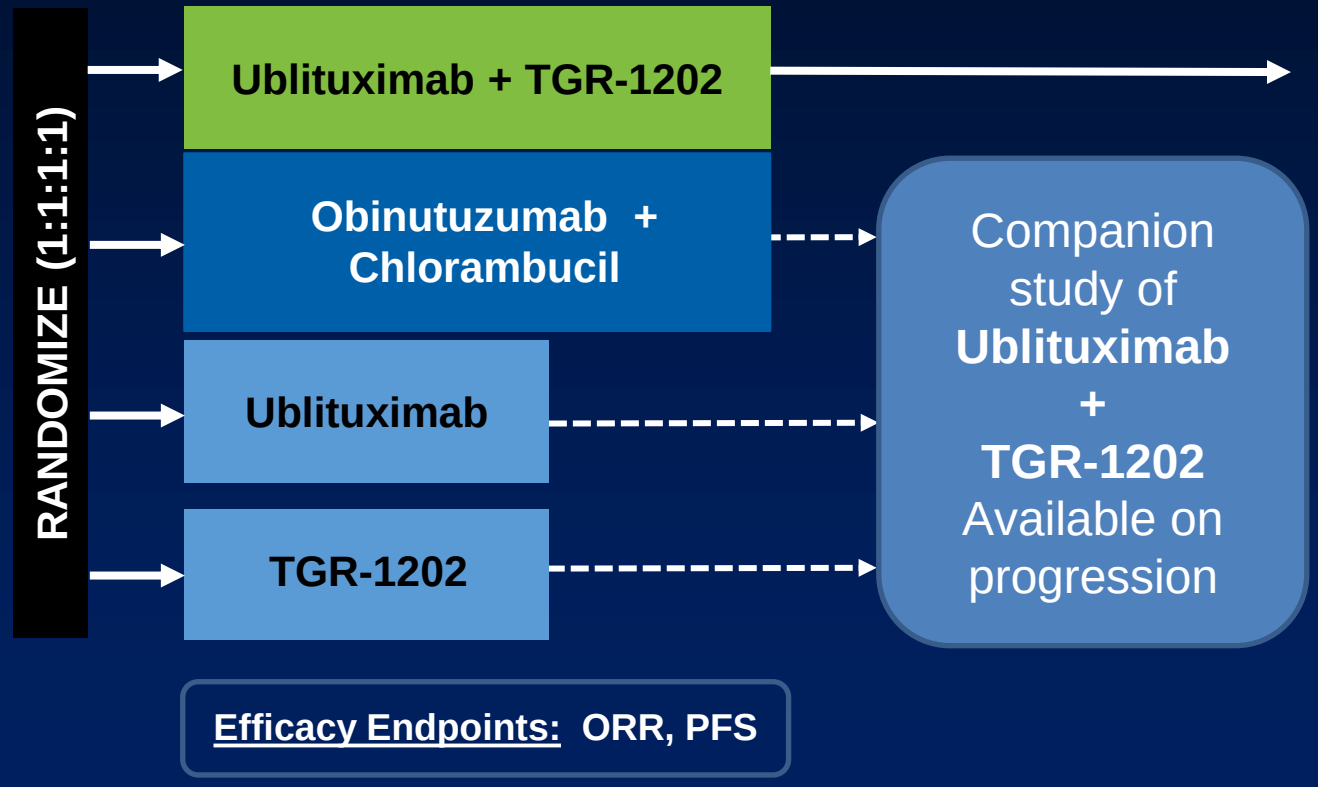


O'Connor O, et al. Presented at the 19th European Hematology Association; Milan, Italy; June 2014. Abstract 444.

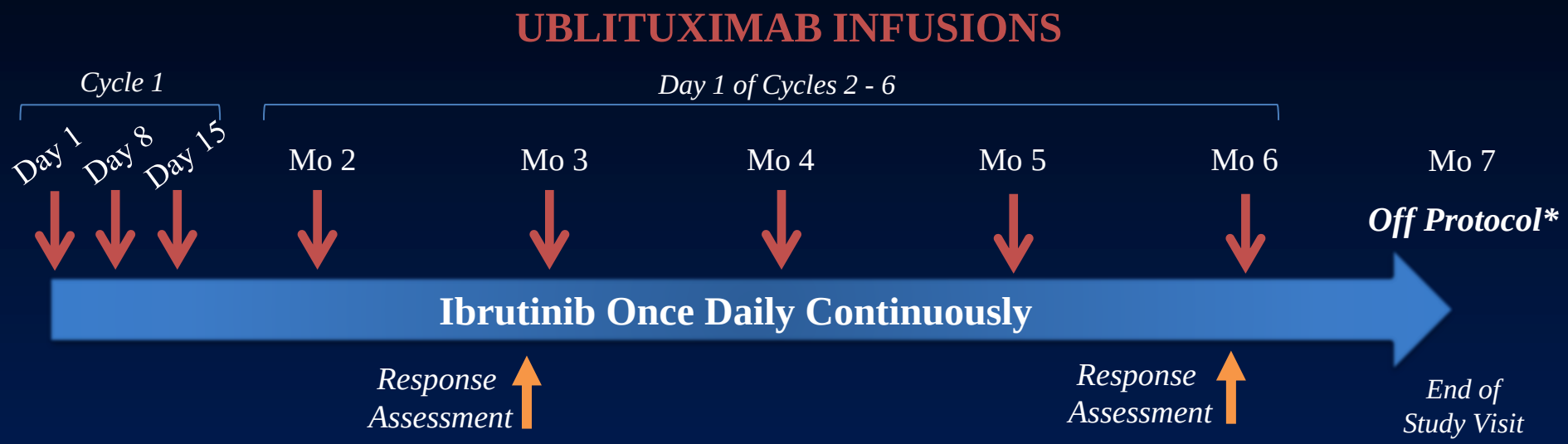
UNITY-CLL 304: Phase 3 Trial for Patients with CLL
Treatment-naïve or Previously Treated

Key Eligibility Criteria:

- No limit on the number of prior lines of therapy
- ECOG Status 0, 1, or 2
- No prior exposure to a PI3K inhibitor
- No prior exposure to obinutuzumab and/or chlorambucil



Phase II: Ublituximab + Ibrutinib in MCL
Study Design



Ublituximab IV: 900 mg on Days 1, 8 and 15 in Cycle 1 followed by Day 1 of Cycles 2 – 6

Ibrutinib: 560 mg on Day 1 and continued daily through Cycle 6

- 2-part study: Part 1 - safety run-in (n=6); Part 2: expansion phase
- Primary endpoints: Safety and ORR
- Secondary: Time to Response and CR rate

*After month 6, all patients were permitted to stay on ibrutinib single agent, off protocol.

Kolibaba KS, et al. ASH (poster presentation) 2015. Abstract 3980.

Ublituximab + Ibrutinib: Demographics

Evaluable for safety, n	15
Evaluable for efficacy, n	15
Median age, years (range)	71 (55 – 80)
Male/Female, n	13 / 2
ECOG PS 0 / 1, n	9 / 6
Stage 4 disease, n (%)	10 (67)
Prior Regimens, median (range)	3 (1 – 8)
≥ 3 Prior regimens, n (%)	9 (60)
≥ 2 Prior Anti-CD20, n (%)	8 (53)
Prior R-CHOP and/or R-Benda, n (%)	15 (100)
Prior bortezomib, n (%)	6 (40)

Kolibaba KS, et al. ASH Abstract 3980.

Ublituximab + Ibrutinib: Safety

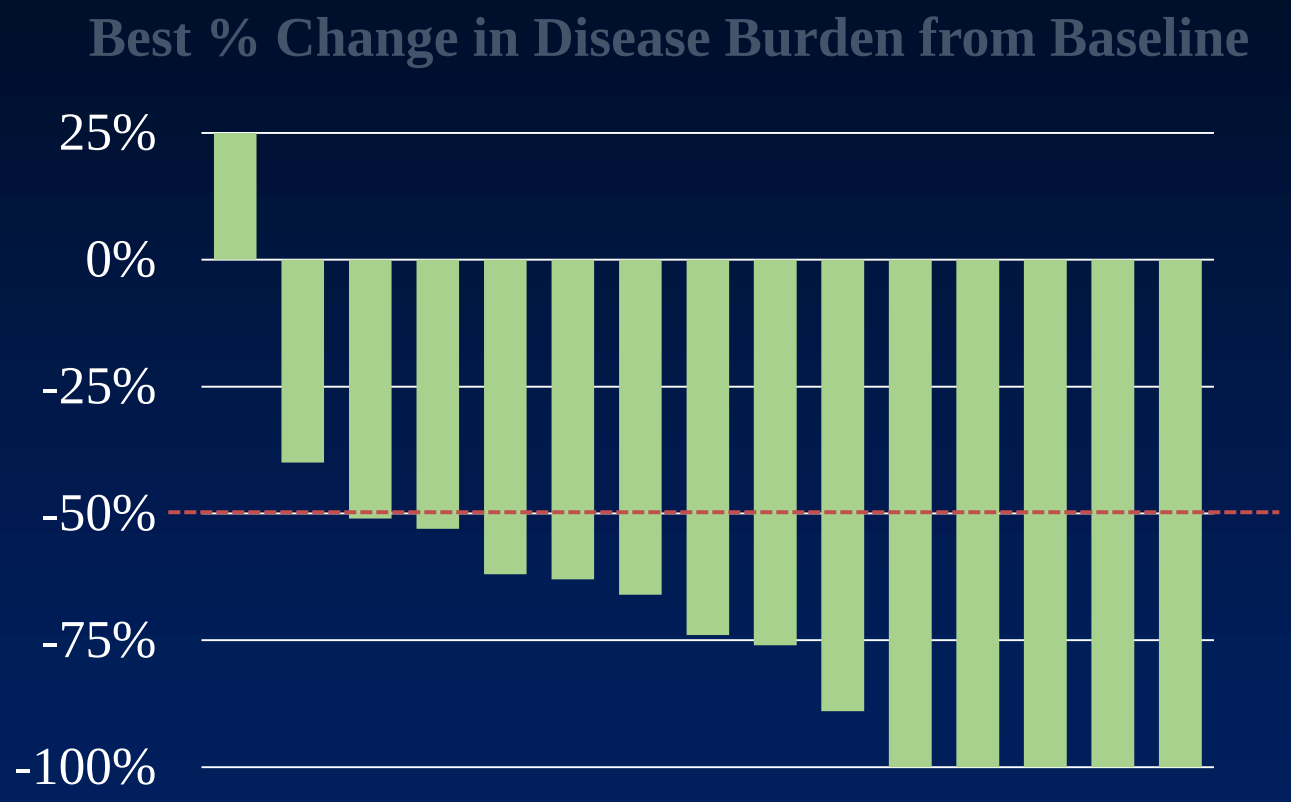
All Causality AE's in > 2 Patients (n=15)		
Adverse Event	**All Grades,** n (%)	**Grade 3/4,** n (%)
Fatigue	8 (53)	1 (7)
Diarrhea	6 (40)	-
Rash	6 (40)	1 (7)
Muscle spasms	5 (33)	-
Nausea	5 (33)	-
Stomatitis	5 (33)	-
Constipation	4 (27)	-
Hypomagnesemia	4 (27)	-
Neutropenia	4 (27)	3 (20)
Thrombocytopenia	4 (27)	-
Contusion	3 (20)	-
Cough	3 (20)	-
Decreased appetite	3 (20)	-
Night sweats	3 (20)	-

- Ibrutinib dose reductions: n=3; 20% (hypertension, rash, fatigue)
  - 1 patient discontinued due to ibrutinib related AE (atrial fibrillation) – atrial fibrillation occurred in 2 patients overall
- No ublituximab dose reductions
- No infusion reactions observed with ublituximab

Kolibaba KS, et al. ASH (poster presentation) 2015. Abstract 3980.

Ublituximab + Ibrutinib in MCL: Efficacy

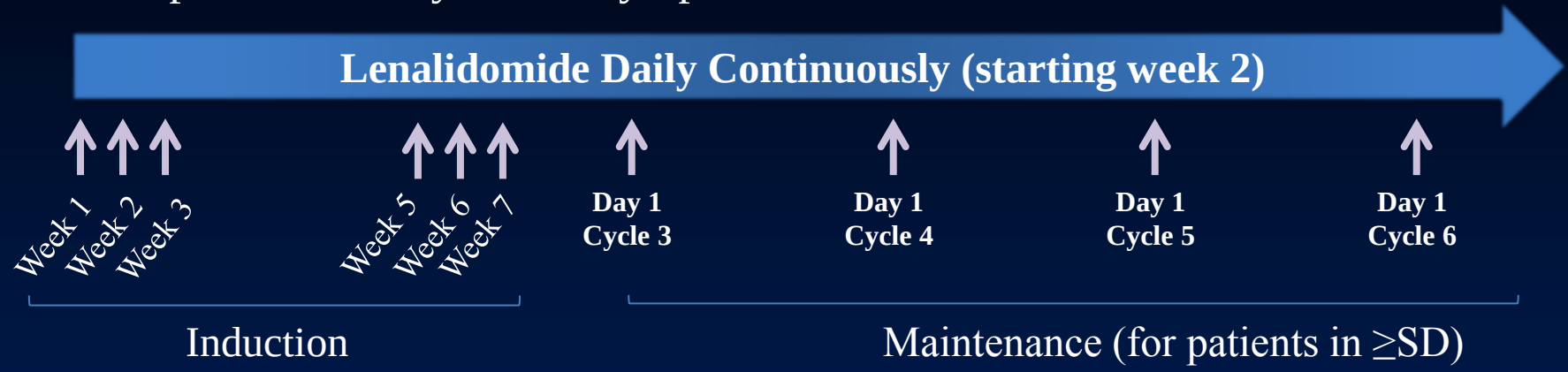
ORR: 87%
CR: 33%



Kolibaba KS, et al. ASH (poster presentation) 2015. Abstract 3980.

Ublituximab + Lenalidomide: Study Design

- Relapsed/refractory B-cell Lymphoma



UBLITUXIMAB INFUSIONS

Dose Escalation Schema

Cohort	Patients	Ublituximab	Lenalidomide
1	3 – 6	450 mg	10 mg
2	3 – 6	450 mg	15 mg
3	3 – 6	600 mg	10 mg*
4	3 – 6	900 mg	10 mg*

*Lenalidomide dose titrated per patient tolerability. The protocol was amended during Cohort 2 to allow a revised administration schedule for lenalidomide in which patients would start at 10 mg QD, and titrate dose in 5 mg increments per cycle based on individual tolerability.

O'Connor OA, et al. EHA 2014. Poster 444.

Ublituximab + Lenalidomide: Baseline Characteristics and Safety

Characteristic	
Evaluable for safety, n	10
Evaluable for efficacy*, n	9
Baseline characteristic	
Median age, years (range)	66 (47-76)
Male/female, n	7/3
ECOG PS, O/1	2/8
Median prior regimens, n (range)	3 (3-6)
≥3 prior rituximab, %	100
Refractory to prior treatment, %	90
Refractory to rituximab, %	70
Prior rituximab-bendamustine, %	90
Prior BTK/PI3K, %	30
Lymphoma subtype, n CLL/SLL Follicular lymphoma Mantle cell lymphoma Burkitt lymphoma	 5 1 3 1

1 patient not evaluable due to non-related SAE.

Adverse Event	Total AEs All Grades	UTX related		LEN related	
		Gr 1/2	Gr 3/4	Gr 1/2	Gr 3/4
Infusion reaction	6	5	1	0	0
Neutropenia	5	0	2*	1	4*
Diarrhea	4	0	0	4	0
Constipation	3	0	0	3	0
Fatigue	3	2*	0	3*	0
Nausea	4	1	0	3	0
Anemia	2	0	1*	1	1*
Hoarseness	2	1	0	1	0
Rash	2	0	0	2	0
Tumor flare	2	0	0	2	0

*Causality of some events were attributed to both UTX and LEN

- 3 patients had their LEN dose reduced or withdrawn (2 neutropenia, 1 nausea); 1 had their UTX dose reduced due to neutropenia
- Although no DLT's were reported, dose interruptions or reductions occurred in 6/10 patients while on study

O'Connor OA, et al. 2014 European Hematology Association (EHA) Meeting, June 13, 2014. Poster 444.

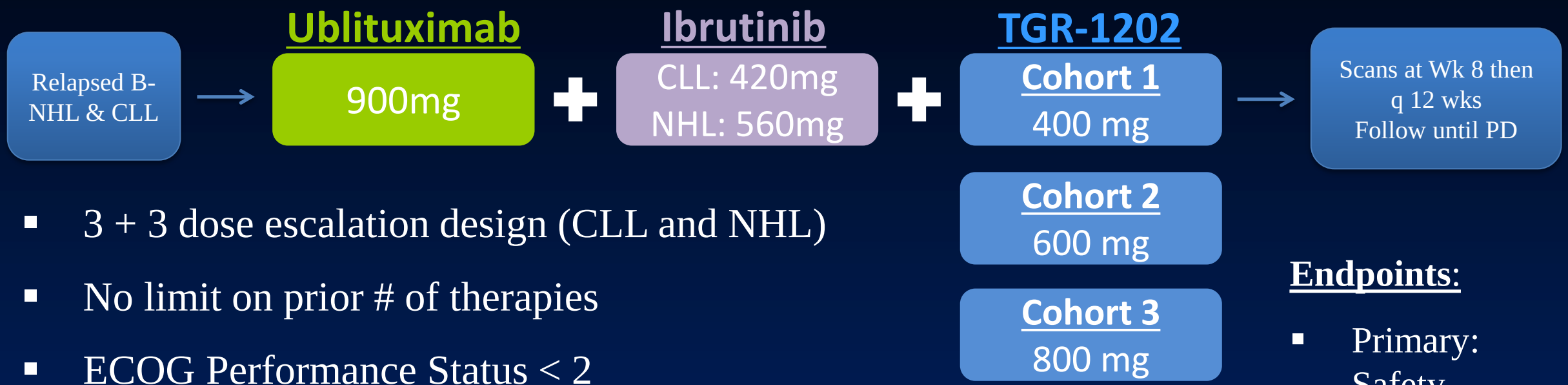
Ublituximab + Lenalidomide: Efficacy

- 22% (2 of 9) patients achieved a PR
  - 1 PR in MCL refractory to idelalisib + rituximab
  - 1 PR in FL refractory to rituximab
  - 22% CLL patients achieved SD > 6 months

  - Lymphocyte depletion observed.
    > 90% reduction in CLL and 80% reduction in MCL after 1 cycle (3 infusions of UTX)

O'Connor OA, et al. 2014 European Hematology Association (EHA) Meeting, June 13, 2014. Poster 444.

Trial Design: TGR-1202 + Ublituximab + Ibrutinib



- 3 + 3 dose escalation design (CLL and NHL)
- No limit on prior # of therapies
- ECOG Performance Status ≤ 2
- ANC > 500 / Plts > 30,000
- Patients with Richter's Transformation, or refractory to prior PI3Kδ inhibitors or prior BTK inhibitors are eligible
- All 3 agents started on Day 1

Endpoints:

- Primary: Safety
- Secondary: ORR, DOR, PFS

Fowler, N et al ASCO 2015

Safety: TGR-1202 + Ublituximab + Ibrutinib

Cohort Summary

- CLL and NHL cohorts evaluated separately

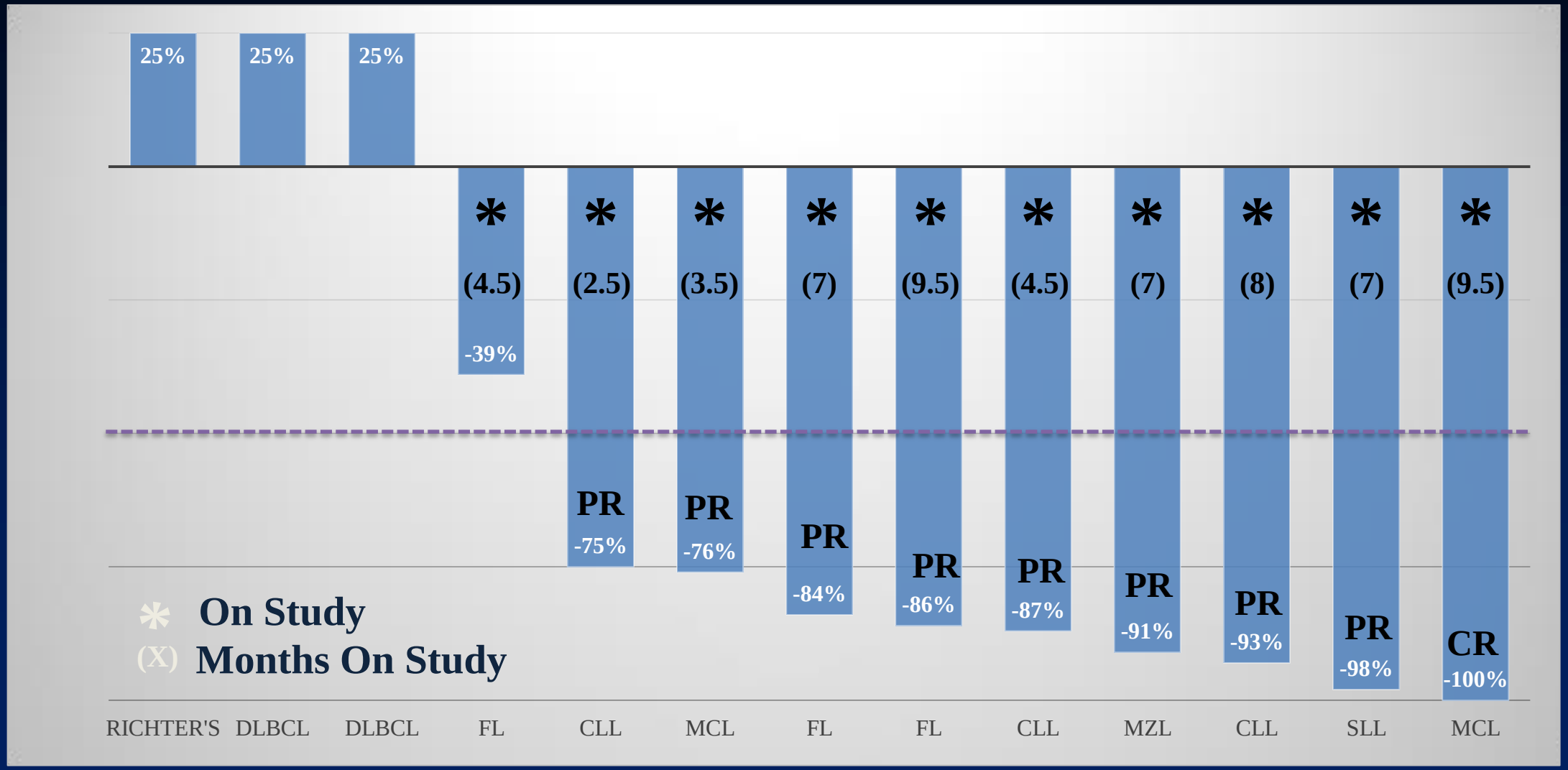
					NHL Pts	# DLT	CLL Pts	# DLT
1:	Ublituximab 900mg	Ibrutinib 420/560mg	+	TGR-1202 400 mg	3	0	5	1*
2:	Ublituximab 900mg	Ibrutinib 420/560mg	+	TGR-1202 600 mg	4	0	0	0
3:	Ublituximab 900mg	Ibrutinib 420/560mg	+	TGR-1202 800 mg	4	0	0	0

**DLT of reactivated varicella zoster – no additional DLT's to date in CLL cohort*

- Median time on study = 4 mos (range 1 – 9 mos)
- DLT in CLL 400 mg cohort
- 800 mg TGR-1202 cohort cleared in NHL

Fowler, N et al ASCO 2015

Activity in NHL: TGR-1202 + Ublituximab + Ibrutinib



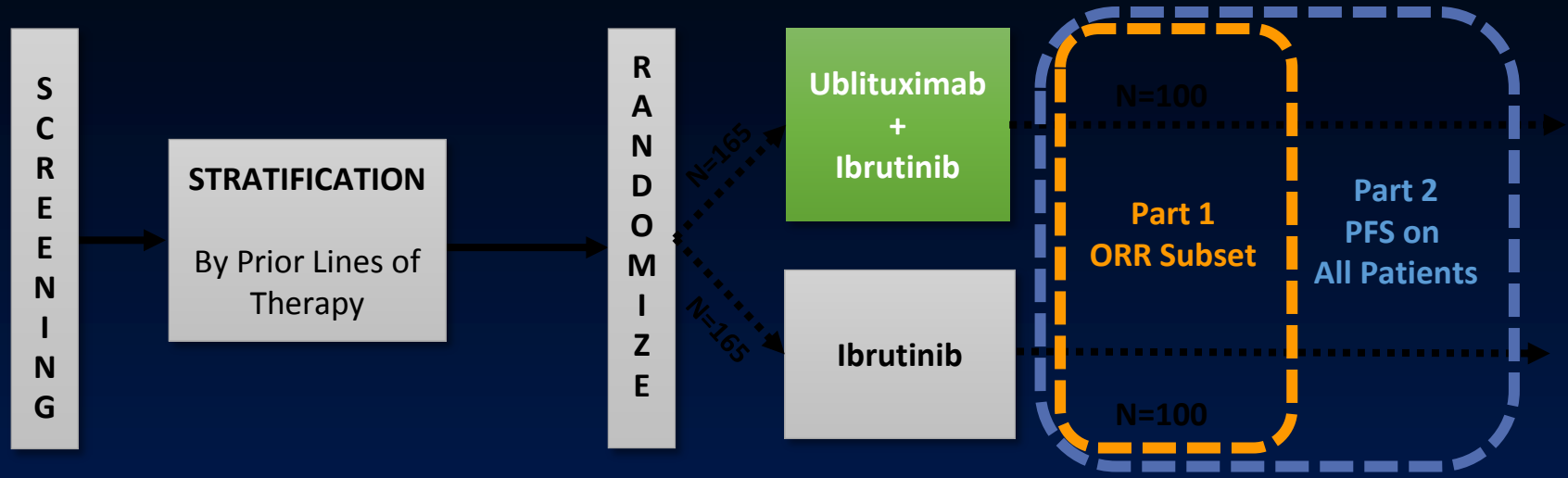
Fowler, N et al ASCO 2015

Conclusions

- Ublituximab is a novel type I monoclonal antibody with activity in relapsed CLL and NHL, including patients with rituximab refractory disease.
- Combination studies appear safe with PI3K, Ibrutinib, and lenalidomide.
- Combination studies are underway in multiple B-cell malignancies.

Questions?

The GENUINE Phase 3 Trial



- Design, endpoints, and statistics agreed to via Special Protocol Assessment (SPA)
- Enrolling ~330 patients with high-risk CLL
- Study Chair: Jeff Sharman, MD
- Part 1: ORR among first 200 patients
- Part 2: PFS of all 330 patients
  - Part 1 to be analyzed following full enrolment of study

GENUINE
TG THERAPEUTICS
GLYCOENGINEERED UBLITUXIMAB PLUS IBRUTINIB

Ublituximab Monotherapy in CLL: Impact on Cytokines

- Plasma IL-6, IL-8, IL-10, and TNF levels significantly increased at 6 hours, at ±90 minutes, an
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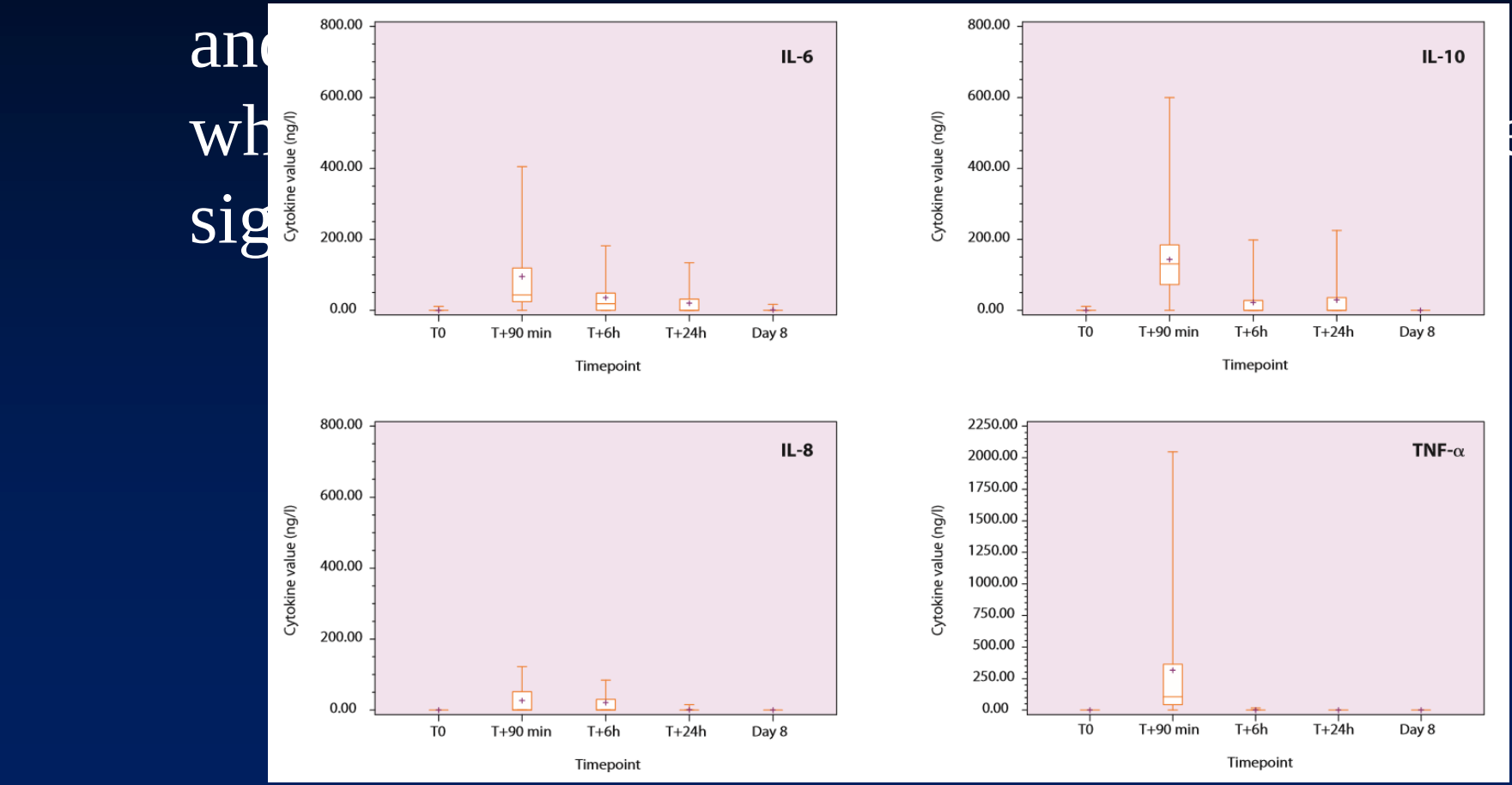
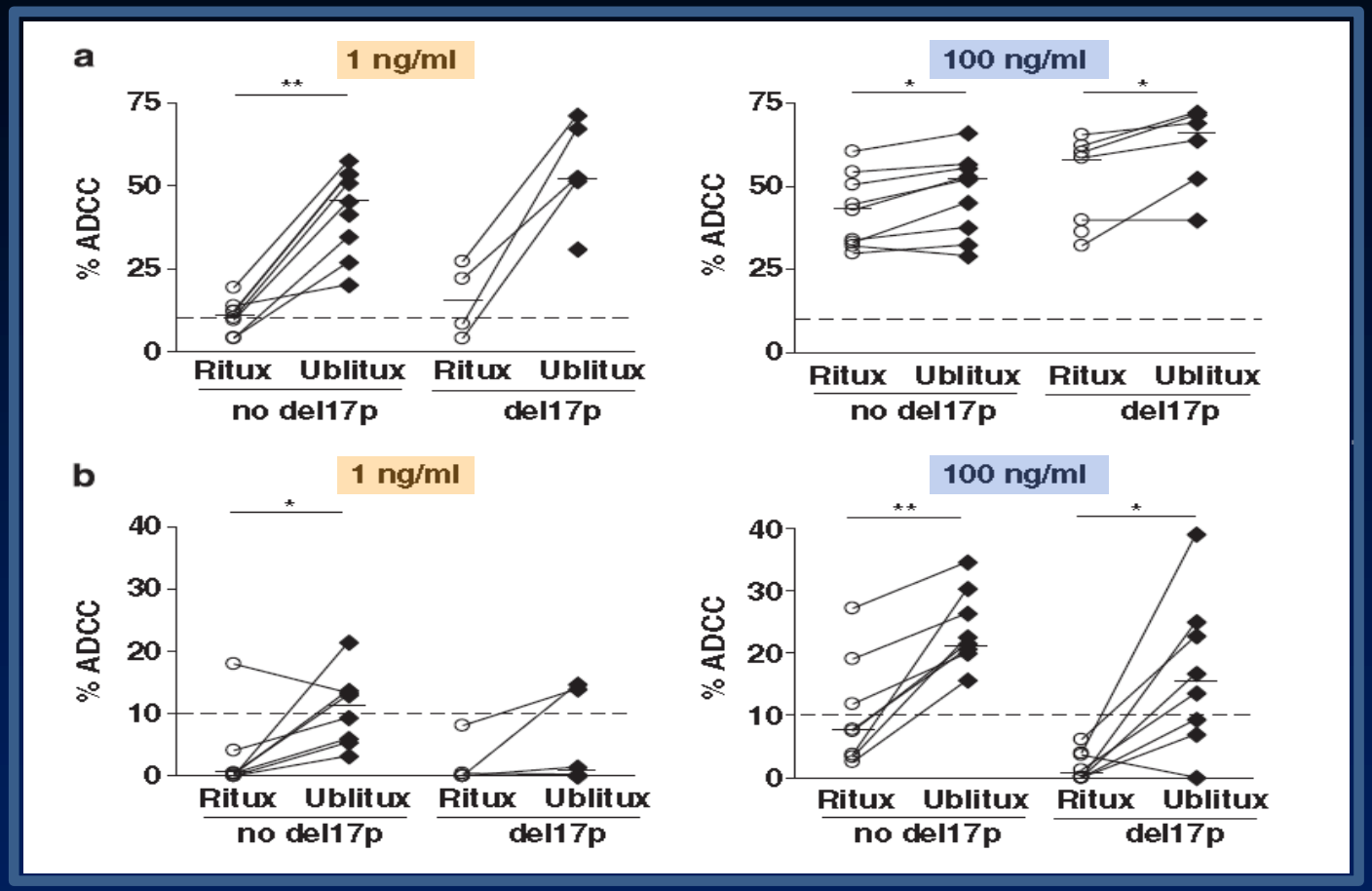


Catron G, et al. Presented at the 52nd Annual American Society of Hematology Meeting; Orlando, FL; December 2010. Abstract 2447.

Enhanced ADCC with Ublituximab, Independent of p53 Status



○ - Rituximab
◆ - Ublituximab

(a)ADCC of Raji cells by NK cells from CLL patients ± del17p induced by 1 and 100 ng/mL RTX or UTX
(b)ADCC of CLL B cells by autologous NK cells from CLL patients ± del17p induced by 1 and 100 ng/mL RTX or UTX

Le Garff-Tavernier M, et al. *Leukemia*. 2014;28(1):230-3.