TG Therapeutics

ASCO 2017

Investor & Analyst Event

June 5, 2017

GENUINE
TG THERAPEUTICS
GLYCOENGINEERED UBLITUXIMAB + IBRUTINIB
PHASE 3 TRIAL IN HIGH-RISK CLL

UNITY CLL
TG THERAPEUTICS
GLYCOENGINEERED UBLITUXIMAB + PI3K DELTA TGR-1202
PHASE 3 TRIAL IN CLL

TG Therapeutics

Welcome & Agenda

Michael S. Weiss
Executive Chairman & CEO

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AGENDA

Topic	Presenter
Welcome / Introductions	Michael S. Weiss, CEO TG Therapeutics
GENUINE Phase 3 Trial Results!	Anthony Mato, MD
TG-1101 + TGR-1202 + Ibrutinib Triple Combo	Anthony Mato, MD
TGR-1202 Safety & Efficacy	Ryan Jacobs, MD
UNITY-CLL Phase 3 Trial Current Update	Ryan Jacobs, MD
CLL Landscape Discussion	Anthony Mato, MD Ryan Jacobs, MD
Closing Remarks	Michael Weiss

TG Therapeutics, Inc.

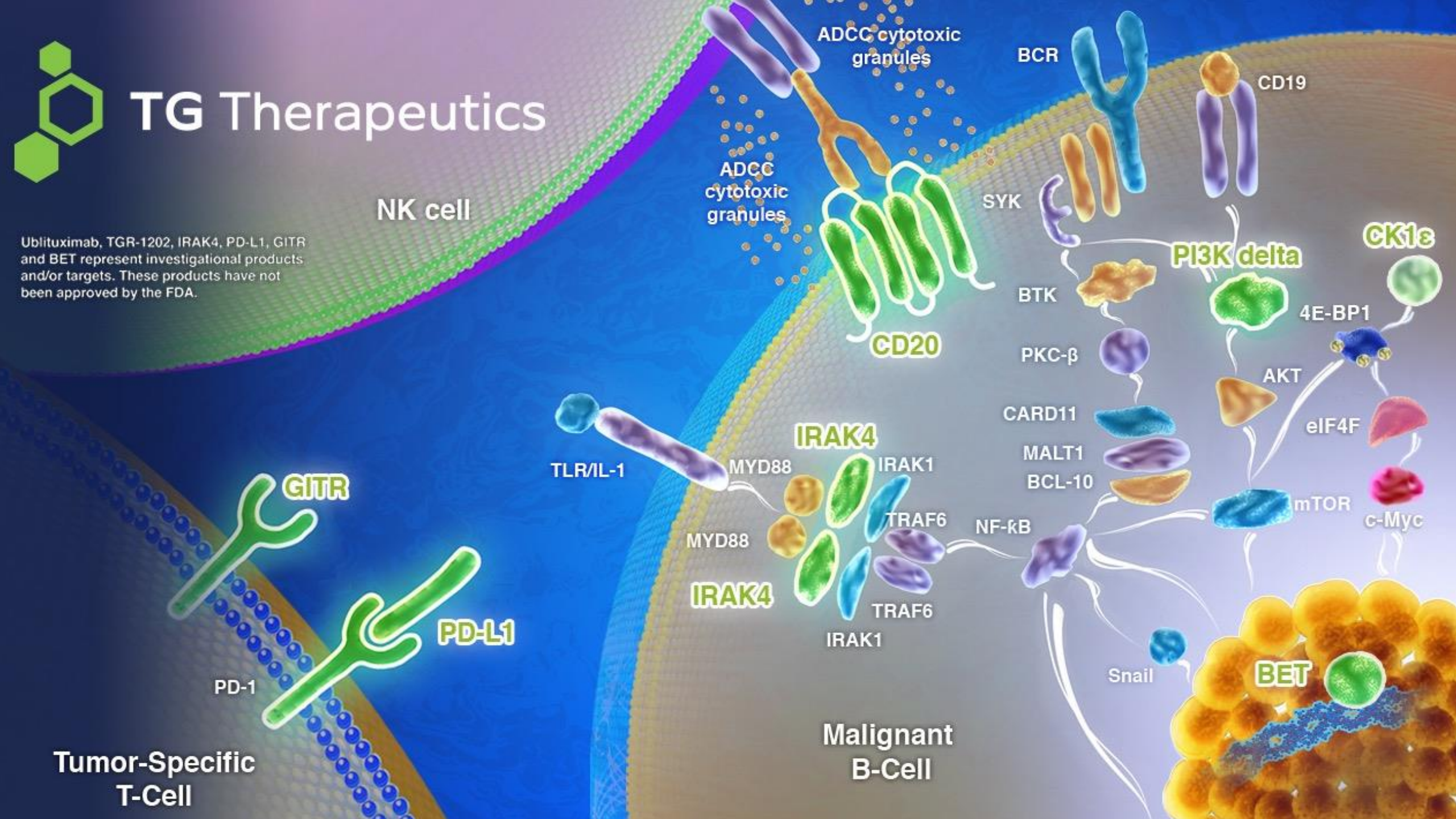
- Biopharmaceutical company focused on B-cell cancers (CLL and NHL) & autoimmune-related diseases (RA, MS, NMO, Lupus)
- **Headquarters:** New York, NY
- **NASDAQ:** TGTX

- Developing portfolio of B-cell targeted agents
- **TGR-1202 – Now named umbralisib! – Novel PI3Kδ inhibitor**
  - Highly active and well tolerated as monotherapy and in combination treatment
  - Demonstrated best-in-class attributes
  - **Currently in registration directed Phase 3 studies under FDA-Special Protocol Assessment**

- **TG-1101 – (ublituximab) Novel Glycoengineered, Anti-CD20 monoclonal antibody**
  - Enhanced ADCC profile for increased potency, similar to Gazyva® (GA101)
  - Robust activity demonstrated in CLL and NHL in Phase 1/2 studies
  - **GENUINE Phase 3 Registration directed study results to be shared!**

- **Anti-PD-L1 & Anti-GITR Research Programs**

- **IRAK4 – Pre-clinical development program**


TG Therapeutics
NK cell
Ublituximab, TGR-1202, IRAK4, PD-L1, GITR and BET represent investigational products and/or targets. These products have not been approved by the FDA.
ADCC cytotoxic granules
ADCC cytotoxic granules
BCR
CD19
SYK
PI3K delta
CK1ε
BTK
4E-BP1
CD20
PKC-β
AKT
CARD11
eIF4F
MALT1
IRAK4
TLR/IL-1
MYD88
IRAK1
BCL-10
mTOR
c-Myc
TRAF6
NF-κB
MYD88
IRAK4
TRAF6
IRAK1
GITR
PD-L1
PD-1
Snail
BET
Tumor-Specific T-Cell
Malignant B-Cell

TG Therapeutics Strategy For Building Value

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- FDA Meeting 3Q/4Q17
- BLA targeted for 1Q/2Q18

OPPY

$200-$500MM

UNITY CLL
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PHASE 3 TRIAL IN CLL

UNITY NHL
TG THERAPEUTICS
GLYCOENGINEERED UBLITUXIMAB + PI3K DELTA TGR-1202
PREVIOUSLY TREATED NHL PATIENTS

- TG1303: CLL, iNHL and DLBCL
- CLL complete enrollment YE18
- DLBCL 2b complete by YE17/Early ‘18

$2-$3BB+

ULTIMATE–MS

TG Therapeutics
Phase 3 in MS

- TG1101 for MS
- Ph.3 to start mid-2017

$1BB+

TG-1101 & GENUINE Phase 3 Results

Anthony R. Mato, MD
Director, Center for CLL
University of Pennsylvania

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PHASE 3 TRIAL IN CLL

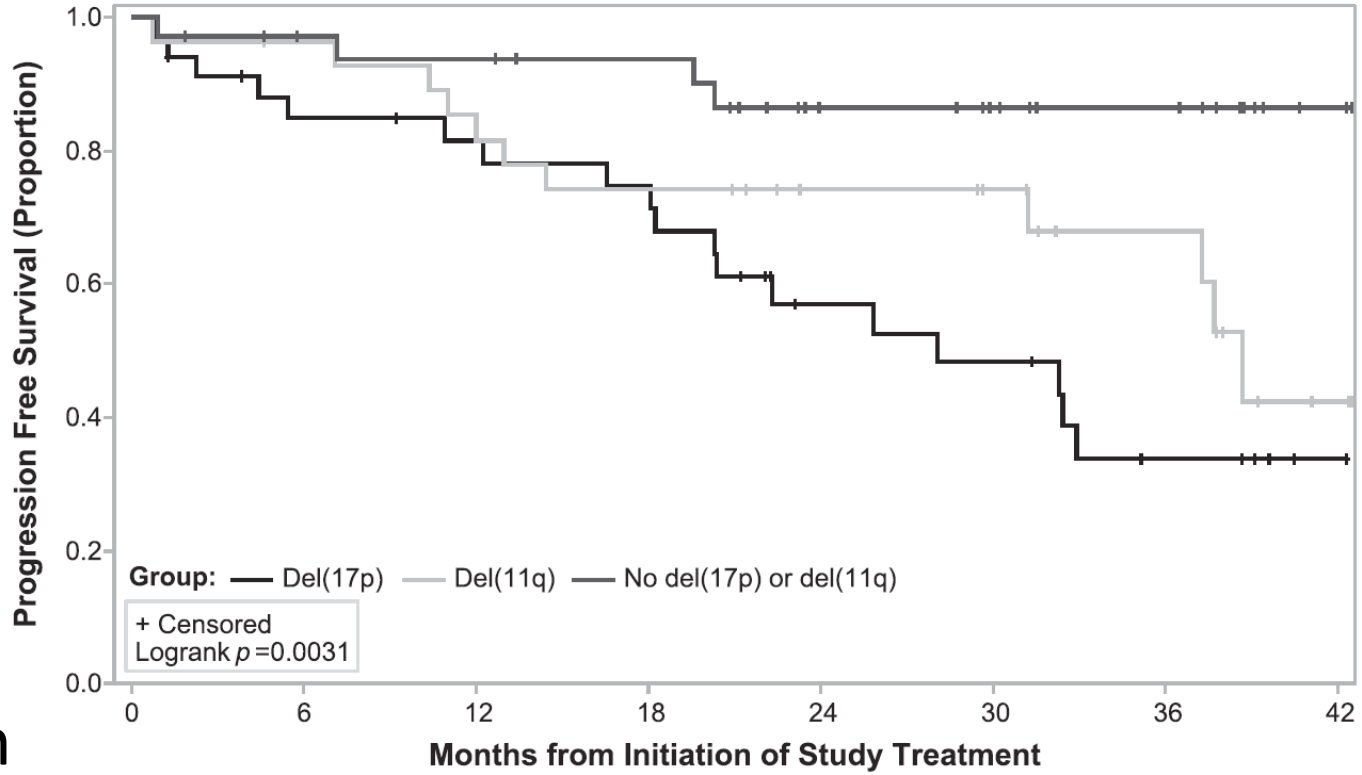
Ublituximab and ibrutinib for previously treated genetically high-risk chronic lymphocytic leukemia: results of the GENUINE phase 3 study

Jeff P. Sharman,[1, 17] Danielle M. Brander,[2] Anthony Mato,[3] Suman Kambhampati,[4] John M. Burke,[5, 17] Frederick Lansigan,[6] Marshall T. Schreeder,[7] Scott D. Lunin,[8] Nilanjan Ghosh,[9] Alexander Zweibach,[10, 17] Mikhail Shtivelband,[11] Patrick M. Travis,[12] Jason Chandler,[13] Kathryn S. Kolibaba,[14, 17] Peter Sportelli,[15] Hari P. Miskin,[15] Michael S. Weiss,[15] and Ian W. Flinn[16]

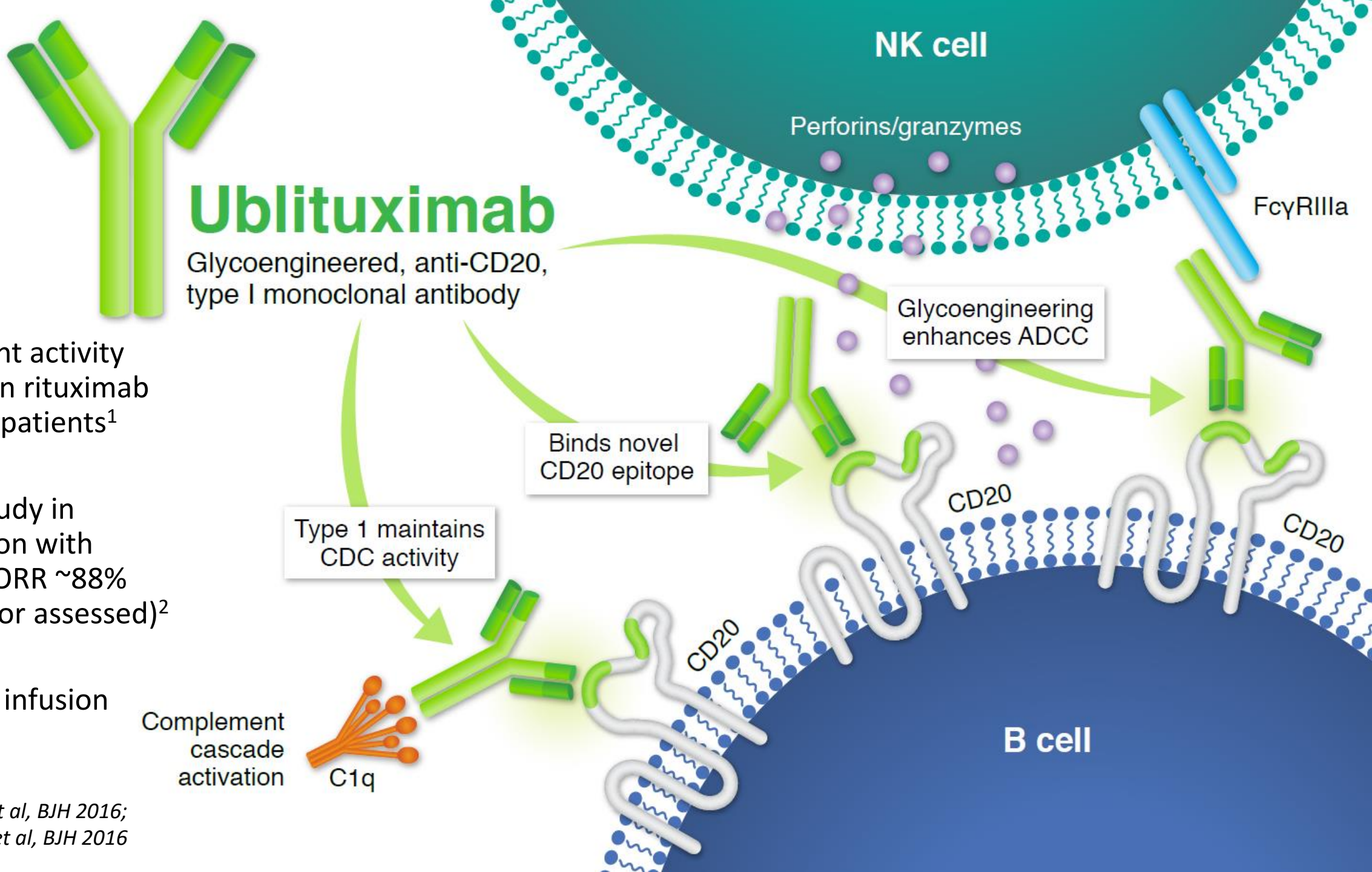
[1]Willamette Valley Cancer Institute, Springfield, OR; [2]Duke University Medical Center, Durham, NC; [3] Center for CLL, University of Pennsylvania, Philadelphia, PA; [4]Sarah Cannon Research Institute at Research Medical Center, University of Kansas Cancer Center, Kansas City, KS; [5]Rocky Mountain Cancer Centers, Aurora, CO; [6]Dartmouth-Hitchcock Medical Center, Lebanon, NH; [7]Clearview Cancer Institute, Huntsville, AL; [8]Florida Cancer Specialists, Sarasota, FL; [9]Levine Cancer Institute, Charlotte, NC; [10]Cancer Care Centers of South Texas, New Braunfels, TX; [11]Ironwood Cancer and Research Center, Chandler, AZ; [12]Highlands Oncology Group, Fayetteville, AR; [13]West Cancer Center, Memphis, TN; [14]Compass Oncology, Vancouver, WA; [15]TG Therapeutics, Inc., New York, NY; [16]Sarah Cannon Research Institute, Nashville, TN; [17]US Oncology Research, Woodlands, TX

Introduction

- Despite the introduction of ibrutinib and other targeted agents, patients with CLL continue to relapse and complete remissions are rare
- Patients with high risk cytogenetic features still have the poorest outcome on ibrutinib
- Improving ibrutinib therapy through combinations remains a high priority



Byrd et al, Blood 2015

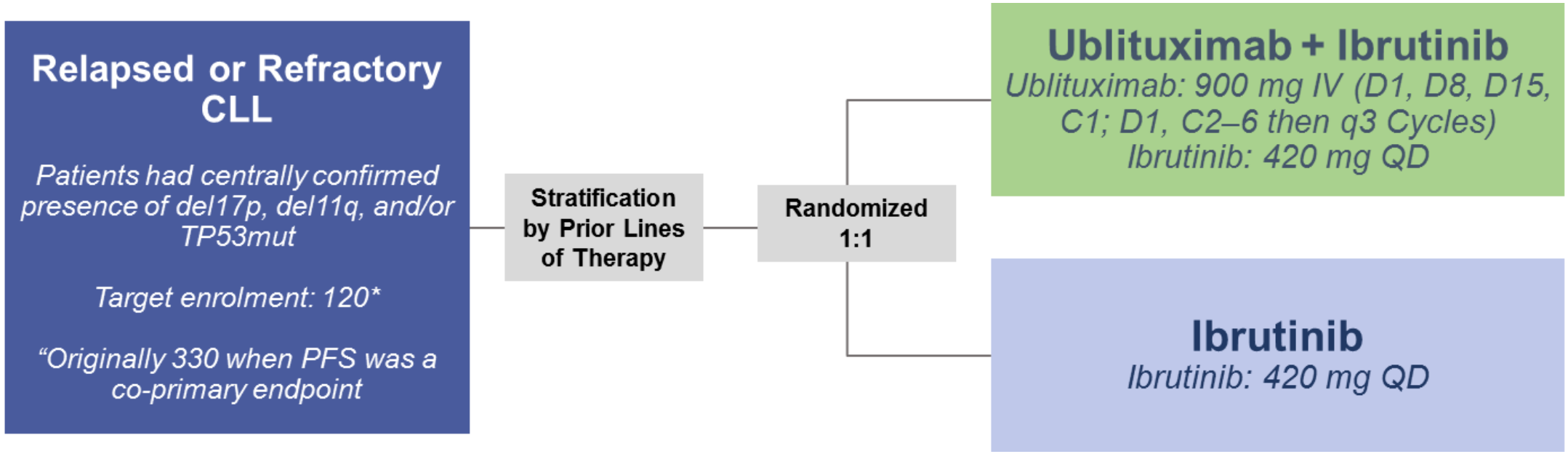


- Single agent activity observed in rituximab refractory patients[1]
- Phase 2 study in combination with ibrutinib: ORR ~88% (investigator assessed)[2]
- 90 minute infusion times

[1]O'Connor et al, BJH 2016;
[2]Sharman et al, BJH 2016

UTX-IB-301 (GENUINE) Study Design

- Open-label, multicenter, randomized, Phase III study in relapsed or refractory high-risk CLL
- Originally designed with ORR and PFS as co-primary endpoints
  - Due to enrollment challenges, lowered target enrollment and removed PFS as a co-primary



- Response assessments occurred at Week 8, 16, and 24, and every 12 weeks thereafter

Study Endpoints

- **Primary endpoint:** Overall Response Rate as assessed by Independent Central Review Committee (IRC) by iwCLL (Hallek 2008) criteria – Evaluated when all enrolled patients had at least two efficacy evaluations

- **Secondary endpoints:**
  - CR rate
  - MRD negativity
  - PFS, DOR, TTR
  - Safety

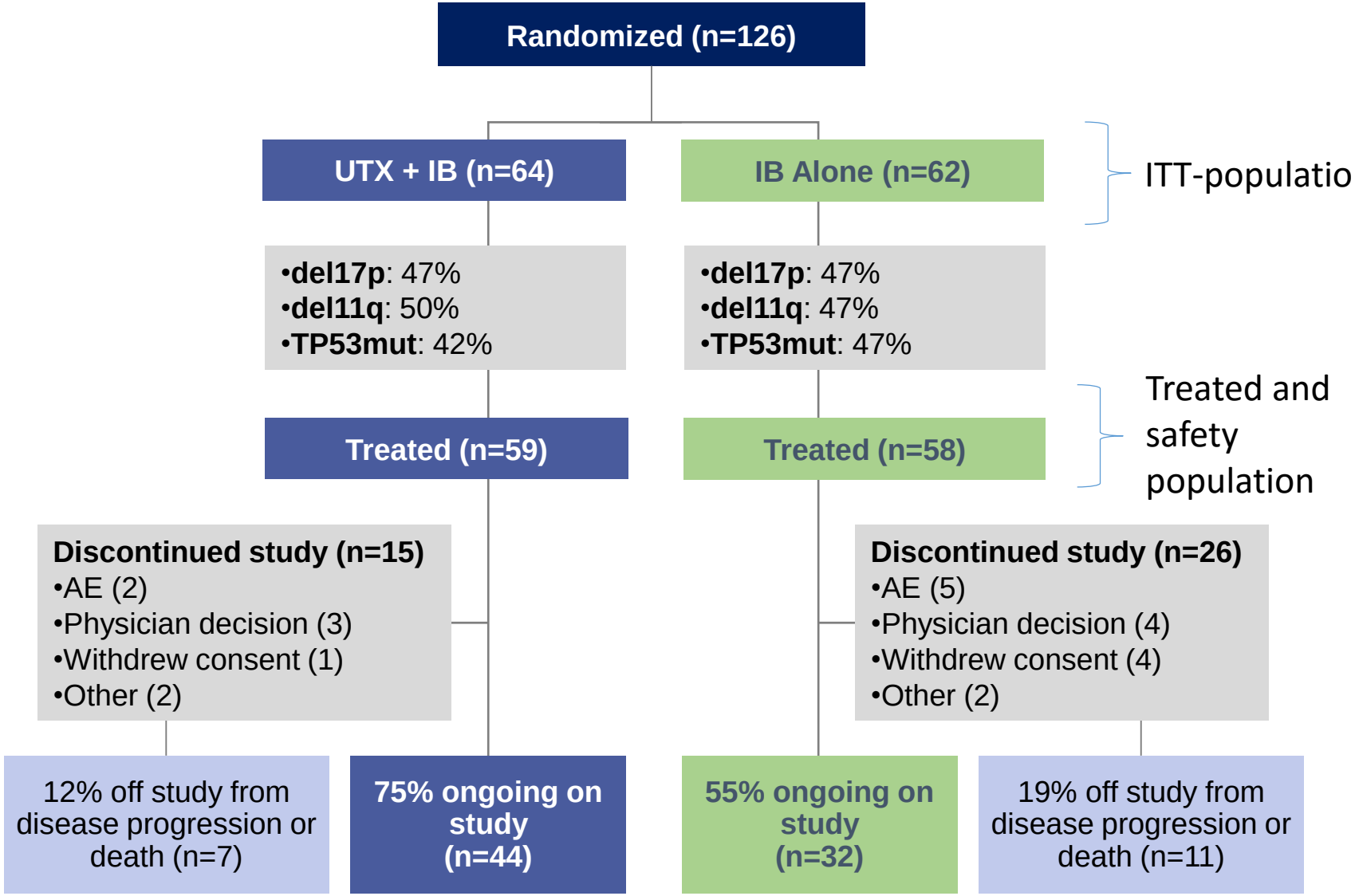
- **Statistical Assumptions:**
  - 120 patients required to have 90% power to detect an absolute difference in ORR of approximately 30%

Key Eligibility Criteria

- Age ≥18 y
- Relapsed/refractory CLL requiring treatment
  - Centrally confirmed presence of 17p del, 11q del, and/or TP53 mut
- Measurable disease
- ECOG ≤2
- No history of transformation of CLL
- No prior BTK inhibitor therapy

Patient Disposition

- 126 patients randomized, 9 never treated
- 100% were either:
  - del17p, del11q or TP53
- 64% of UTX + IB patients and 66% of IB Alone patients were del17p or TP53 mut
- 36% of UTX + IB patients and 34% of IB Alone patients were del11q only
- Median Follow up: 11.4 mo



Data Cutoff: February 15, 2017

Demographics

Characteristic, % (n)	Ublituximab + Ibrutinib n=64	Ibrutinib n=62
Mean age, years (range)	67 (43 - 87)	67 (51-86)
Mean time from diagnosis to randomization, years (range)	6.6 (3 mos – 22 yrs)	6.5 (3 mos – 20 yrs)
Male	44 (69%)	46 (74%)
ECOG performance status at baseline		
0–1	61	60
2	3	2
Rai stage III-IV, %	32 (50%)	26 (42%)
IGHV unmutated, %	51 (80%)	51 (82%)
Bulky disease at baseline (≥ 5cm)	29 (45%)	16 (26%)
Number of prior lines of therapy, median (range)	3 (1-7)	3 (1-8)
Most common prior regimens		
FC ± Rituximab	30 (47%)	29 (47%)
BR	27 (42%)	29 (47%)
Rituximab	54 (84%)	57 (92%)
Obinutuzumab ± Chlorambucil	5 (8%)	4 (6%)
Idelalisib ± Rituximab	5 (8%)	4 (6%)

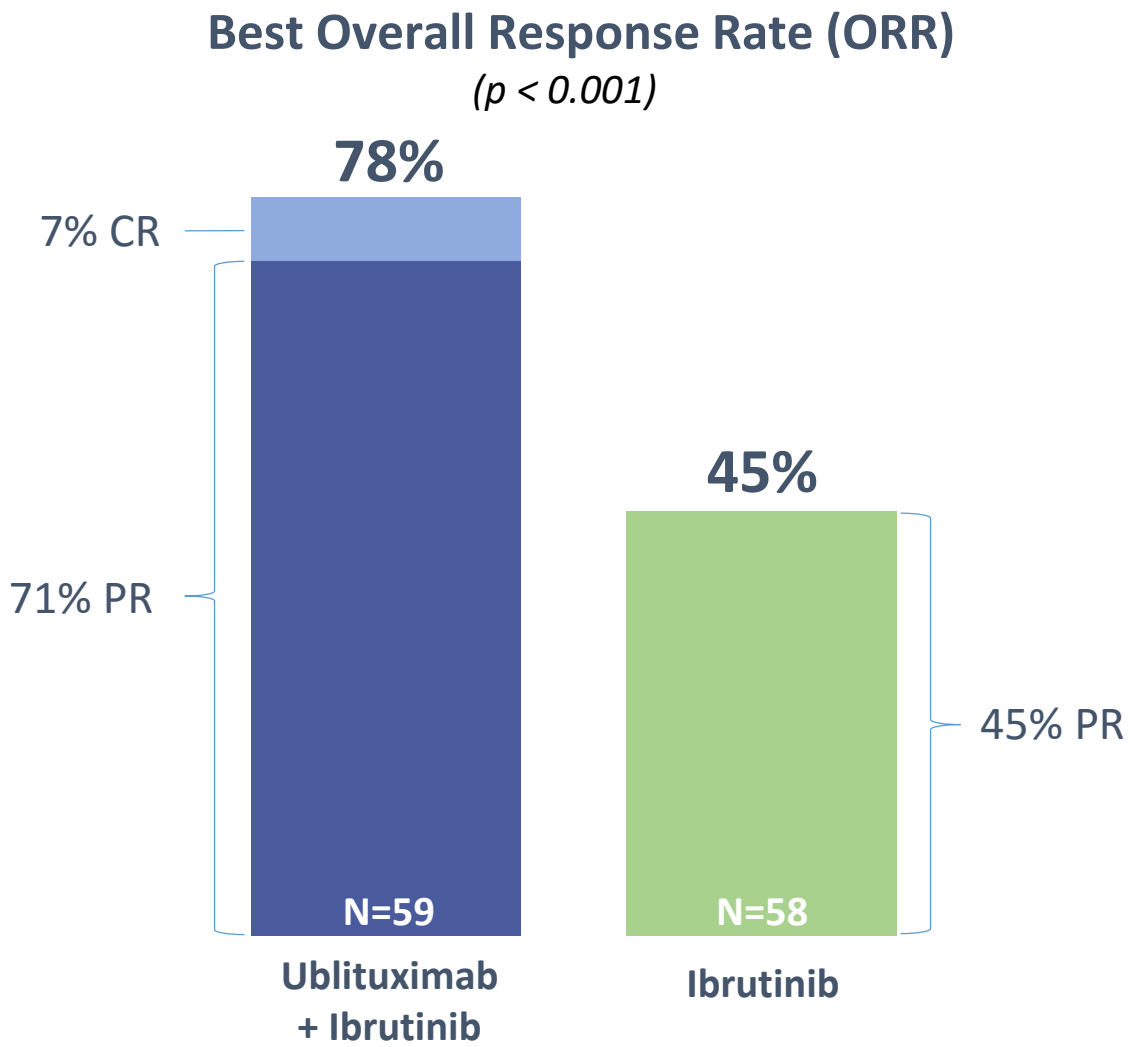
Safety: Adverse Event Summary (≥ 10%)

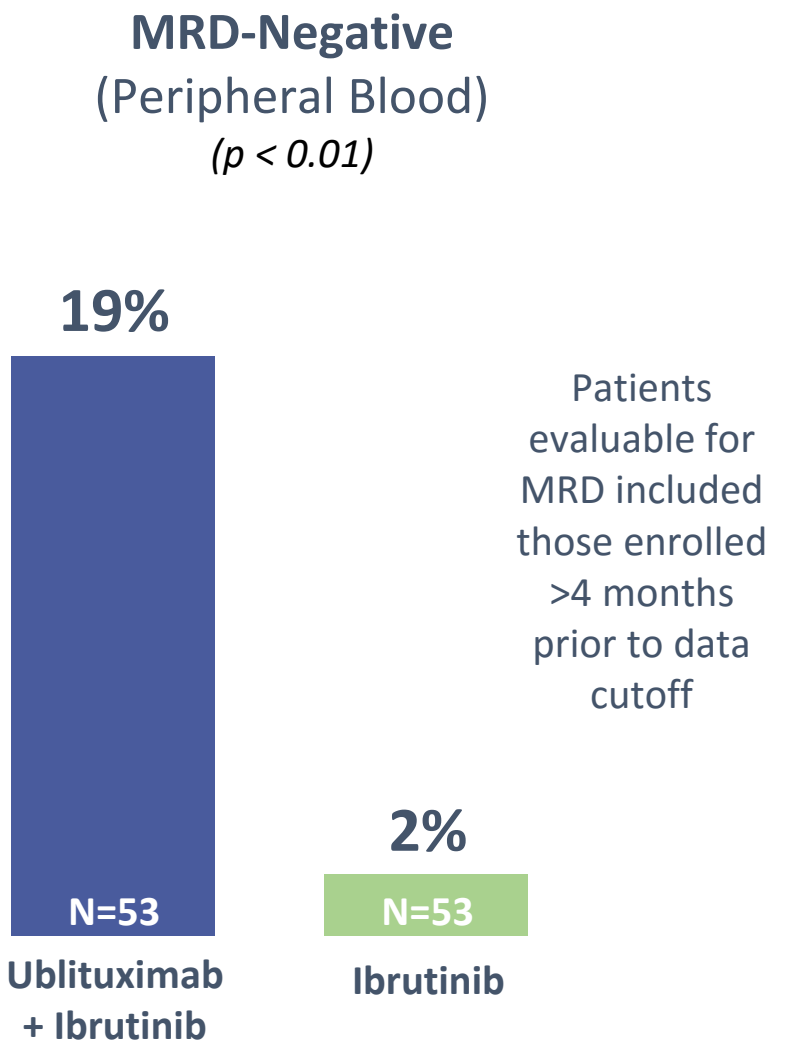
	Ublituximab + Ibrutinib (N=59)		Ibrutinib (N=58)	
	All Grades	**Grade 3/4**	**All Grades**	**Grade 3/4**
Infusion reaction	54%	5%	-	-
Diarrhea	42%	3%	40%	3%
Fatigue	27%	-	33%	2%
Insomnia	24%	-	10%	2%
Nausea	22%	-	21%	2%
Headache	20%	-	28%	2%
Arthralgia	19%	2%	17%	-
Cough	19%	-	24%	-
Abdominal Pain	15%	-	9%	-
Stomatitis	15%	2%	9%	2%
Upper Respiratory Infection	15%	-	12%	2%
Dizziness	15%	-	22%	2%
Contusion	15%	-	29%	-
Anemia	14%	5%	17%	7%
Peripheral Edema	10%	-	21%	-
Adverse Events <10% of Special Interest				
Pneumonia	5%	0%	9%	5%
Atrial Fibrillation	3%	3%	5%	2%
Febrile Neutropenia	3%	3%	2%	2%

Safety: Key Laboratory Abnormalities

	Ublituximab + Ibrutinib (N=59)		Ibrutinib (N=58)	
	Any Grade n (%)	**Grade ≥3** n (%)	**Any Grade** n (%)	**Grade ≥3** n (%)
ALT elevation	1 (2%)	-	2 (3%)	1 (2%)
AST elevation	1 (2%)	-	2 (3%)	1 (2%)
Anemia	8 (14%)	3 (5%)	10 (17%)	4 (7%)
Neutropenia	13 (22%)	5 (9%)	7 (12%)	6 (10%)
Thrombocytopenia	8 (14%)	-	6 (10%)	2 (3%)
Blood creatinine increase	5 (9%)	-	1 (2%)	-
Blood uric acid increase	5 (9%)	-	1 (2%)	-

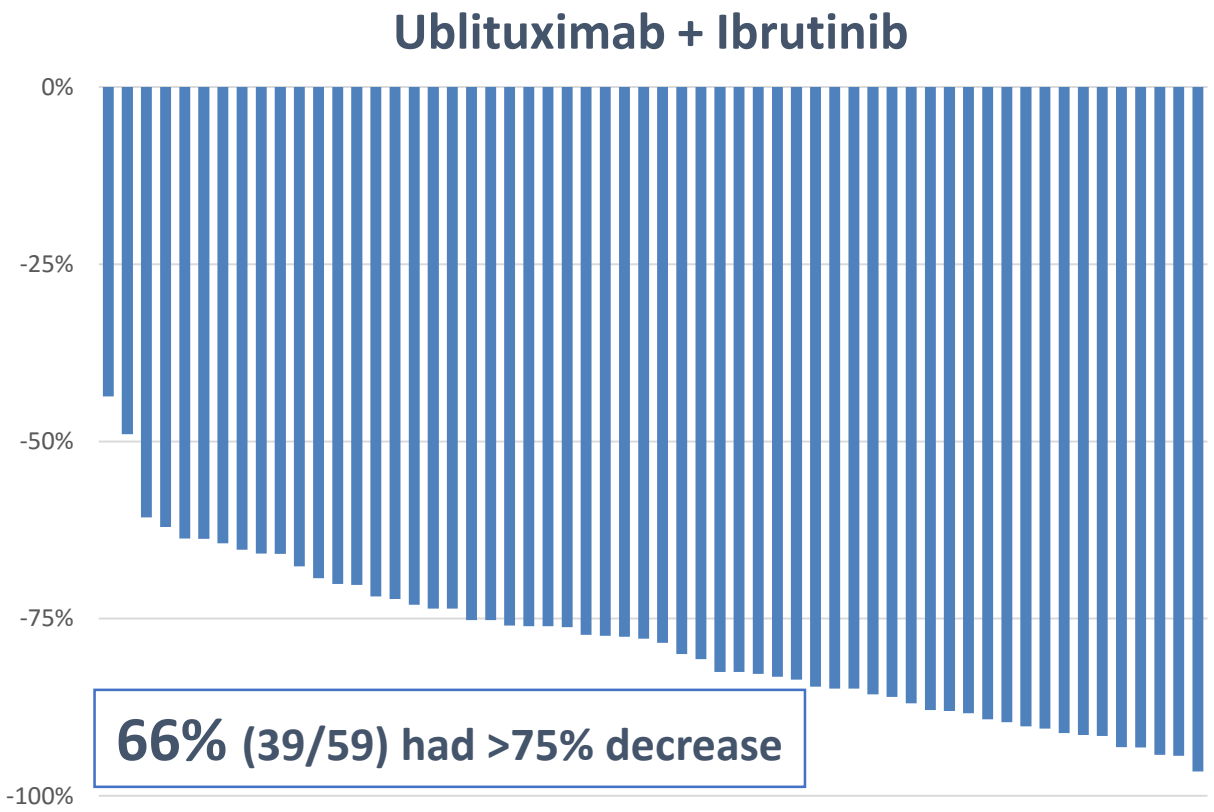
Efficacy: IRC Assessed ORR, CR, & MRD-Negativity

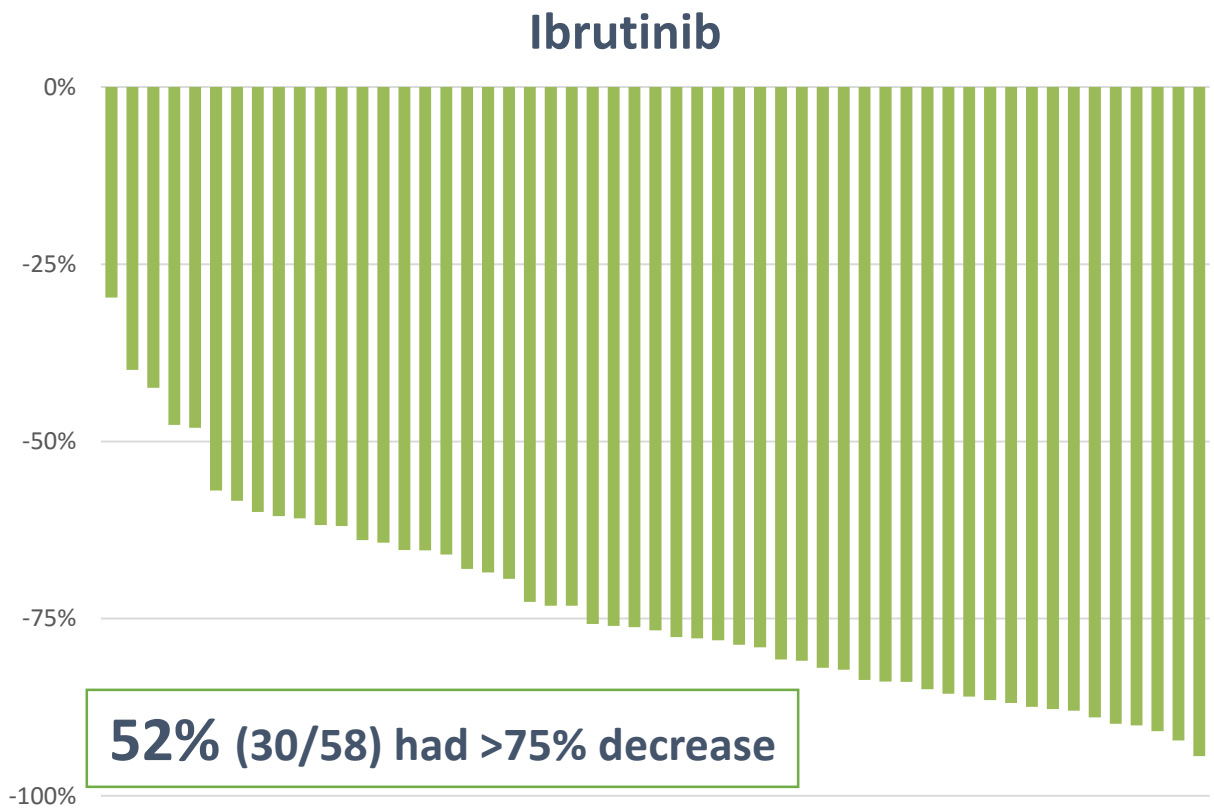




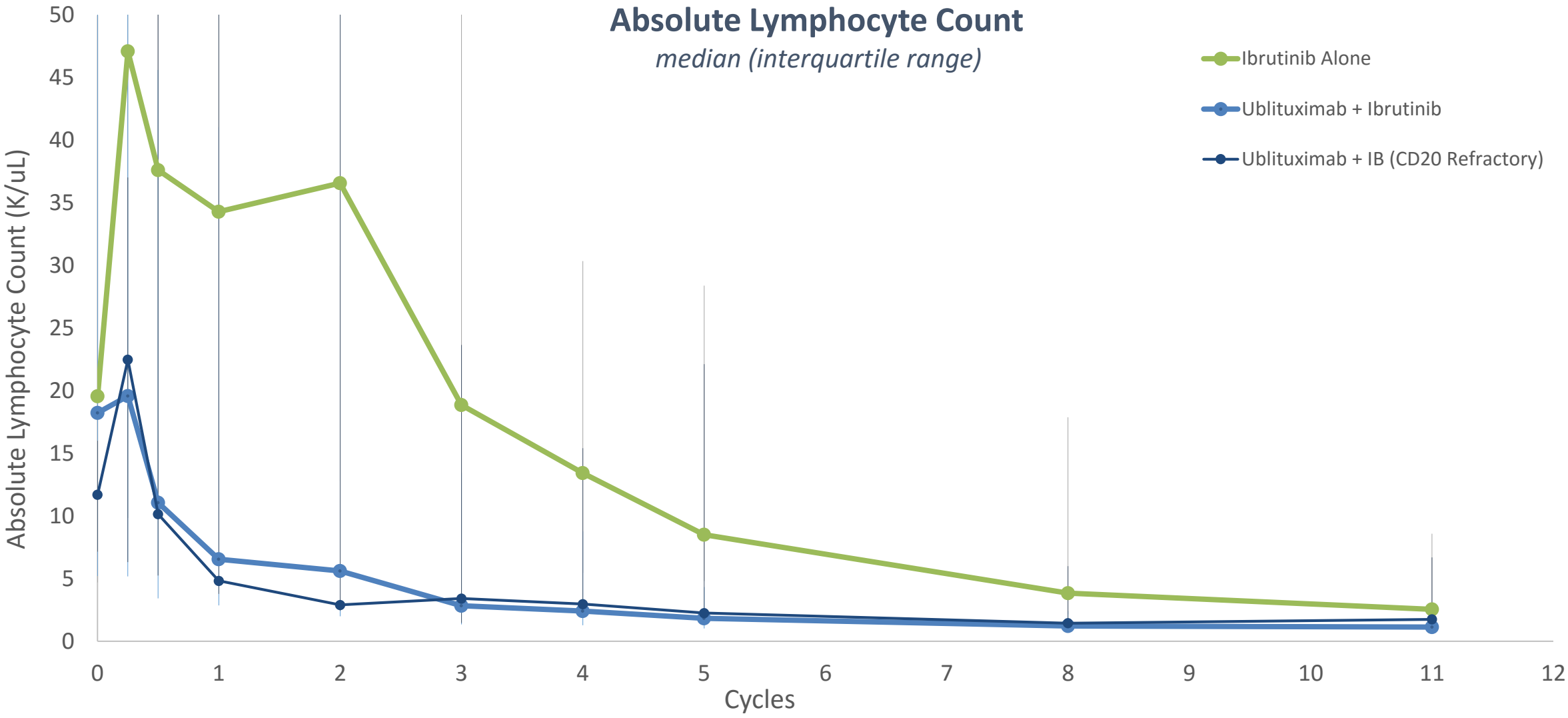
ITT ORR: p < 0.01

Best Percent Change in Nodal Size

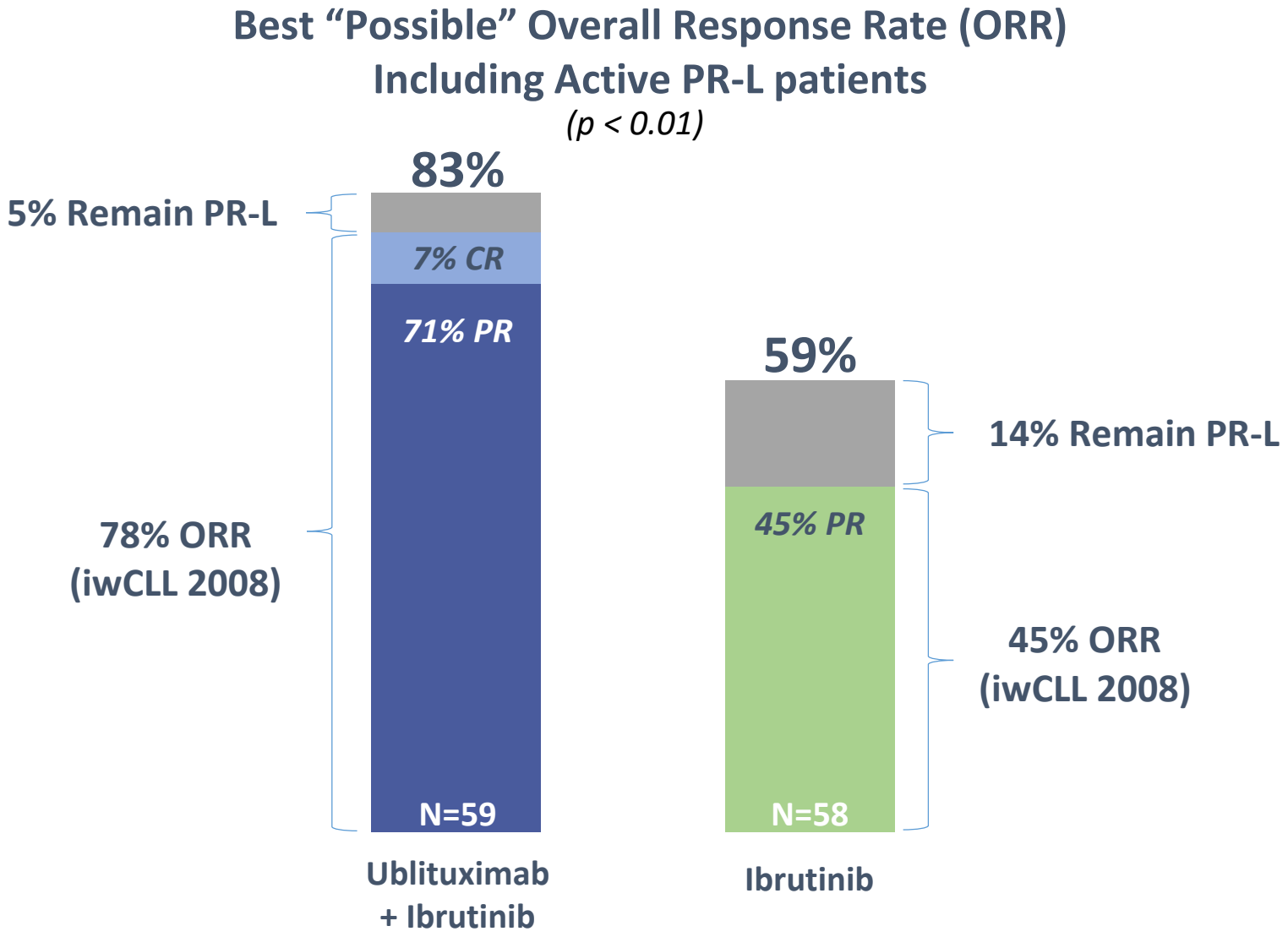




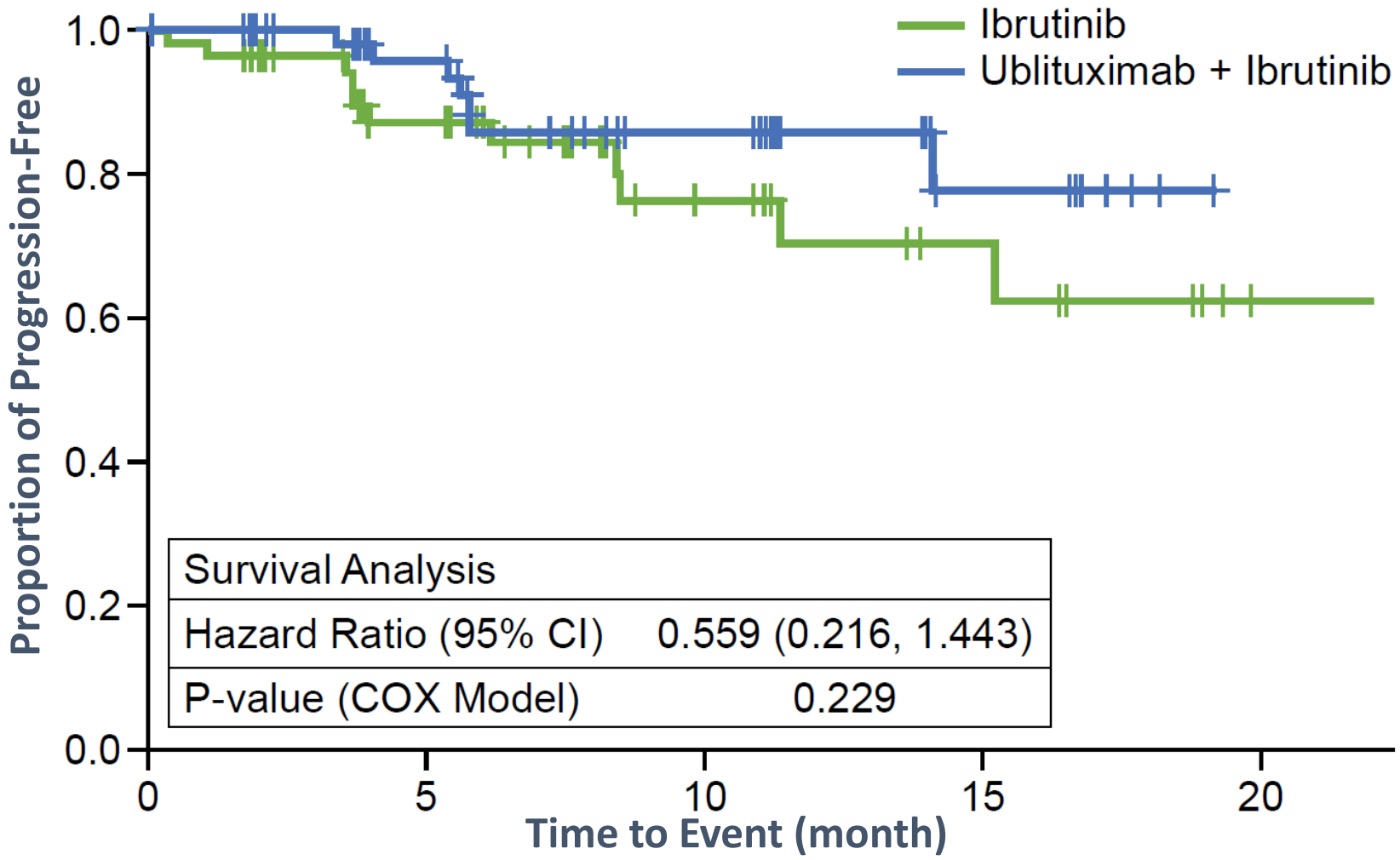
Lymphocytosis



Efficacy: Impact of including “PR-L” on ORR



Efficacy: IRC-Assessed PFS



Ubli + IB	59 (0)	41 (2)	25 (6)	9 (7)	0 (7)
IB Alone	58 (0)	35 (6)	16 (9)	8 (11)	1 (11)

Conclusions

- The GENUINE study met its primary endpoint, demonstrating that ublituximab in combination with ibrutinib yields superior ORR to ibrutinib alone in high-risk CLL
  - ORR 78% (UTX+IB) vs. 45% (IB), $p<0.001$
  - CR rate 7% vs. 0 (secondary endpoint)
  - MRD- rate 19% vs. 2% (secondary endpoint), $p<0.01$
- Secondary endpoint shows trend (HR=0.559) in improvement of PFS however not statistically significant at time of analysis
- With the exception of infusion related reactions, ublituximab did not alter the safety profile of ibrutinib monotherapy

Acknowledgements

- **The authors would like to thank the patients and their families, and all participating investigators:**
  - **USA**: Ian Flinn, Danielle Brander, Anthony Mato, Suman Kambhampati, John Burke, Frederick Lansigan, Marshall Schreeder, Scott Lunin, Alexander Zweibach, Jason Chandler, Mikhail Shtivelband, Nilanjan Ghosh, Patrick Travis, Bipin Amin, Charles Farber, David Wright, Habte Yimer, Herbert Eradat, Jason Melear, Jeff Sharman, John Pagel, Kenneth Miller, Michael Boxer, Michael Guarino, Mohit Narang, Noel Laudi, Russell Baur, Subhash Sharma, Thomas Sunnenberg, Vincent Hansen, Adam Olszewski, Andrew Bernstein, Anthony Gulati, Burke Brooks, David Riseberg, Dhatri Kodali, Gilles Lugassy, James Essell, Joseph Leach, Kathleen Phelan, Leonard Klein, Mazen Khalil, Nashat Gabrail, Ndegwa Njuguna, Robert Gordon, Robert Jacobson, Robert Siegel, Sharad Jain, Spencer Shao, Stefano Tarantolo, Sunil Babu, Suzanne Fanning, Yuvraj Choudhary. **ISRAEL**: Gilles Lugassy

- **This study was funded by TG Therapeutics, Inc.**

Also Selected for Oral Presentation at ICML-Lugano 2017!

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GENUINE PHASE 3
Q & A

GENUINE TG THERAPEUTICS GLYCOENGINEERED UBLITUXIMAB + IBRUTINIB PHASE 3 TRIAL IN HIGH-RISK CLL

UNITY CLL TG THERAPEUTICS GLYCOENGINEERED UBLITUXIMAB + PI3K DELTA TGR-1202 PHASE 3 TRIAL IN CLL

TG-1101 + TGR-1202 (umbralisib) + Ibrutinib Triple Combination Data in CLL & NHL

Anthony R. Mato, MD
Director, Center for CLL
University of Pennsylvania

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PHASE 3 TRIAL IN CLL

TG-1101 + TGR-1202 + Ibrutinib: Demographics

Evaluable for Safety (n)	38	
Evaluable for Efficacy† (n)	36	
Median Age, years (range)	65 (32 – 85)	
Male/Female	29/9	
Histology	**CLL/SLL**	20
	DLBCL	6
	FL	6
	MCL	4
	MZL	2
ECOG, 0/1/2	14/21/3	
Prior Therapy Regimens, median (range)	3 (0 – 6)	
Patients with ≥ 3 Prior Therapies, n (%)	21 (55%)	
Refractory to Prior Therapy, n (%)	13 (34%)	
Refractory to Rituximab, n (%)	15 (39%)	

†2 patients discontinued prior to first efficacy assessment (1 Pneumonia, 1 Investigator Discretion)

- 3 CLL patients were treatment naïve, all other patients were relapsed or refractory to prior therapy

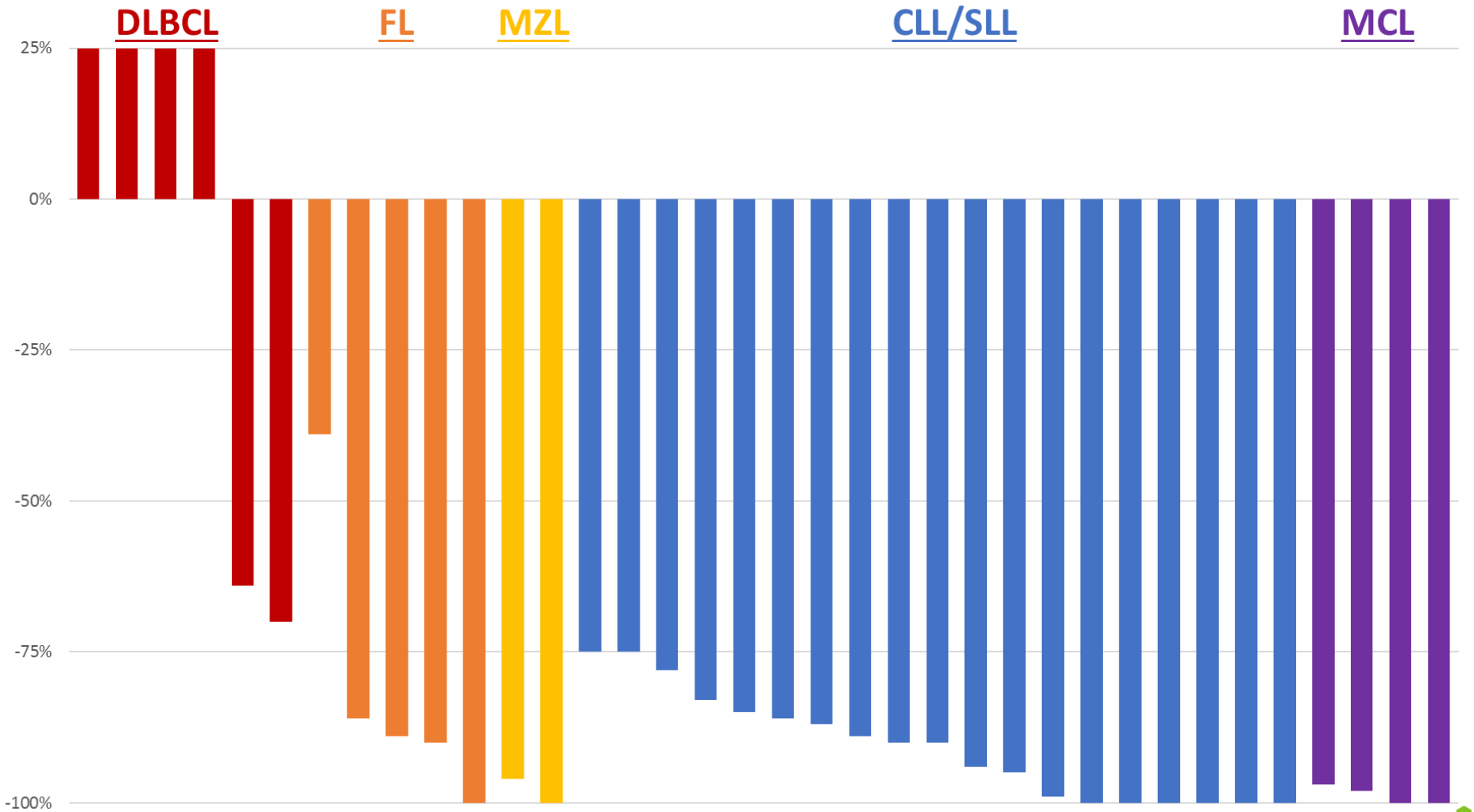
TG-1101 + TGR-1202 + Ibrutinib: Safety

Adverse Event	All Grades		Grade 3/4	
	N	%	N	%
Diarrhea	18	47%	1	3%
Fatigue	18	47%	-	-
Dizziness	14	37%	1	3%
Insomnia	13	34%	-	-
Nausea	13	34%	-	-
Neutropenia	12	32%	7	18%
Cough	12	32%	-	-
Infusion related reaction	12	32%	-	-
Thrombocytopenia	11	29%	3	8%
Pyrexia	11	29%	1	3%
Rash	11	29%	1	3%
Anemia	10	26%	1	3%
Sinusitis	9	24%	-	-
Dyspnea	8	21%	1	3%
Stomatitis	8	21%	1	3%

- 1 DLT (*reactivated varicella zoster*) was observed in the CLL cohort at level 1. No other DLT's were observed.
- Diarrhea was majority Gr. 1 (32%) and Gr. 2 (13%), with no Gr. 4 event reported. Pneumonia (18% all grades, 11% Gr. 3/4) and neutropenia were the only Gr. 3/4 AE's in >10% of patients
- Two patients discontinued due to an AE (sepsis and pneumonia)
- Median time on study 11.1 months (range 0.4 – 30+ months)

TG-1101 + TGR-1202 + Ibrutinib: Efficacy

Best Percent Change from Baseline in Disease Burden



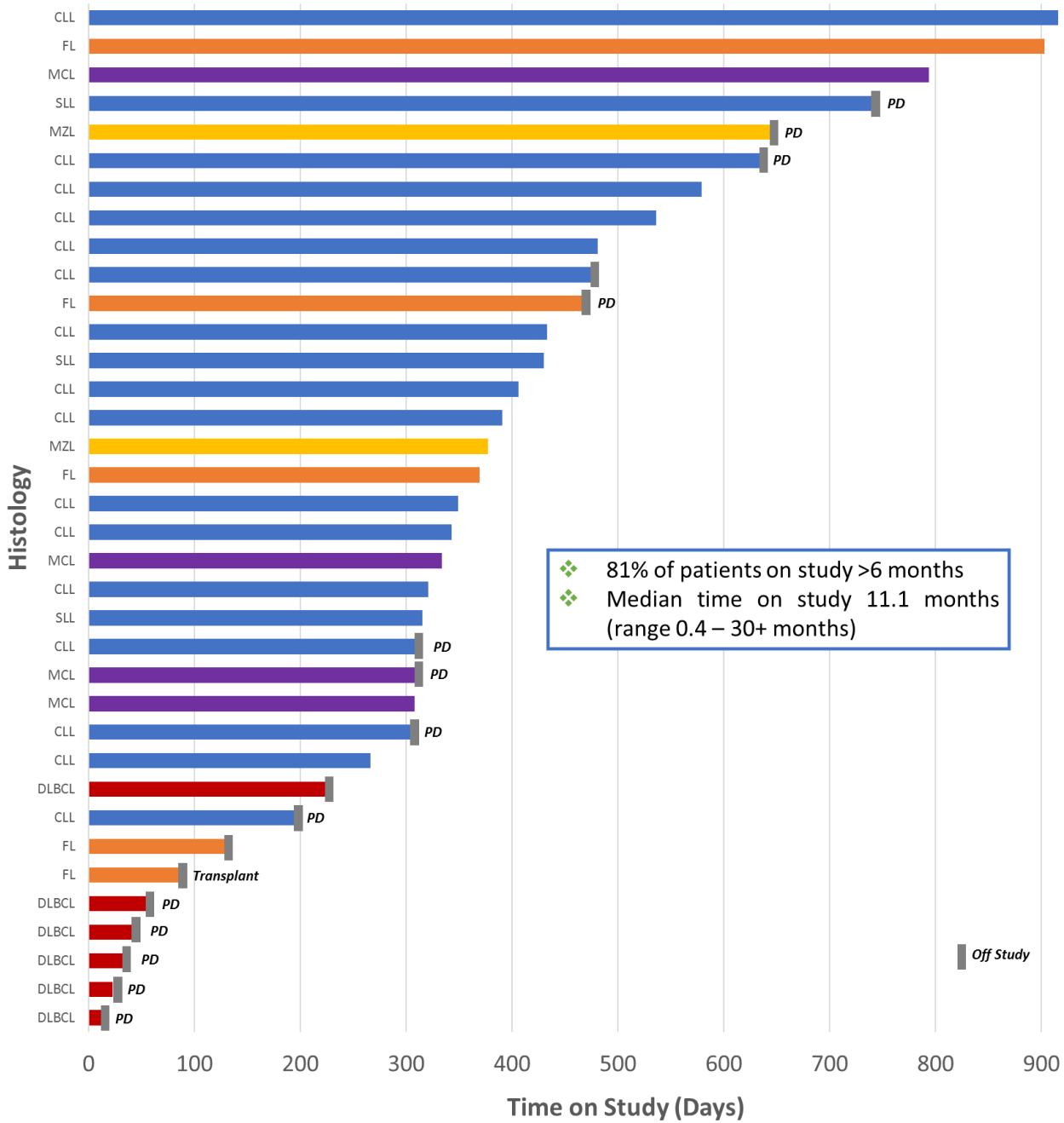
TG-1101 + TGR-1202 + Ibrutinib: Efficacy

Type	Pts (n)	CR† (n)	PR (n)	ORR n (%)	SD (n)	PD (n)
CLL/SLL	19	6	13	**19 (100%)**	-	-
MZL	2	1	1	**2 (100%)**	-	-
MCL	4	2	2	**4 (100%)**	-	-
FL	5	1	3	**4 (80%)**	1	-
DLBCL	6	-	1	**1 (17%)**	-	5
Total	**36**	**10**	**20**	**30 (83%)**	**1**	**5**

†CLL: 4/6 CR's pending bone marrow confirmation

- 8 CLL patients (50%) had a 17p and/or 11q deletion
- All 3 treatment naïve CLL patients achieved a PR
- 3 CLL patients had prior BTK and/or PI3Kδ inhibitor therapy, including one patient refractory to both idelalisib and ibrutinib who attained a complete response (ongoing for 1.5+ years)
- FL patients were heavily pretreated including 2 with prior ASCT, 1 refractory to prior ibrutinib, and 1 with 5 prior lines of rituximab based therapy
- DLBCL patients had a median of 4 prior therapies, and 4/6 were of non-GCB subtype

Duration on Study



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Overview
TGR-1202 Safety and Efficacy

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Assistant Professor, University of North Carolina
Levine Cancer Center, Charlotte, NC

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Integrated Analysis TGR-1202 Monotherapy and TGR-1202 + TG-1101: Demographics

Evaluable for Safety (n)	165 (90 Single Agent, 75 Combo with UTX)	
Median Age, years (range)	65 (22 - 86)	
Male/Female	106/59	
Histology	**CLL**	43
	FL	42
	DLBCL	40
	MZL	11
	HL	11
	MCL	8
	SLL	3
	WM	3
	T-Cell	2
	HCL	1
	Richter's	1
Median ECOG	1	
Prior Therapies, median (range)	3 (0 - 14)	
Patients with ≥ 3 Prior Therapies (%)	94 (57%)	
Patients Refractory to Prior Therapy (%)	85 (52%)	

Burris et al, ASCO 2016

TGR-1202 Integrated Analysis: Safety

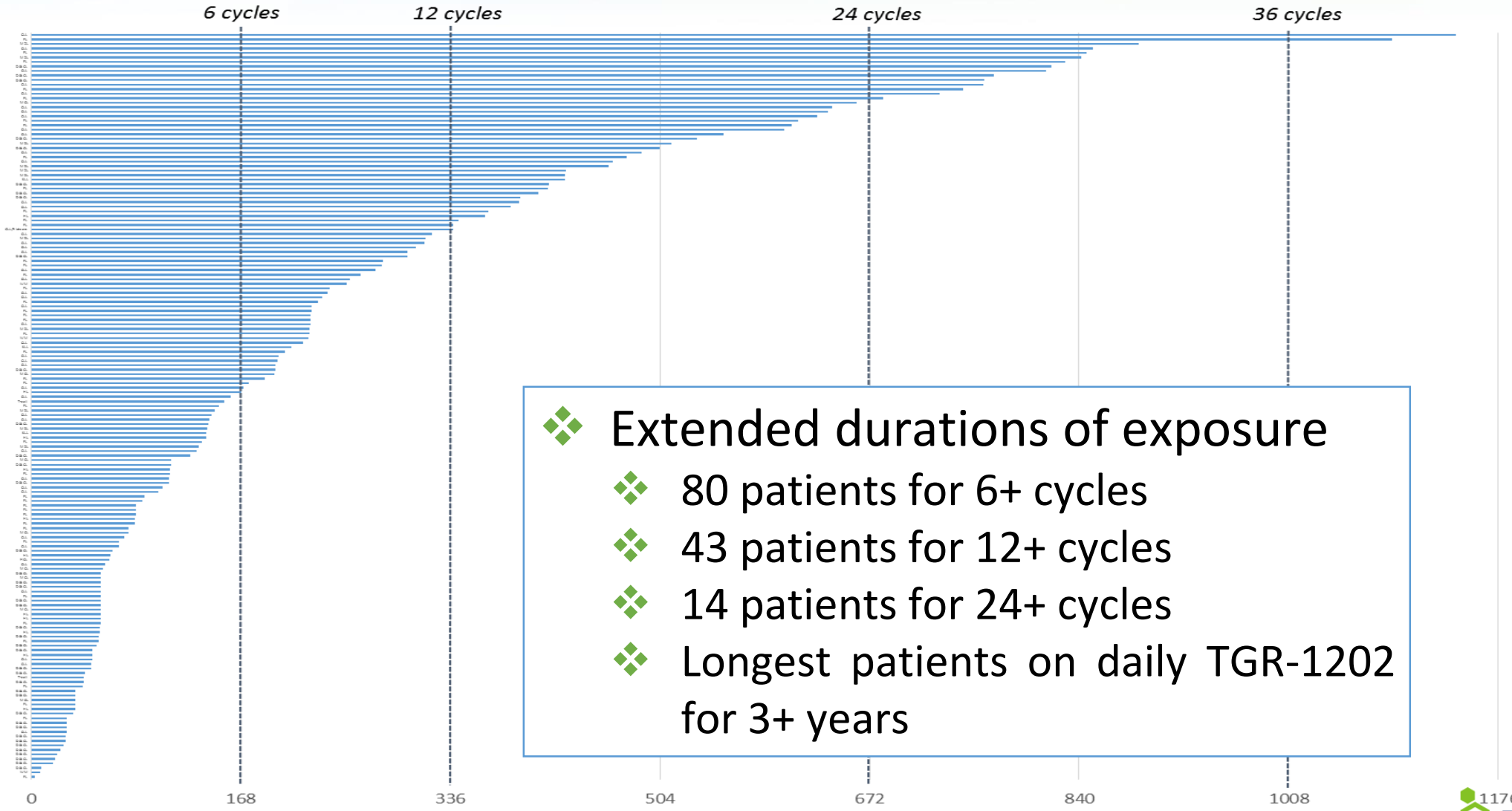
All Causality AE's Occurring in ≥ 10% of Patients (n = 165)

Adverse Event	All Grades		Grade 3/4	
	N	%	N	%
Diarrhea	78	**47%**	5	**3%**
Nausea	74	**45%**	2	**1%**
Fatigue	61	**37%**	5	**3%**
Vomiting	44	**27%**	-	**-**
Neutropenia	34	**21%**	30	**18%**
Cough	32	**19%**	-	**-**
Dyspnea	30	**18%**	6	**4%**
Dizziness	29	**18%**	-	**-**
Headache	28	**17%**	2	**1%**
Pyrexia	26	**16%**	2	**1%**
Decreased appetite	26	**16%**	-	**-**
Rash	26	**16%**	6	**4%**
Sinusitis	25	**15%**	2	**1%**
Anemia	24	**15%**	9	**5%**
Constipation	24	**15%**	1	**1%**
Insomnia	23	**14%**	-	**-**
Hypokalemia	22	**13%**	5	**3%**
Back pain	20	**12%**	1	**1%**
Abdominal pain	18	**11%**	4	**2%**
Upper respiratory infection	18	**11%**	-	**-**

- Grade 3/4 AST/ALT increase was 3% (8% all grades), predominantly observed above the Phase 3 dose
- Two events of pneumonitis (<1.5%) were reported
- *13% of patients had a TGR-1202 dose reduction*
- **<8% of patients discontinued due to a TGR-1202 related AE**

Burris et al, ASCO 2016

Integrated Analysis: Duration of Treatment



- Extended durations of exposure
  - 80 patients for 6+ cycles
  - 43 patients for 12+ cycles
  - 14 patients for 24+ cycles
  - Longest patients on daily TGR-1202 for 3+ years

Burris et al, ASCO 2016

Safety Summary – Common Toxicities GR 3/4 Events

	1101+1202+ Ibrutinib	1101+1202+ Benda	1202 + Ibrutinib	1202 + Ruxolitinib	1202 + B-Ved	Integrated Analysis	TOTAL
	N=38	N=19	N=31	N=12	N=14	N=165	N=279
Diarrhea	3%	5%	-	17%	7%	3%	**3%**
Colitis	-	5%	-	-	7%	1%	**1%**
AST/ALT	3%	-	-	-	14%	3%	**3%**
Pneumonia	11%	-	-	8%	-	1%	**2%**
Neutropenia	18%	21%	13%	8%	43%	18%	**18%**
URI	-	-	-	-	-	-	**0%**
Thrombocytopenia	8%	5%	3%	-	-	5%	**5%**

Integrated Analysis: Common “Delta” Toxicities

Toxicities (Gr. 3/4)	800mg Dose n=40	All Patients n=165
AST/ALT	5% (2)*	3% (5)*
Pneumonitis	0% (0)	1.5% (2)
Colitis	0% (0)	1.5% (2)

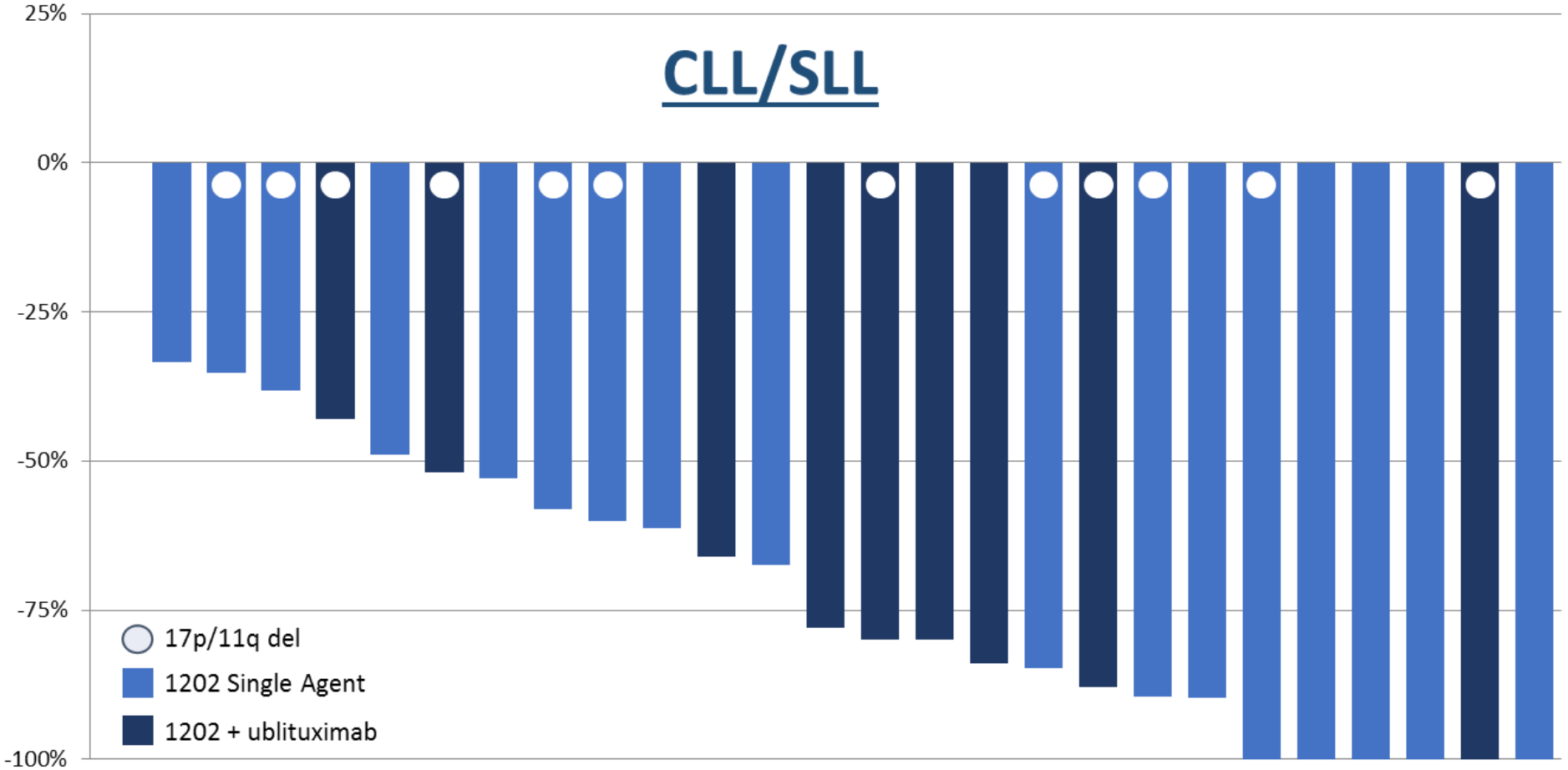
* Fisher's exact test: The two-tailed P value equals 0.6243

Burris et al, ASCO 2016

Integrated Analysis: TGR-1202 Monotherapy and TGR-1202 + Ublituximab - CLL/SLL Efficacy

Patients Treated at "Higher Doses" of TGR-1202

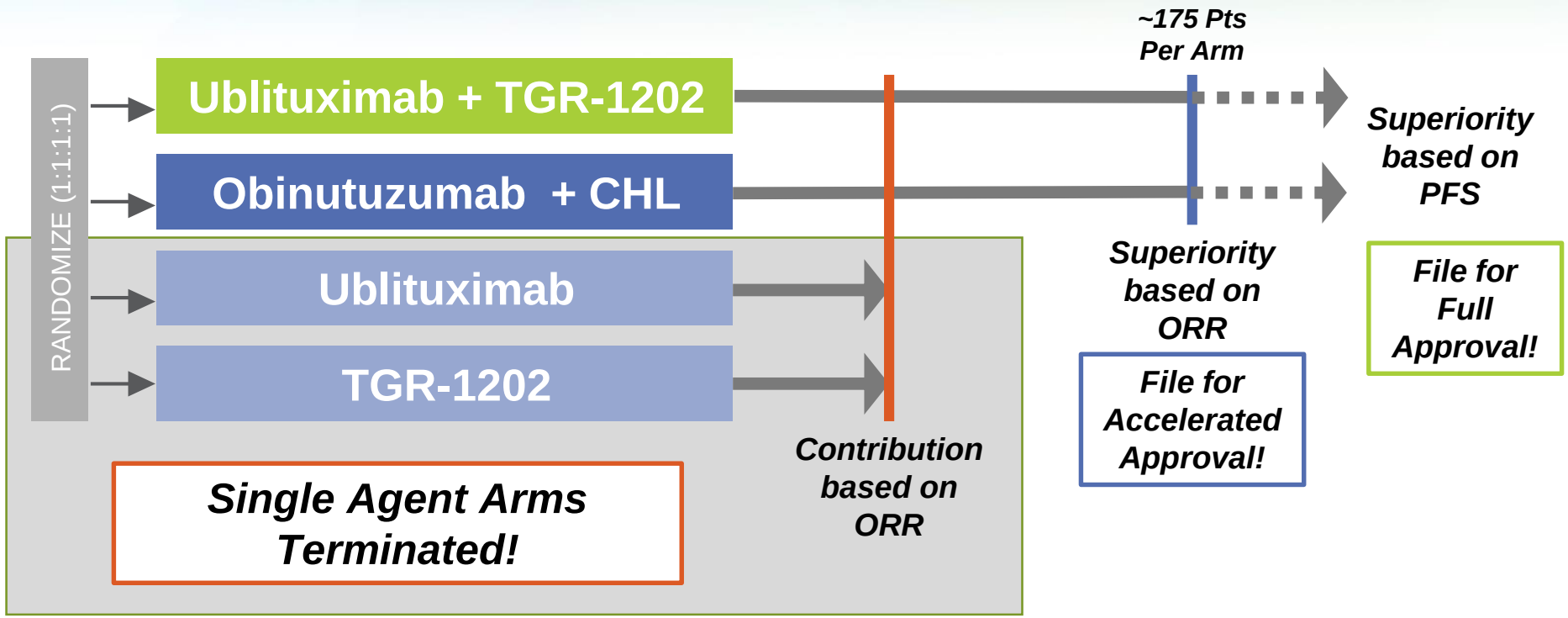
Best Percent Change from Baseline in Disease Burden



Higher Doses: 1200 mg of the initial formulation, or ≥600 mg of the micronized formulation

Burris et al, ASCO 2016

UNITY-CLL – Phase 3 Trial Front Line & Rel/Ref CLL



- Design, Endpoints, and Statistics agreed to via Special Protocol Assessment (SPA)
- Enrolling ~450 patients with previously treated and previously untreated CLL
- **Target Complete Enrollment by Year-End 2017**

UNITY CLL
TG THERAPEUTICS
GLYCOENGINEERED UBLITUXIMAB + PI3K DELTA TGR-1202
PHASE 3 TRIAL IN CLL

UNITY-CLL Study Update

- Open to enrollment at 100+ Sites in the US, UK, Italy, Poland, Russia and Israel
  - Additional sites to open in Spain, Ukraine, and Bulgaria
- Enrollment proceeding ahead of projections in 2017
  - Averaging ~40 patients/month with approximately half from ex-US
- Targeting completion of enrollment Year-End 2017

Data Safety Monitoring Board (DSMB)

November 2016

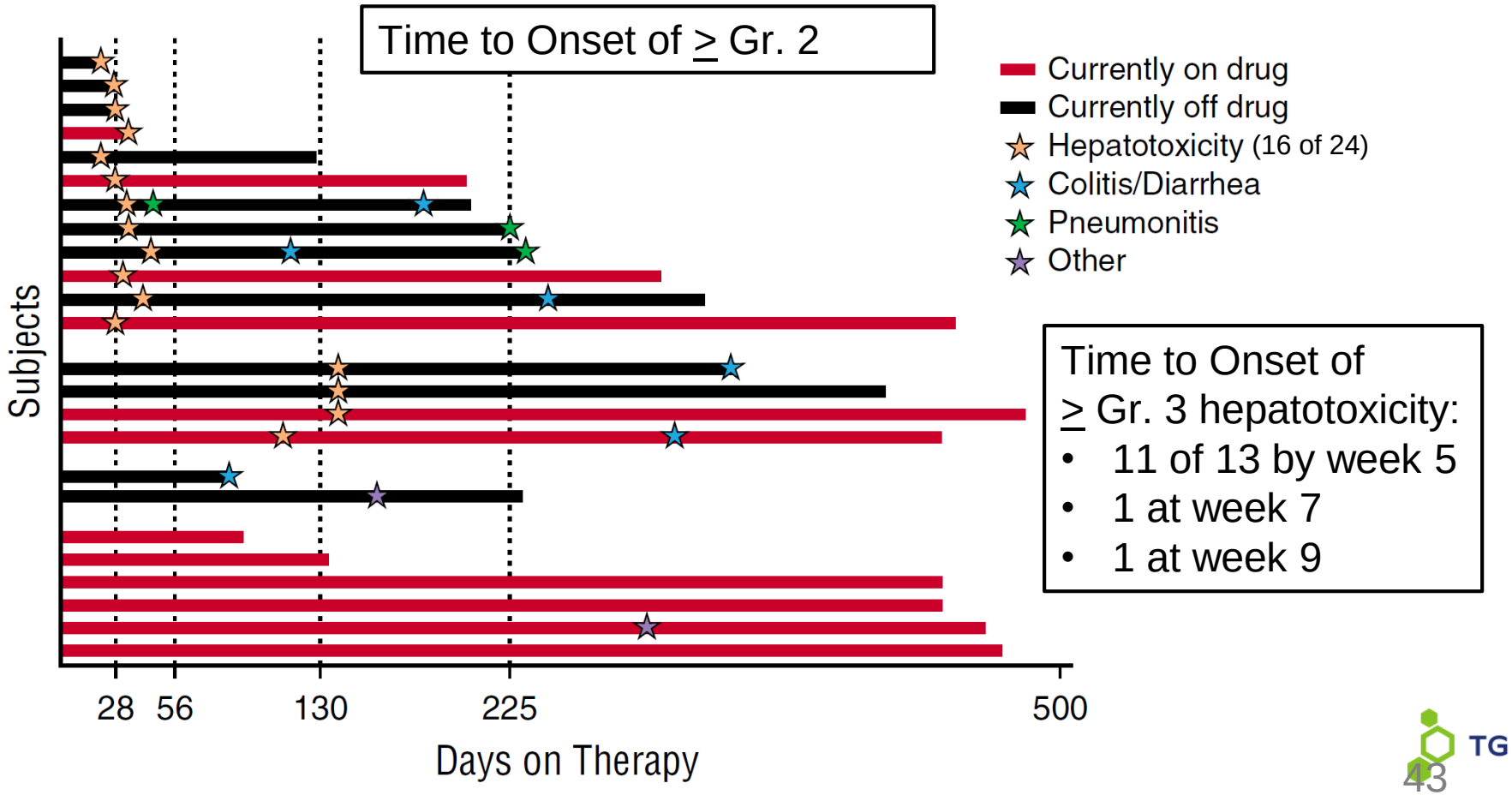
- "The DSMB did not find any safety concerns and recommended the study continue without modification"

May 2017

- "The DSMB reviewed safety data from more than 270 patients, finding no safety concerns and recommended continuation of enrollment without modification"
- "Contribution of single agents in the combo regimen successfully established; DSMB recommends no further enrollment to single agent arms"

Idelalisib Related Hepatotoxicity Front-Line CLL

- Brown et al reported high rates of immune-mediated hepatotoxicity in patients with front-line CLL treated with idelalisib
- Decreases in Treg population implicated
- Transaminitis rates of 79% all grades (gr.3/4 of 54% (13 of 24)), with median onset at 28 days



Lampson, Brown, et al, Blood 2016

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CLL Treatment Landscape Discussion

GENUINE
TG THERAPEUTICS
GLYCOENGINEERED UBLITUXIMAB + IBRUTINIB
PHASE 3 TRIAL IN HIGH-RISK CLL

UNITY CLL
TG THERAPEUTICS
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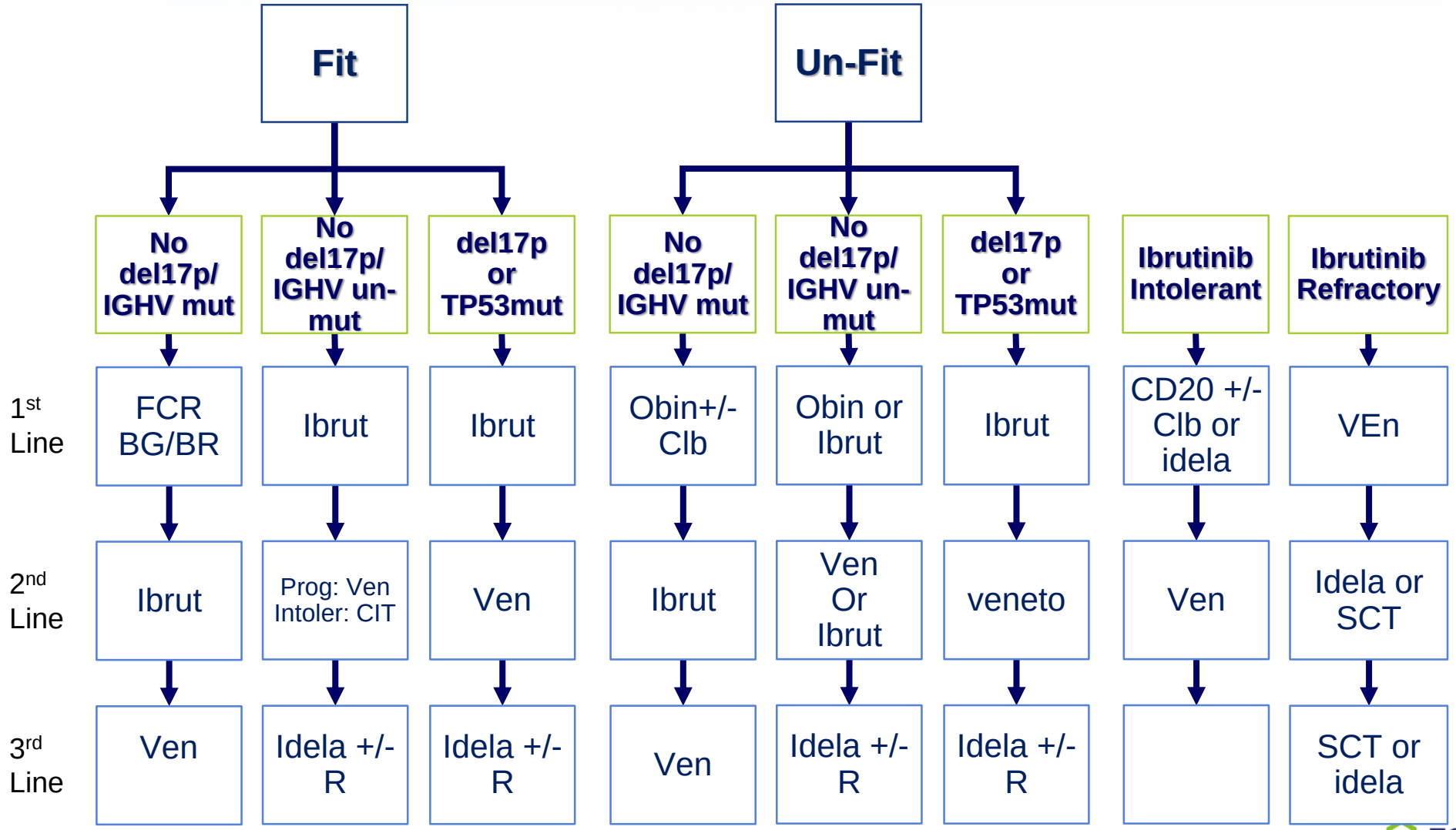
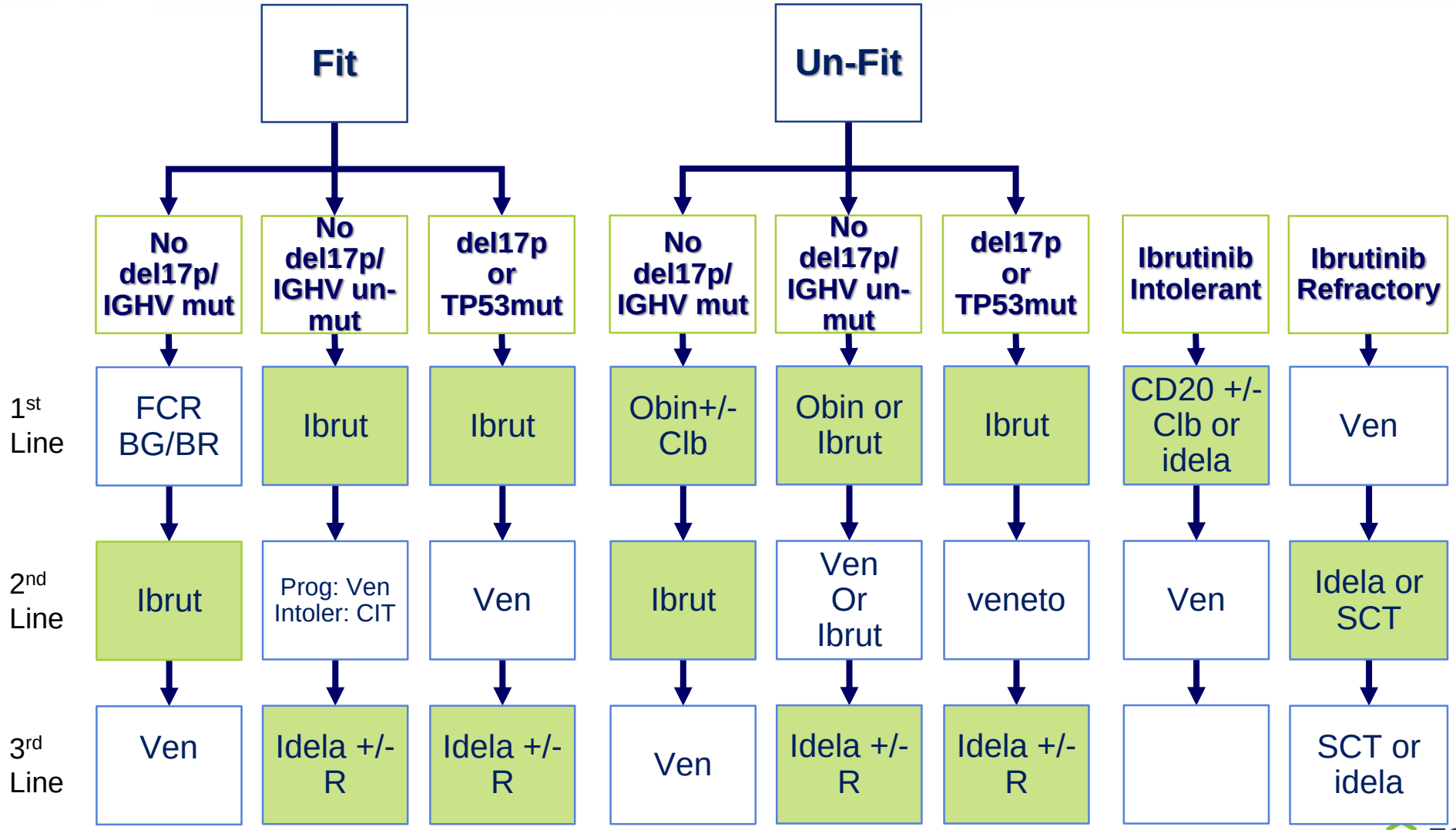
PHASE 3 TRIAL IN CLL

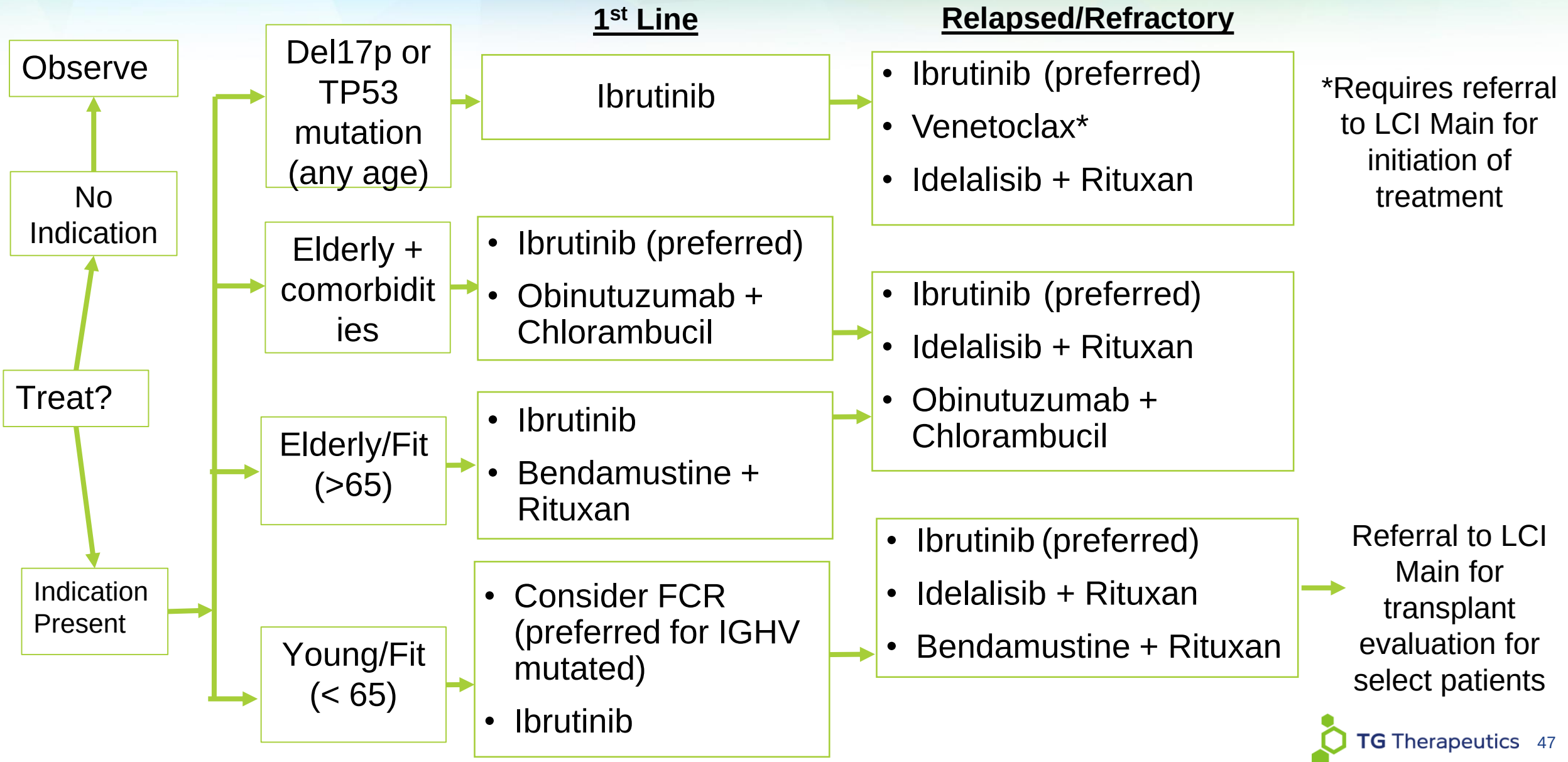
Anthony Mato, MD – CLL Treatment Pathway



Anthony Mato, MD – CLL Treatment Pathway



Levine Cancer Center: CLL/SLL Untreated Disease



TG Therapeutics

Michael S. Weiss

Executive Chairman & CEO

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Question & Answer

GENUINE TG THERAPEUTICS GLYCOENGINEERED UBLITUXIMAB + IBRUTINIB PHASE 3 TRIAL IN HIGH-RISK CLL

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