Updates in CLL from ASH 2022

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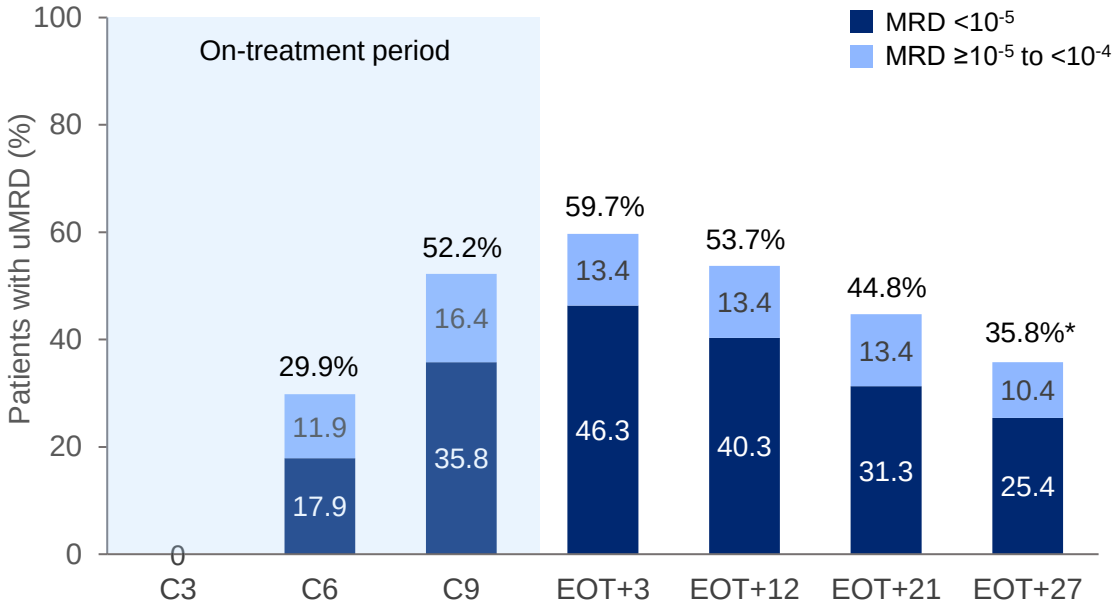
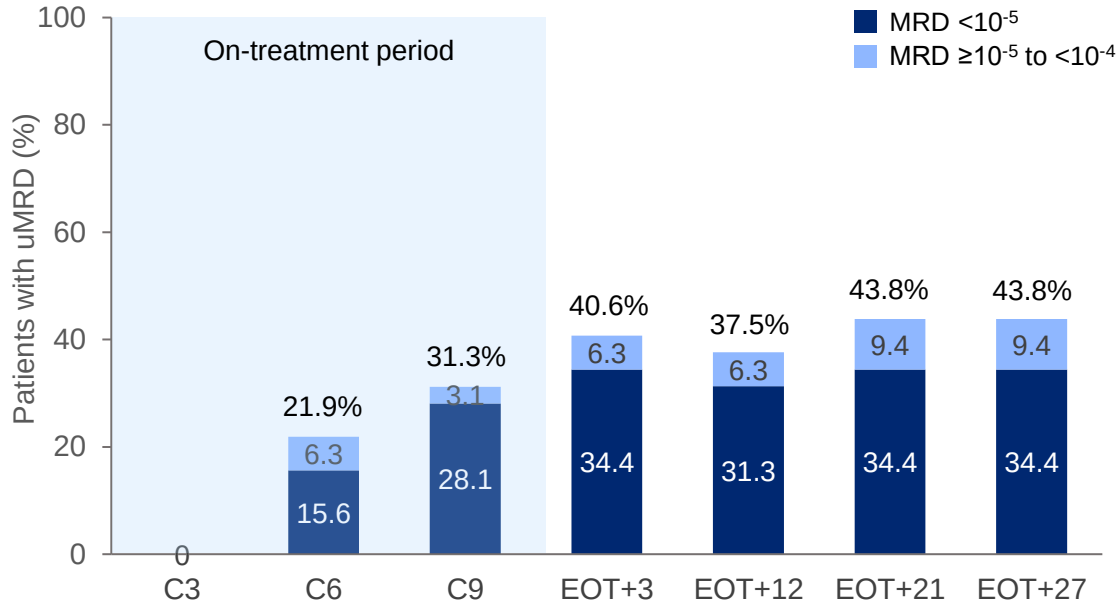
GLOW: Ibr+Ven on-treatment and post-treatment

uMRD dynamics according to IGHV status

ITT uMRD rates in unmutated IGHV (n=67)



ITT uMRD rates in mutated IGHV (n=32)

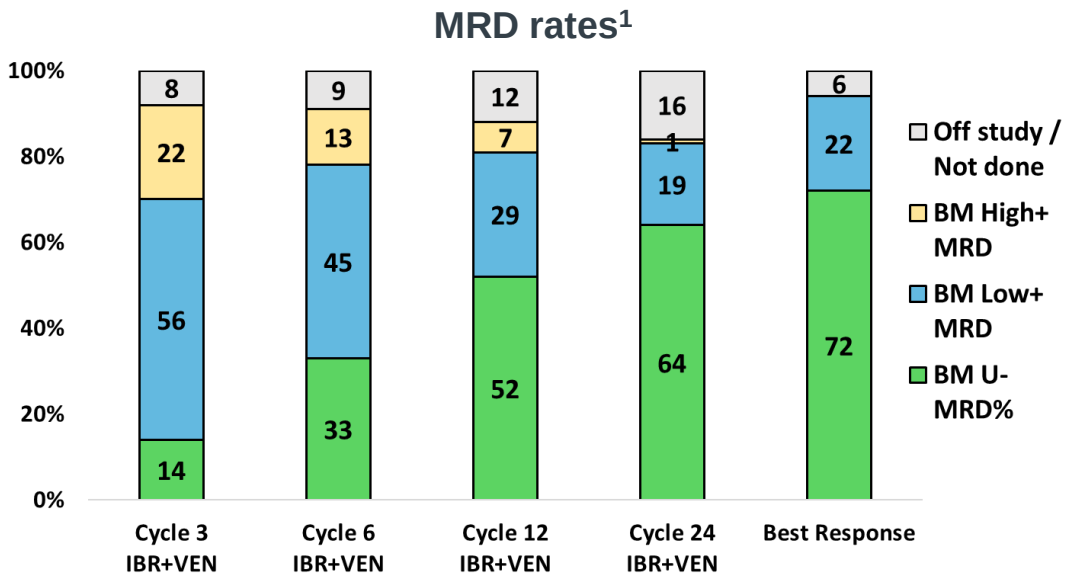


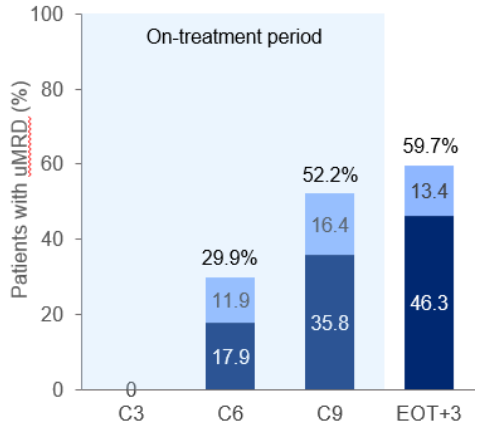
- uMRD rates (including <10^{-5}) were higher and uMRD was achieved faster in patients with uIGHV versus mIGHV CLL
- uMRD was better sustained post-treatment in patients with mIGHV CLL

*7 (10.4%) patients with uMRD (including 5 with uMRD <10^{-5}) at EOT+21 had missing samples and were considered not uMRD at EOT+27.
C, cycle; CLL, chronic lymphocytic leukemia; EOT, end of treatment; EOT+X, EOT plus X months; Ibr, ibrutinib; IGHV, immunoglobulin heavy chain variable; ITT, intent to treat; mIGHV, mutated IGHV; MRD, minimal residual disease; uIGHV, unmutated IGHV; uMRD, undetectable MRD; Ven, venetoclax.
Niemann CU *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 93).

First-line Ibr+Ven: Does patient population and time matter?

Patient baseline characteristics (N=120)		N (%) or median [range][1]
Age, years		64.5 [26–88]
	≥65	60 (50)
	≥70	35 (29)
Male		87 (73)
ALC, K/µL		76.3 (1.14–366)
PLT, K/µL		140 (28–334)
HgB, K/µL		12.0 (7.7–18.4)
B2M, mg/L		3.6 (1.7–13.7)
FISH	Del(17p)	20 (17)
	Del(11q)	31 (26)
	Trisomy 12	23 (19)
	Negative	19 (16)
	Del(13q)	27 (22)
IGHV status (n=116)	Unmutated	100 (86)
Cytogenetics (n=115)	Complex	15 (13)
Mutations (n=119)	*TP53*	19 (16)
	NOTCH1	35 (29)
	SF3B1	26 (22)
	BIRC3	9 (8)
Del(17p)/*TP53*-m		27 (23)





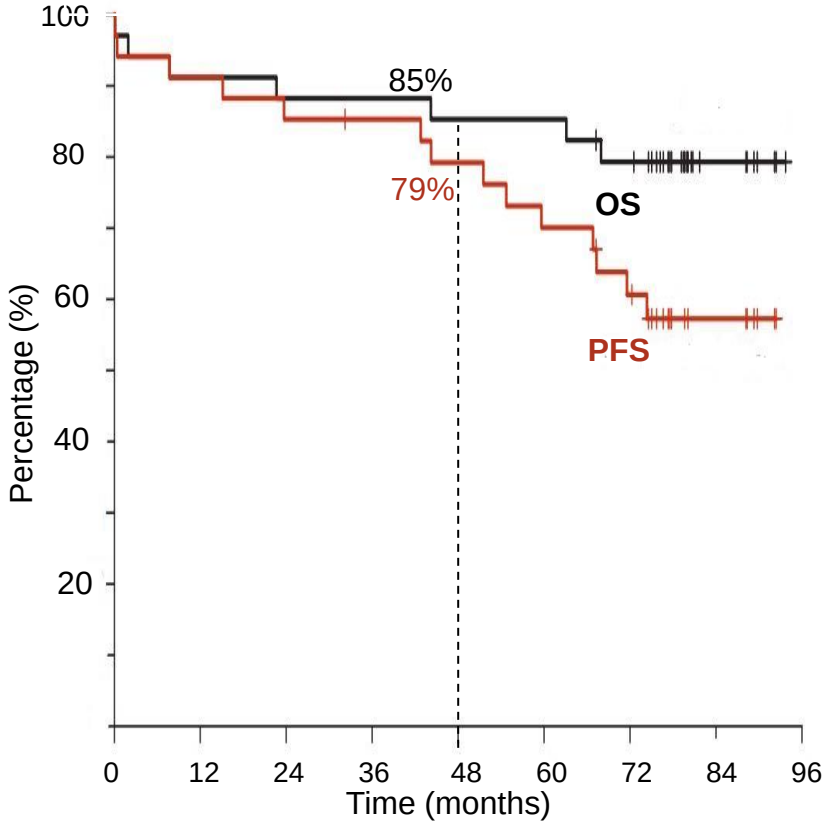
GLOW uMRD rates in IGHV unmutated IGHV (n=67) for comparison[2]

ALC, absolute lymphocytes count; B2M, beta-2 microglobulin; BM, bone marrow; CLL, chronic lymphocytic leukemia; Del, deletion; FISH, fluorescence in situ hybridization; HgB, hemoglobin; Ibr, ibrutinib; IGHV, immunoglobulin heavy chain variable; m, mutated; MRD, minimal residual disease; PLT, platelet count; uMRD, undetectable minimal residual disease; Ven, venetoclax.

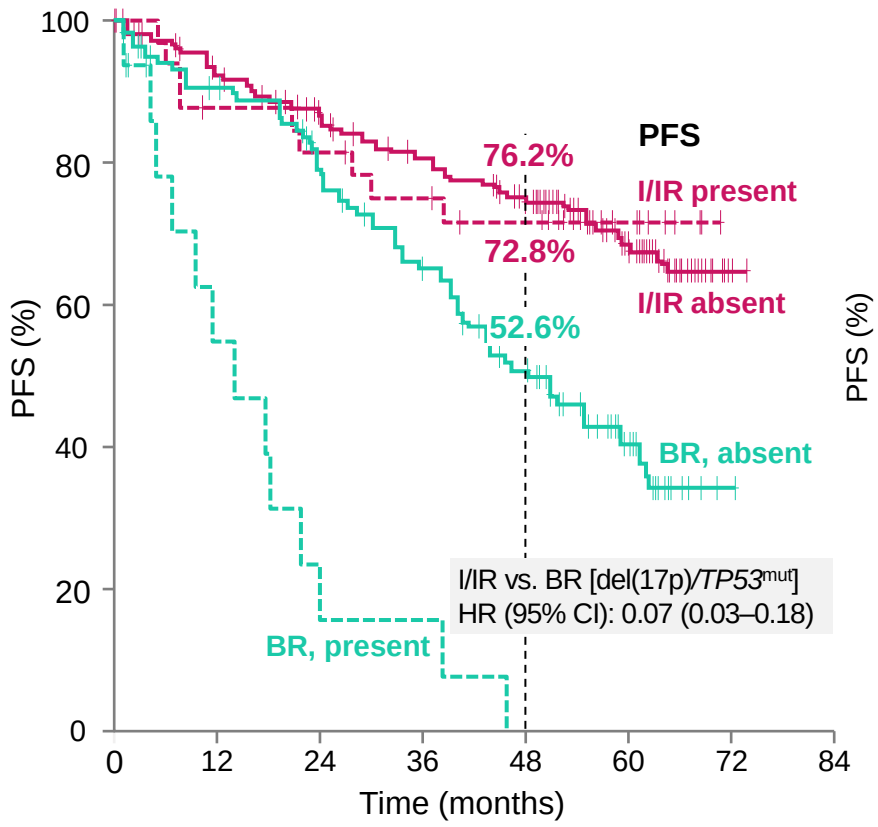
1. Jain N *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 95). 2. Niemann CU *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 93).

Background and rationale

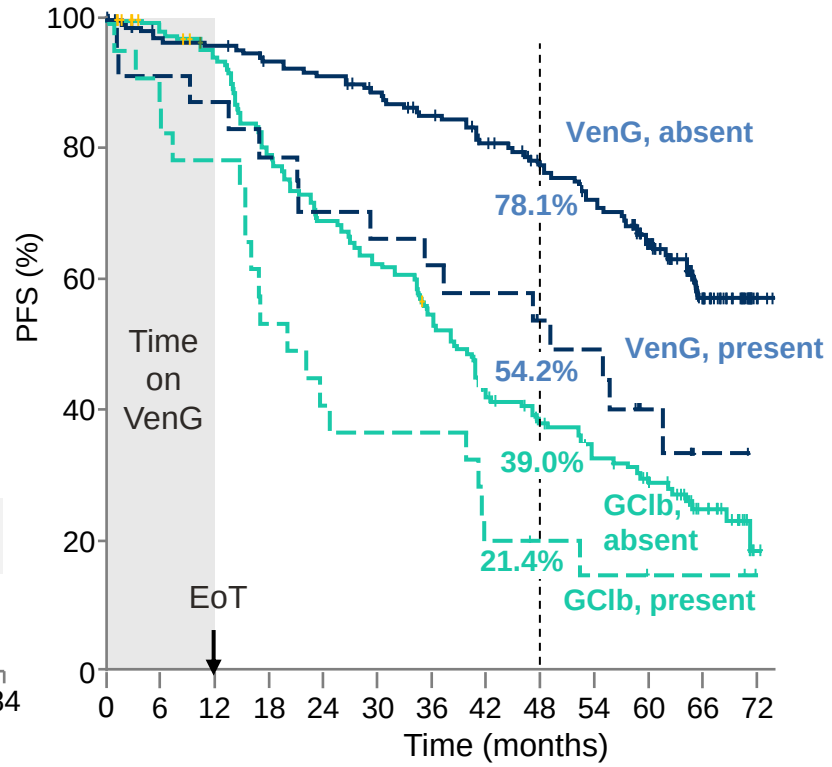
Phase 2 IIT Ibrutinib monotherapy in patients with del(17p)/*TP53*^{mut}
(median follow-up: 6.5 years)[1]



Alliance A041202 : PFS I/IR vs BR by del(17p)/*TP53*^{mut} status (absent/present)
(median follow-up: 55 months)[2]



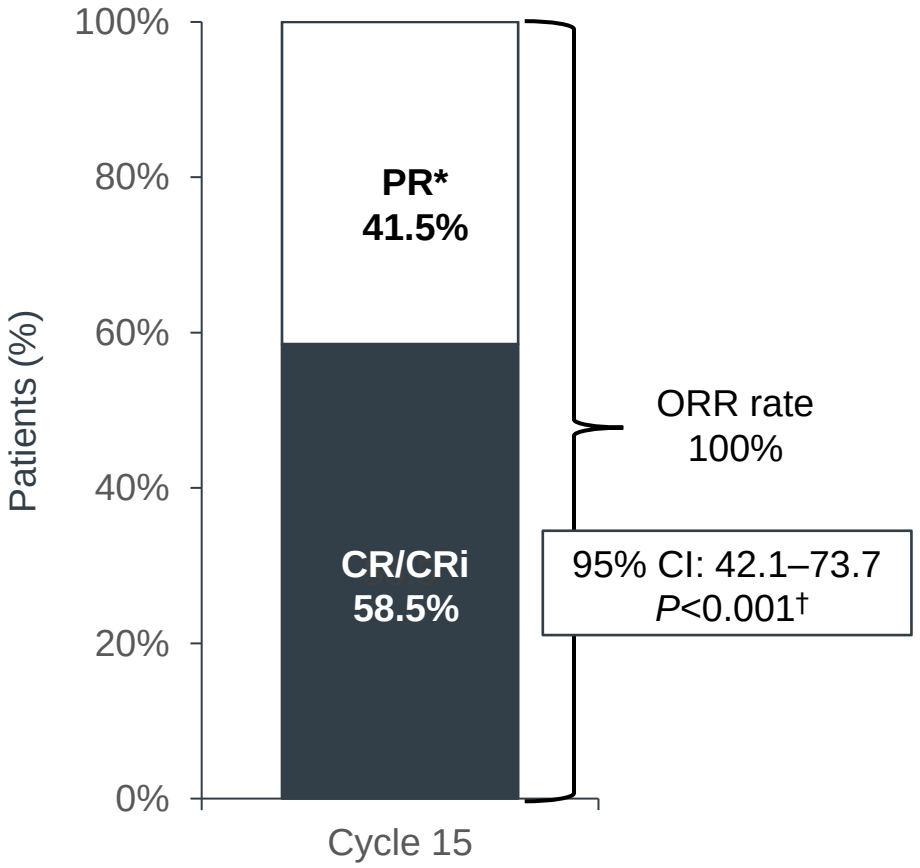
CLL14: PFS VenG vs GClb by del(17p)/*TP53*^{mut} status (absent/present)
(median follow-up: 65.4 months)[3]

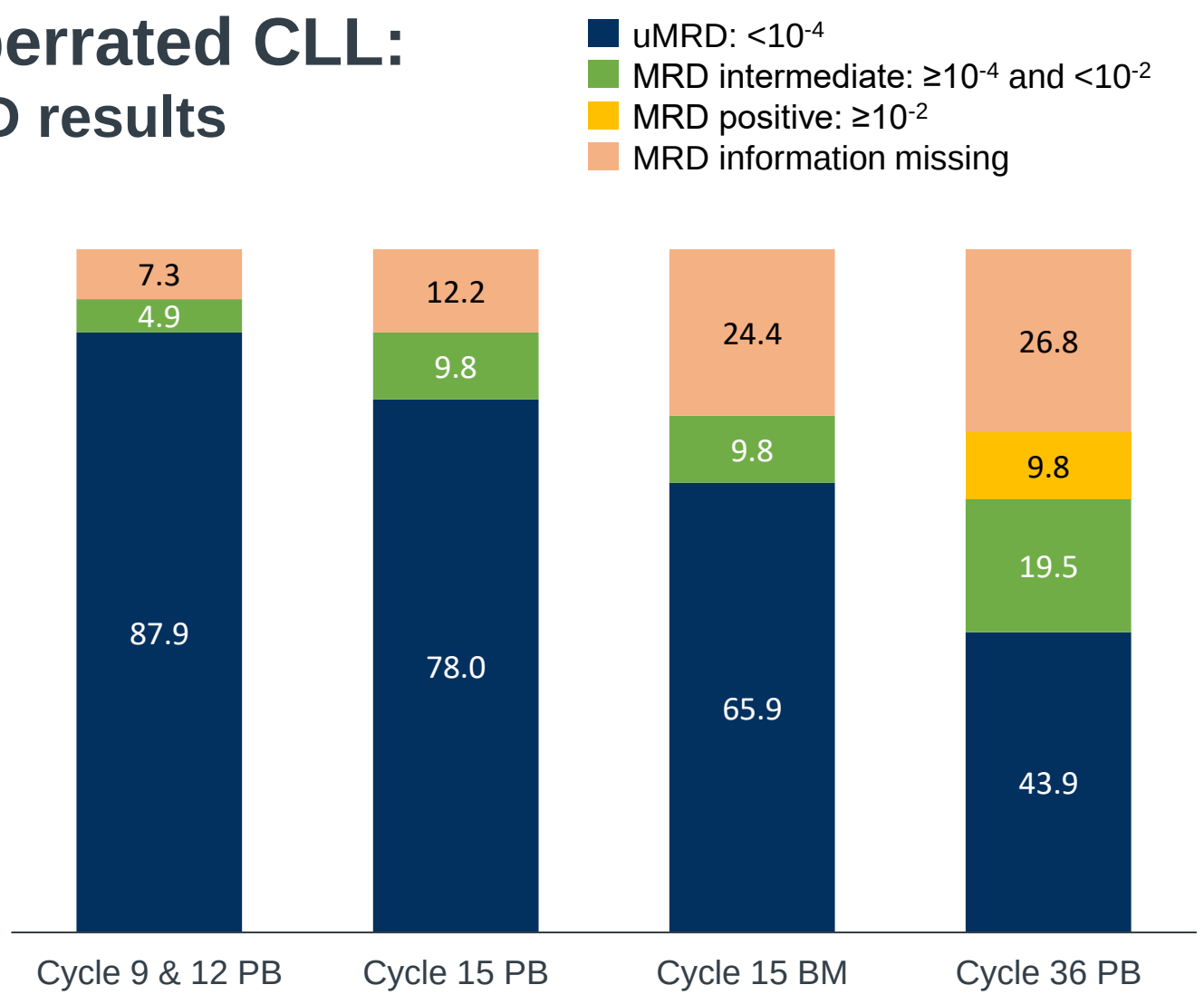


This slide includes data from different clinical trials. These data are meant for demonstration purposes only and are not meant for cross-trial comparison purposes.

BR, bendamustine plus rituximab; CI, confidence interval; EoT, end of treatment; GClb, obinutuzumab and chlorambucil; HR, hazard ratio; I, ibrutinib; IIT, investigator-initiated trial; IR, ibrutinib plus rituximab; OS, overall survival; PFS, progression free survival; VenG, venetoclax and obinutuzumab. 1. Ahn IE *et al*. *N Engl J Med* 2020; 383: 498–500. 2. Woyach J *et al*. Oral presentation at ASH 2021; Atlanta, Georgia, USA, December 11–14, 2021 (Abstract 369). 3. Al-Sawaf O *et al*. Oral presentation at EHA 2022; Vienna, Austria, June 9–12, 2022 (Abstract S148).

CLL2-GIVe triplet for *TP53* aberrated CLL:
CR rate at final restaging and MRD results



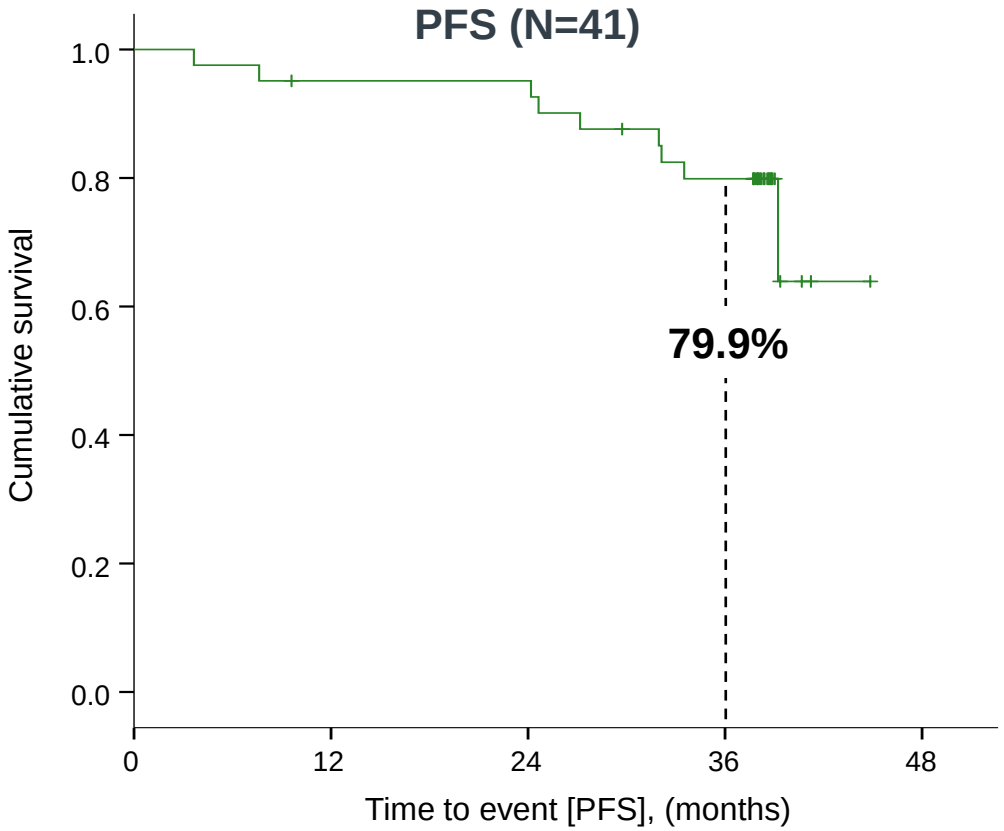


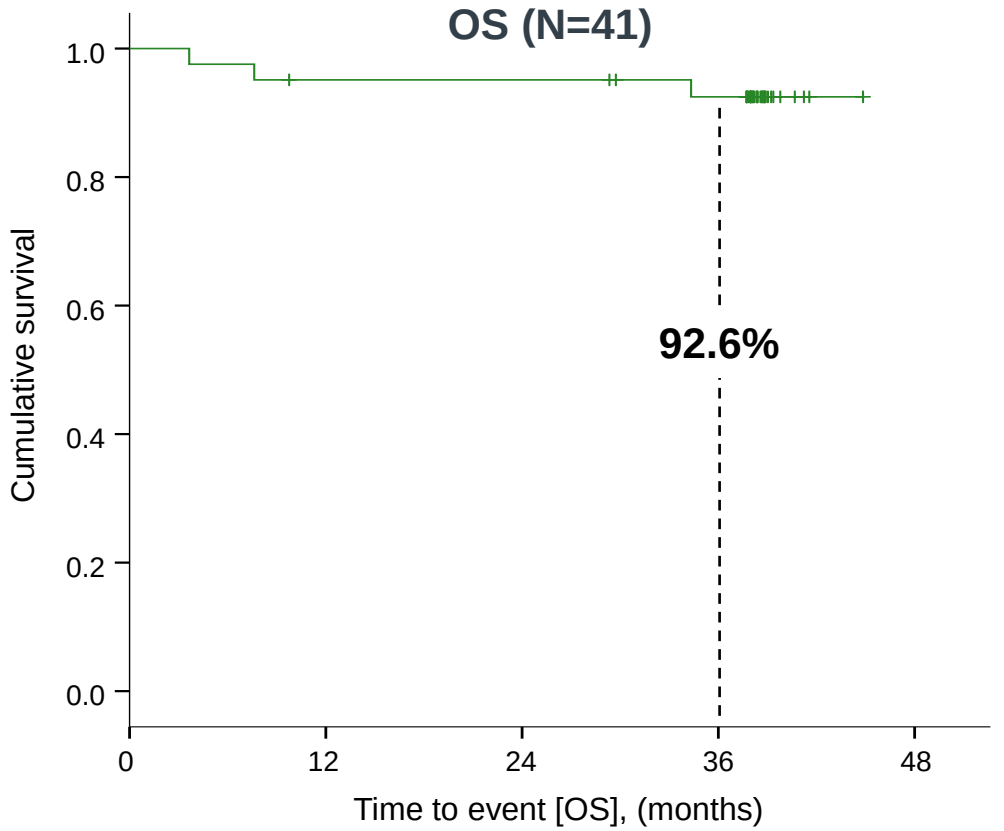
*7.3% not assessable due to 2 deaths at C3 and C9 and 1 withdrawal of informed consent at C9; †Versus the null hypothesis of CR = 25%.
BM, bone marrow; C, cycle; CI, confidence interval; CLL, chronic lymphocytic leukemia; CR, complete response; CRi, complete response with incomplete blood count recovery; GIVe, venetoclax plus obinutuzumab and ibrutinib; MRD, minimal residual disease; ORR, overall response rate; PB, peripheral blood; uMRD, undetectable MRD.
Huber H *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 343).

CLL2-GIVe: Efficacy results

Progression-free survival and overall survival

Median observation time (range): 38.4 months (3.7–44.9)



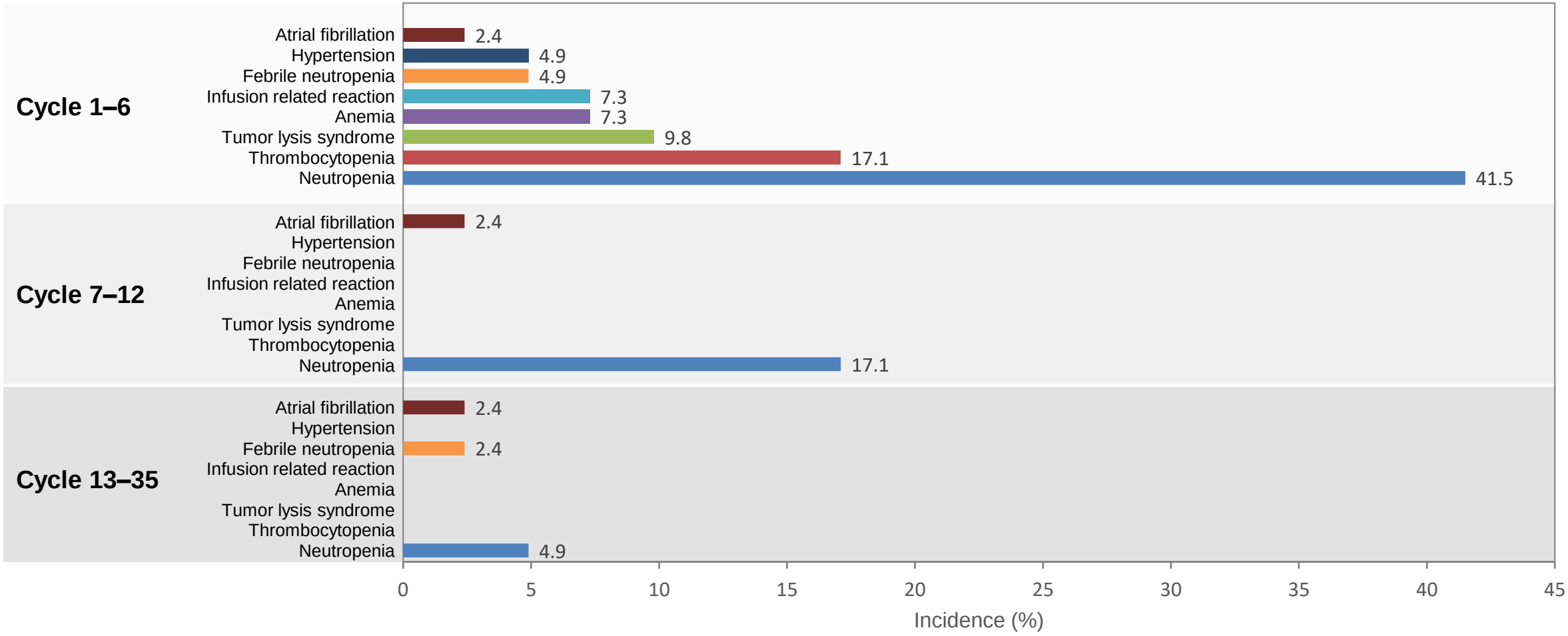


GIVe, venetoclax plus obinutuzumab and ibrutinib; OS, overall survival; PFS, progression-free survival.

Huber H *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 343).

CLL2-GIVe safety results: Incidence of the most frequent AEs Grade ≥3

Only AEs with an occurrence of >5% were considered (excluding atrial fibrillation and hypertension)



AE, adverse event; C, cycle; GIVe, venetoclax plus obinutuzumab and ibrutinib.

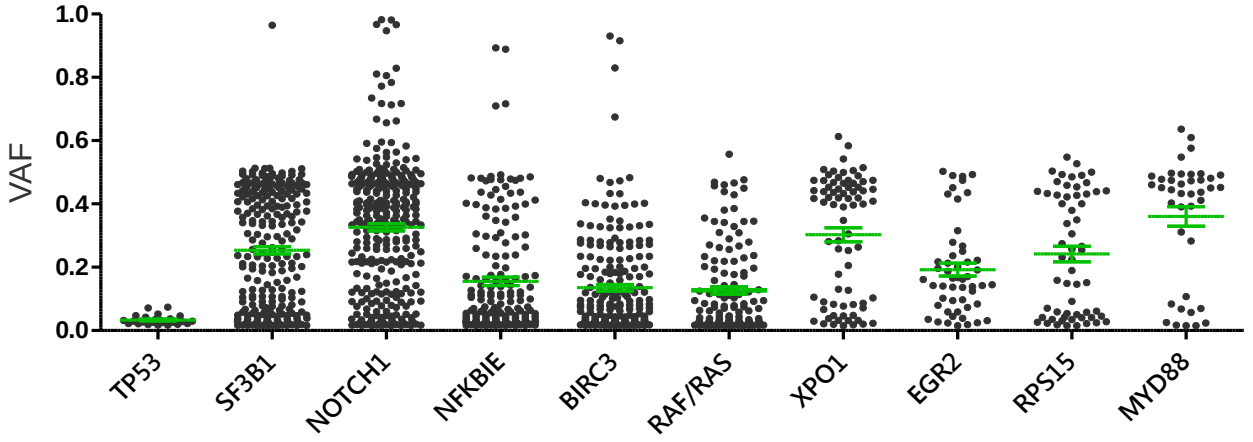
Huber H *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 343).

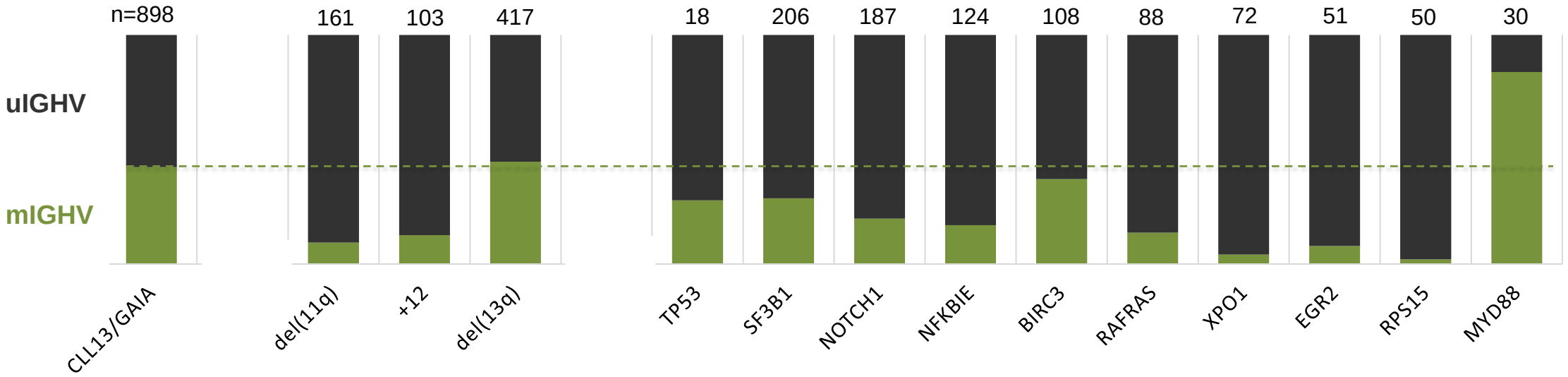
CLL13/GAIA: Venetoclax-based therapy vs. CIT in fit patients with TN CLL

CLL13/GAIA gene mutations and IGHV mutation status

TP53 variants were identified with VAF of 1.7% to 7.4% in cases with wildtype *TP53* status defined by Sanger sequencing.

High risk markers such as del(11q), *NOTCH1*, *NFKBIE*, *XPO1* and *RPS15* were found predominantly in cases with uIGHV.





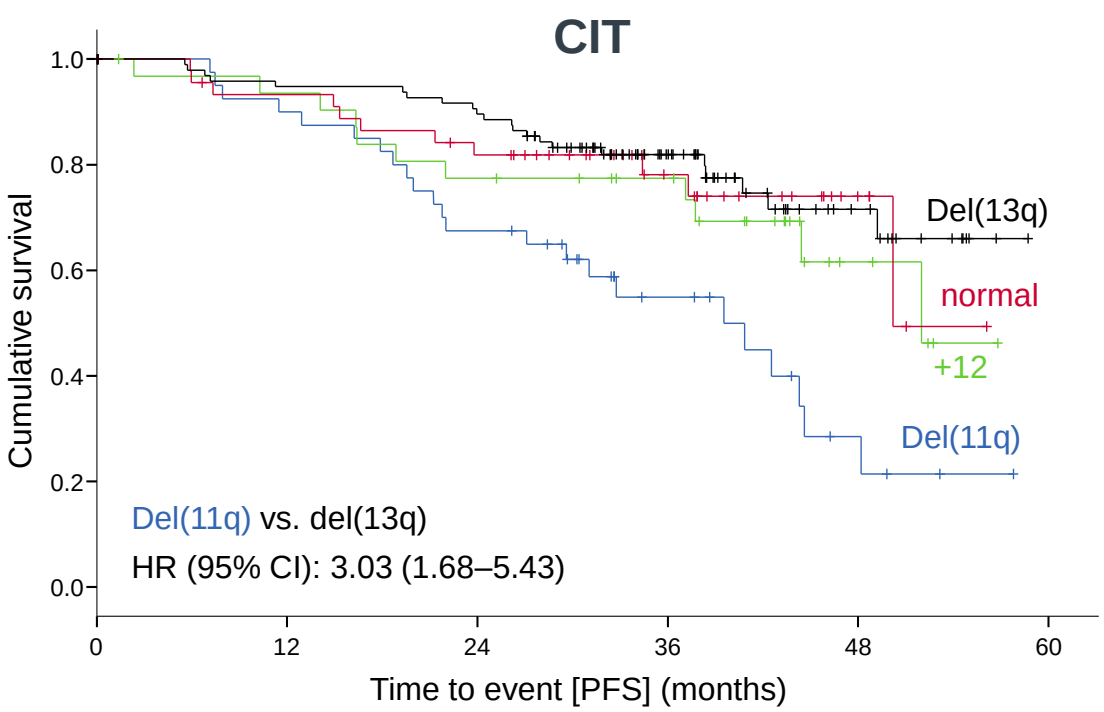
CIT, chemoimmunotherapy; CLL, chronic lymphocytic leukemia; IGHV, immunoglobulin heavy chain variable; mIGHV, mutated IGHV; TN, treatment naive; uIGHV, unmutated IGHV; VAF, variable antigen frequency.

Tausch E *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 345).

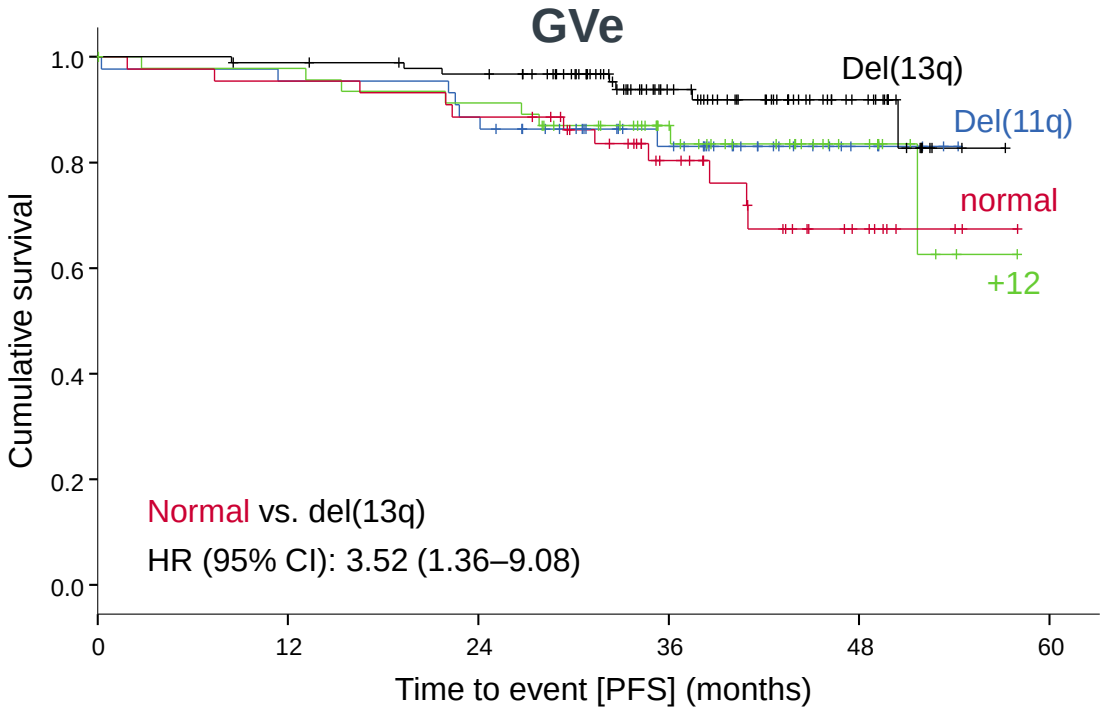
CLL13/GAIA: Efficacy results

Genomic aberrations with CIT and RVe/GVe/GIVe (hierarchical model)

- At a median follow up of 38.8 months 188 PFS events were observed.
- Del(11q) was only associated with shorter PFS when treated with CIT, but not with RVe/GVe/GIVe.
- Del(13q) was associated with significantly longer PFS with GVe therapy.



Del(11q)	41	36	27	13	4
Tris 12	34	29	24	20	5
Normal	53	41	35	19	5
Del(13q)	101	91	86	46	14



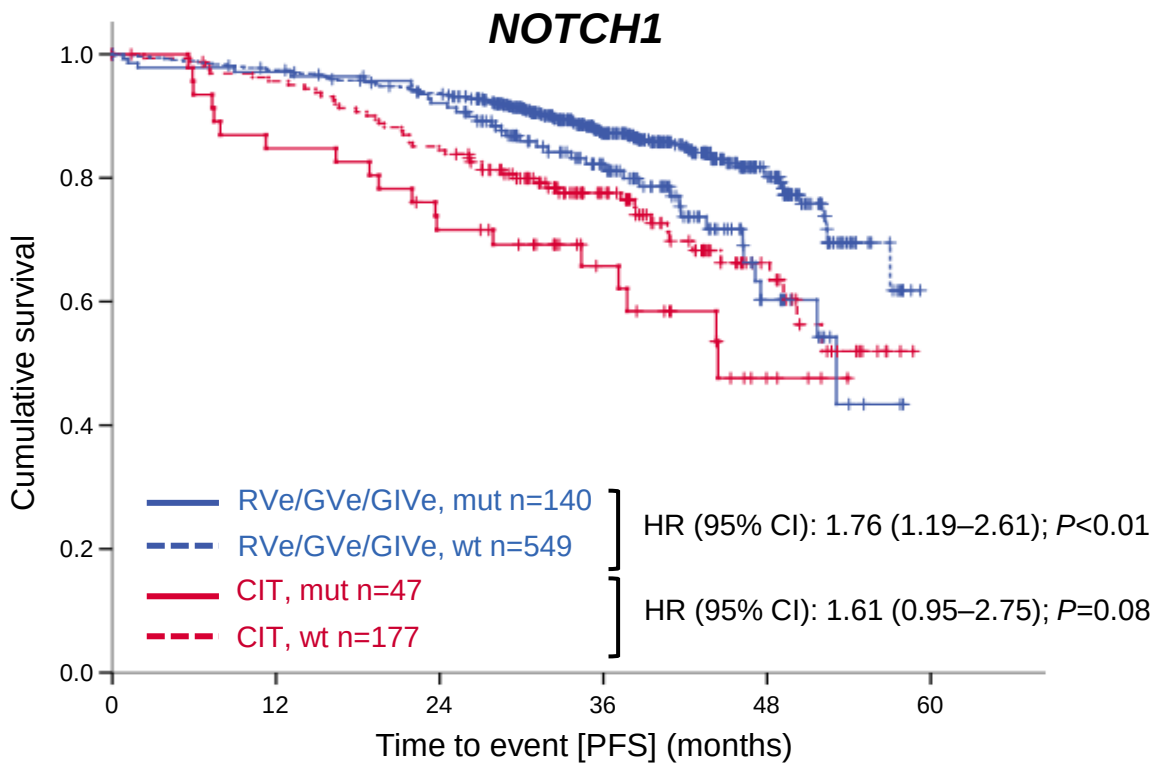
Del(11q)	44	42	39	25	5
Tris 12	47	45	42	26	9
Normal	44	42	39	23	8
Del(13q)	94	92	88	51	20

CI, confidence interval; CIT, chemoimmunotherapy; GIVe, venetoclax plus obinutuzumab and ibrutinib; GVe, venetoclax plus obinutuzumab; HR, hazard ratio; PFS, progression-free survival; RVe, venetoclax plus rituximab.

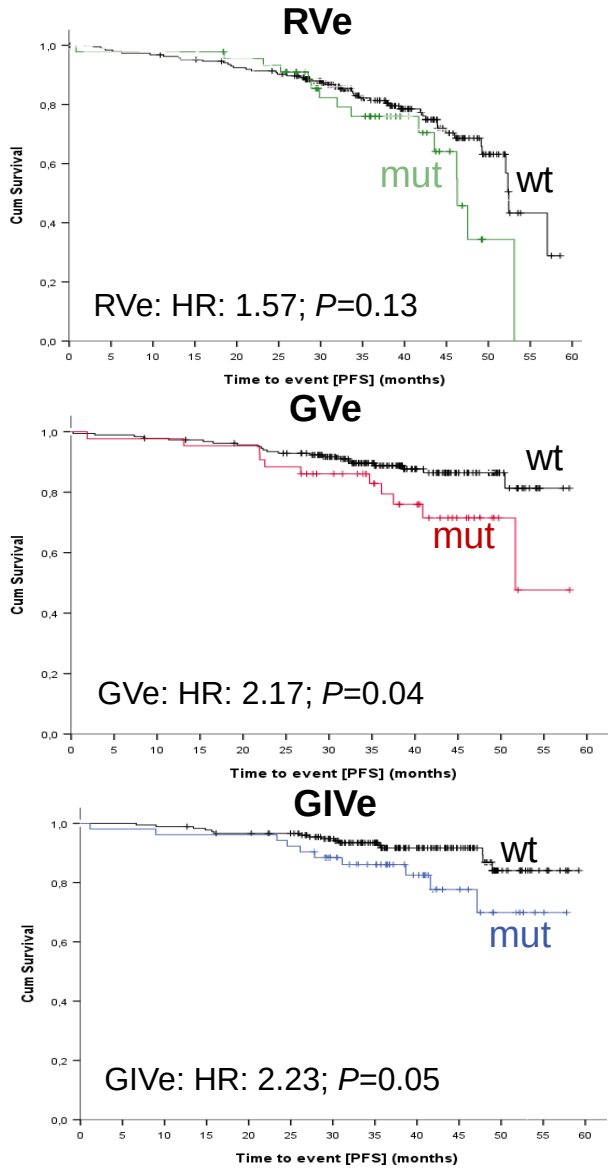
Tausch E *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 345).

CLL13/GAIA: Efficacy results
NOTCH1 mutations and PFS

Patients with *NOTCH1* mutations had a shorter PFS with CIT and RVe/GVe/GIVe



CIT, wt	177	154	136	77	24
CIT, mut	47	39	32	18	4
RVe/GVe/GIVe, wt	549	531	502	296	100
RVe/GVe/GIVe, mut	140	136	128	75	17

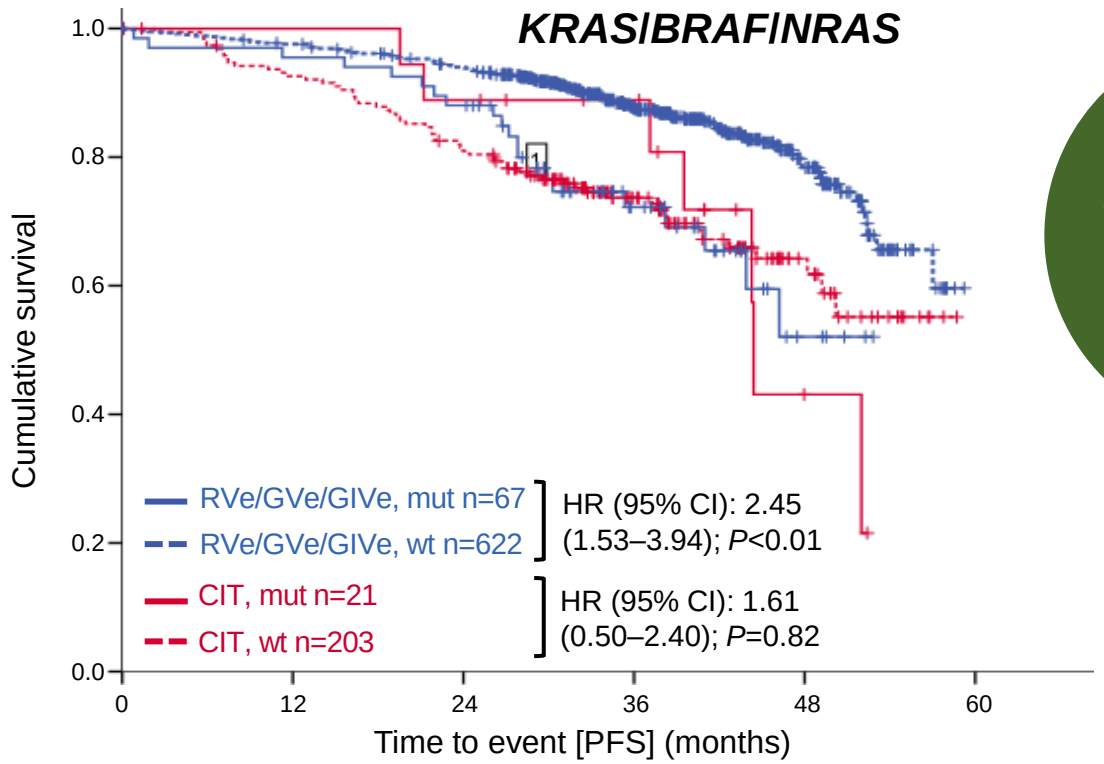


CI, confidence interval; CIT, chemoimmunotherapy; GIVe, venetoclax plus obinutuzumab and ibrutinib; GVe, venetoclax plus obinutuzumab; HR, hazard ratio; mut, mutant; PFS, progression-free survival; RVe, venetoclax plus rituximab; wt, wildtype.

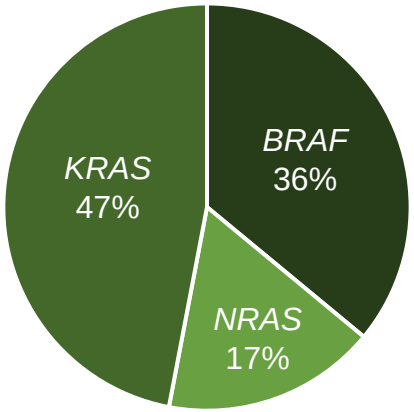
Tausch E *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 345).

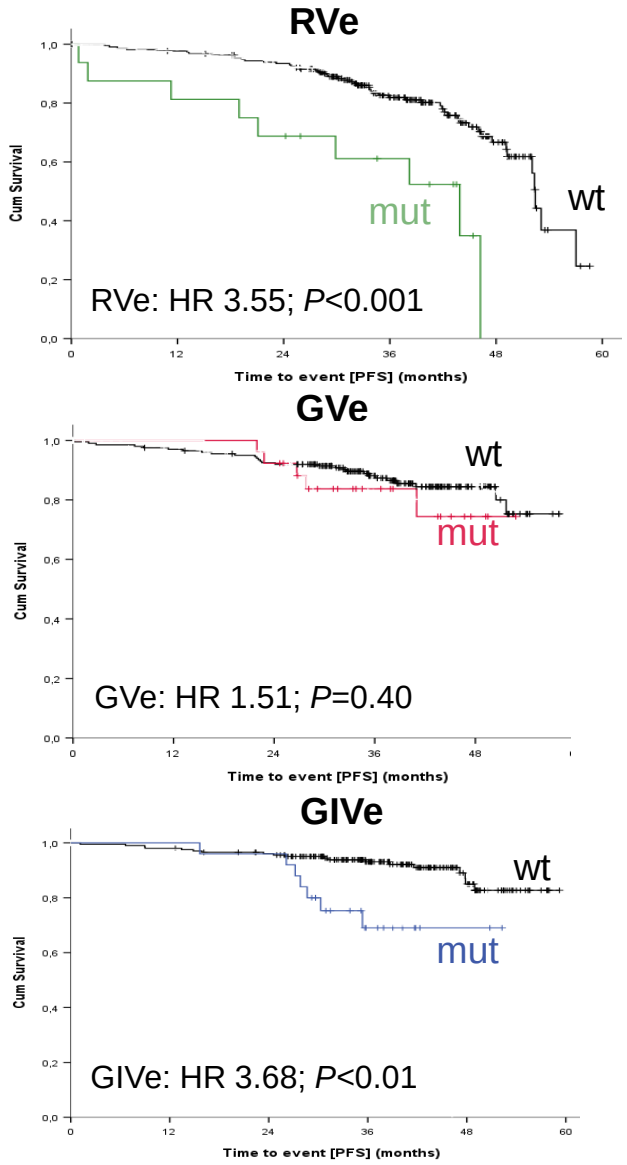
CLL13/GAIA: Efficacy results
RAS/RAF mutations and PFS

Patients with mutations in *KRAS/BRAF/NRAS* had a shorter PFS when treated with RVe or GIVe



CIT, wt	203	175	152	83	26
CIT, mut	21	18	16	12	2
RVe/GVe/GIVe, wt	622	603	571	343	112
RVe/GVe/GIVe, mut	67	64	59	28	5



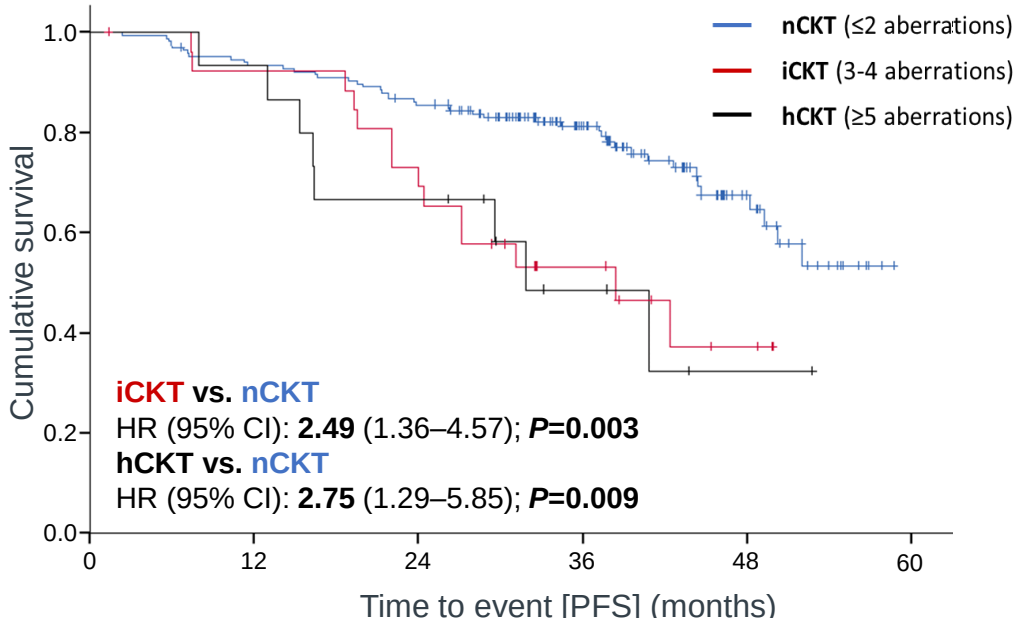


CI, confidence interval; CIT, chemoimmunotherapy; GIVe, venetoclax plus obinutuzumab and ibrutinib; GVe, venetoclax plus obinutuzumab; HR, hazard ratio; mut, mutant; PFS, progression-free survival; RVe, venetoclax plus rituximab; wt, wildtype.

Tausch E *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 345).

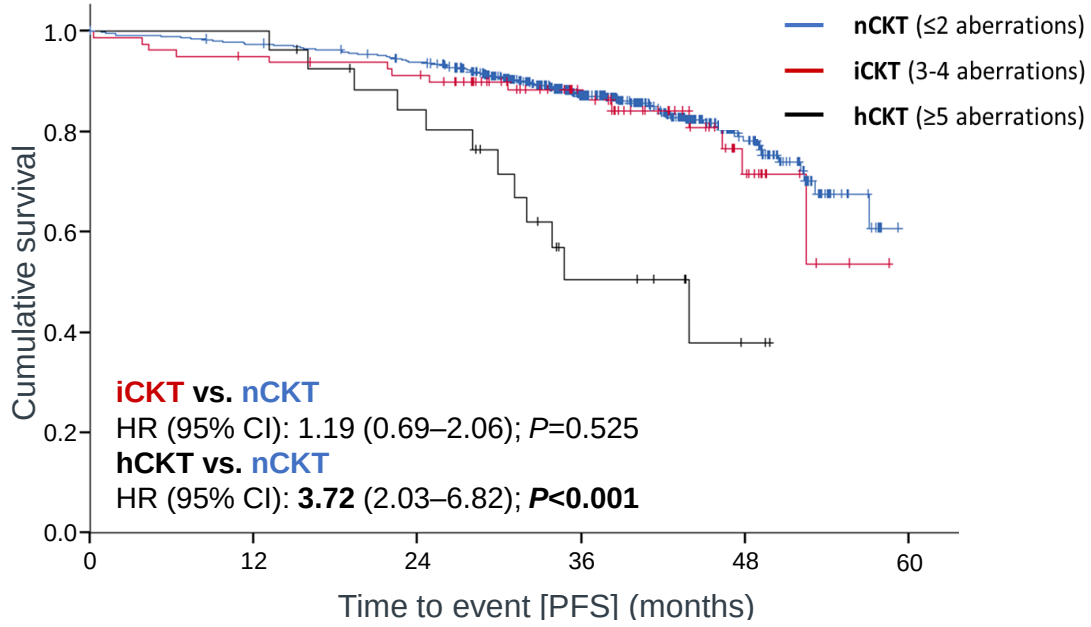
CLL13/GAIA: Impact of hCKT/iCKT on PFS

PFS, chemoimmunotherapy arm



Patients at risk					
nCKT	177	155	141	84	24
iCKT	30	24	18	9	3
hCKT	16	14	10	4	1

PFS, pooled venetoclax arms



Patients at risk					
nCKT	565	547	522	308	99
iCKT	80	75	71	44	14
hCKT	27	27	21	8	2

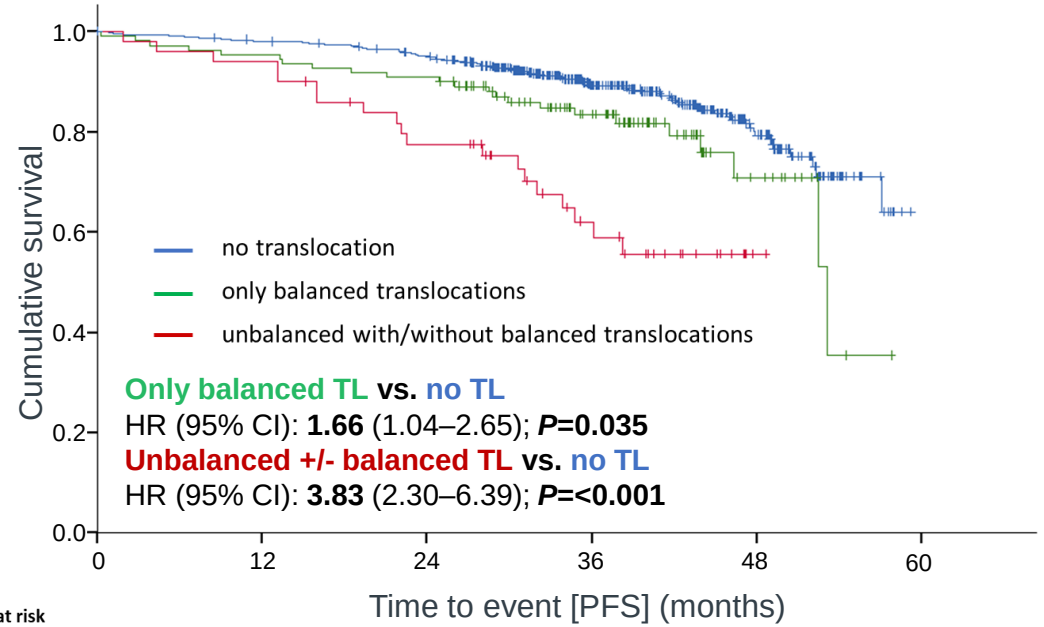
Presence of hCKT but not iCKT is associated with shorter PFS in pooled venetoclax arms

CI, confidence interval; CKT, complex karyotype; hCKT, high CKT; HR, hazard ratio; iCKT, intermediate CKT; nCKT, no CKT; PFS, progression-free survival.

Furstenau M *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 346).

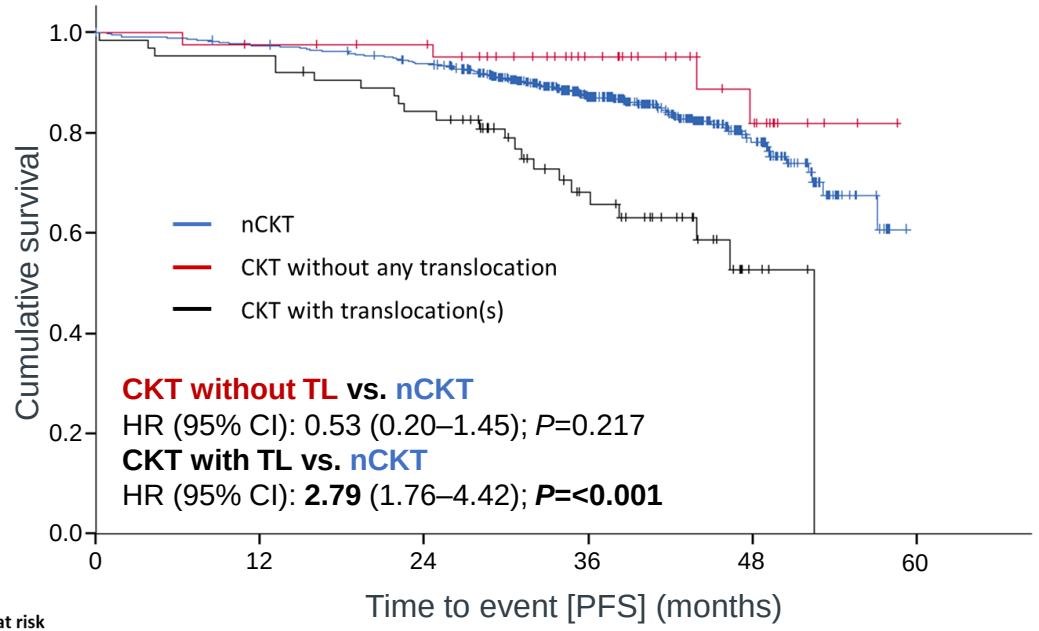
CLL13/GAIA: Impact of translocations on PFS

PFS, pooled venetoclax arms



Patients at risk					
No TL	505	490	470	280	102
Only balanced TL	110	105	100	59	12
Unbalanced +/- balanced TL	50	47	37	20	1

PFS, pooled venetoclax arms

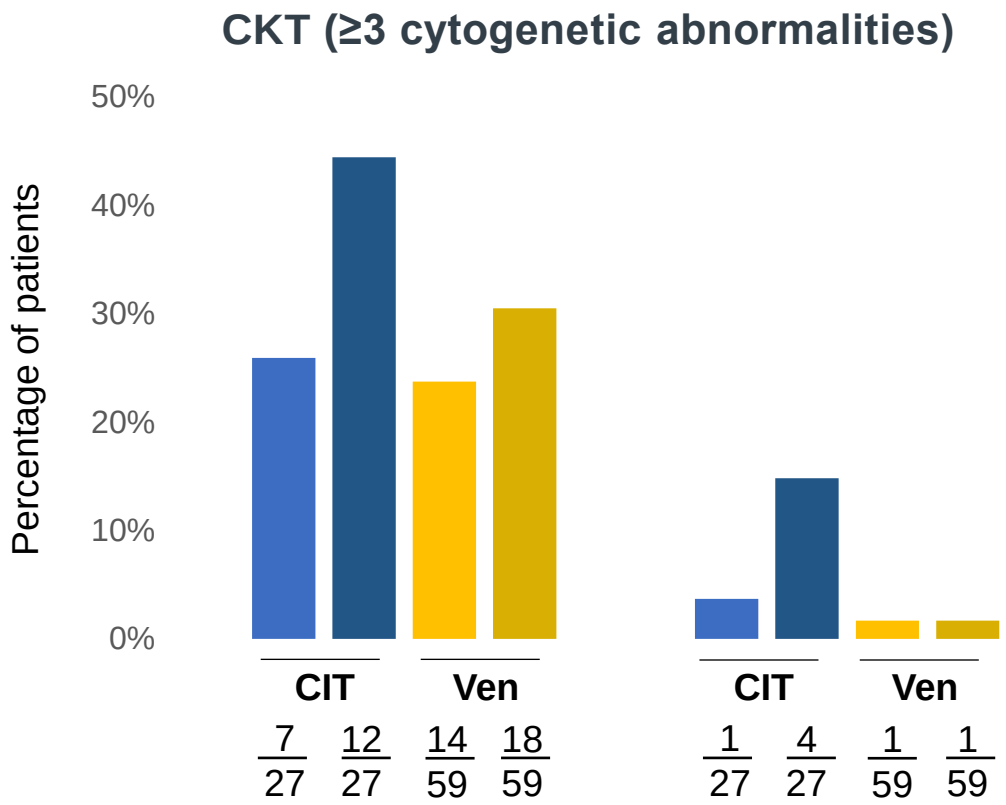


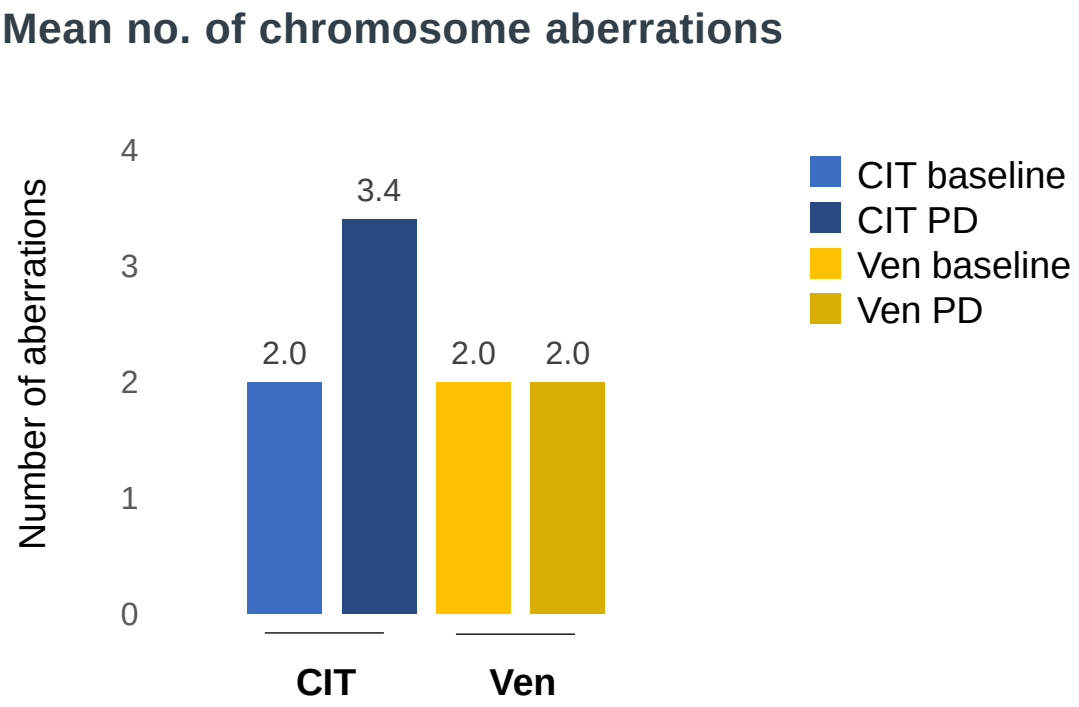
Patients at risk					
nCKT	565	547	522	308	99
CKT without TL	43	41	39	25	12
CKT with TL	64	61	53	27	4

Both **balanced** and **unbalanced translocations are associated with shorter PFS** in pooled venetoclax arms

CI, confidence interval; CKT, complex karyotype; HR, hazard ratio; PFS, progression-free survival; TL, translocation.
Furstenau M *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 346).

CLL13/GAIA: Karyotype evolution at progression





CIT is associated with an **increase in chromosomal aberrations** while venetoclax treatment is not

CIT, chemoimmunotherapy; CKT, complex karyotype; PD, progressive disease; TL, translocation; Ven, venetoclax.
Furstenau M *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 346).

CLL13/GAIA

Multivariate analysis for CIT and RVe/GVe/GIVe

Full trial analysis for PFS

	HR	95% CI	*P*
GVe vs. CIT	0.42	0.27–0.65	<0.001
GIVe vs. CIT	0.33	0.21–0.52	<0.001
uIGHV	2.43	1.70–3.47	<0.001
CKT	1.98	1.42–2.77	<0.001
Binet B/C vs. A	1.55	1.06–2.27	0.03
NOTCH1^{mut}	1.46	1.05–2.05	0.03

uIGHV, CKT and *NOTCH1* mutations were independent prognostic factors for CIT and RVe/GVe/GIVe.

RAS/*RAF* mutations were only prognostic with venetoclax therapy.

CIT for PFS

	HR	95% CI	*P*
uIGHV	3.08	1.55–6.12	0.001
>65 years	2.26	1.34–3.83	0.002
NOTCH1^{mut}	2.12	1.16–3.88	0.01
Del(11q)	1.89	1.06–3.36	0.03
CKT	1.87	1.06–3.27	0.03

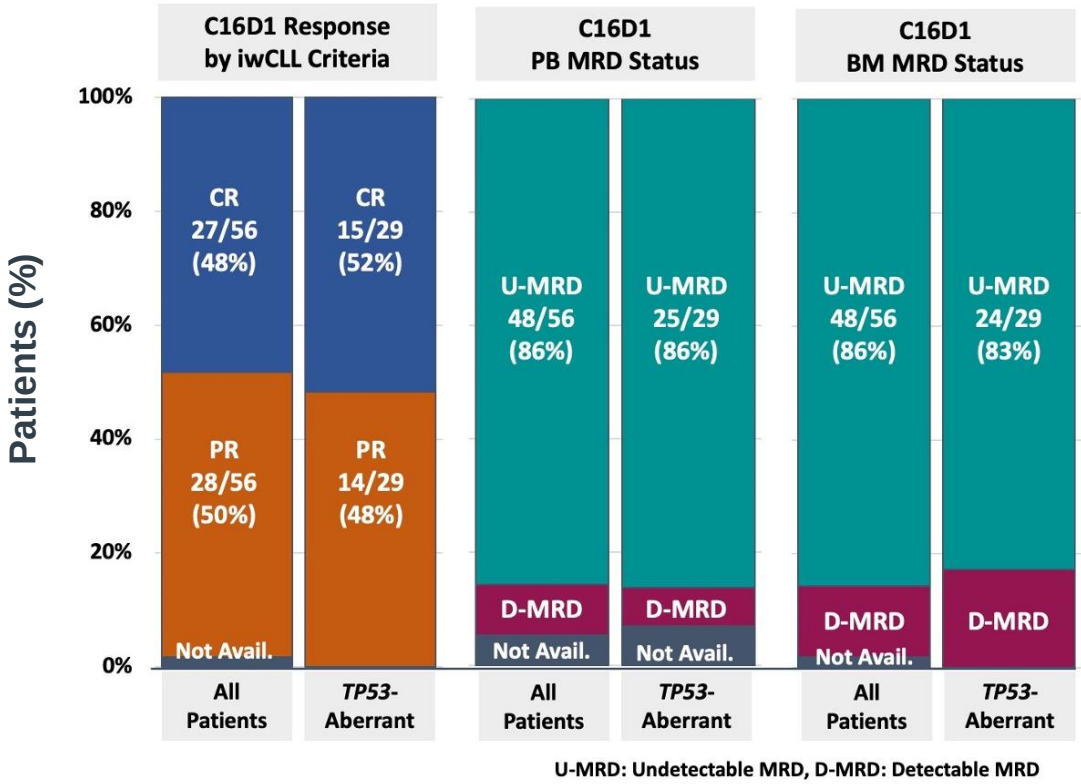
RVe/GVe/GIVe for PFS

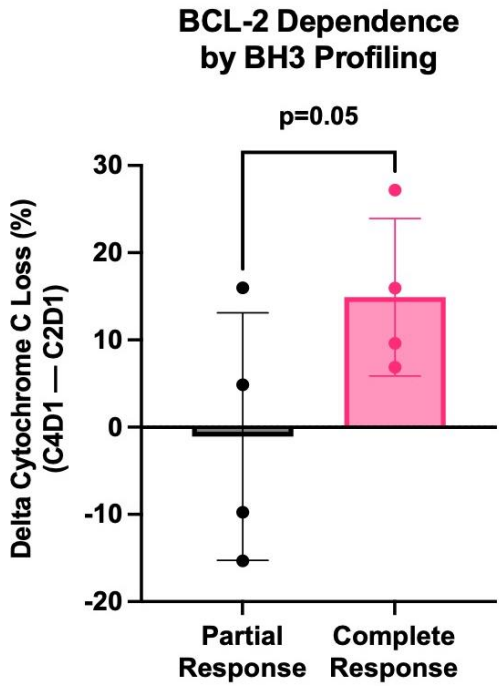
	HR	95% CI	*P*
uIGHV	1.85	1.20–2.84	0.005
RAS/*RAF*^{mut}	1.87	1.14–3.06	0.01
Unbalanced translocations CKT	1.66	1.07–2.56	0.02
b2MG>3.5mg/L	1.56	1.03–2.36	0.04
NOTCH1^{mut}	1.54	1.02–2.33	0.04

CI, confidence interval; CIT, chemoimmunotherapy; CKT, complex karyotype; GIVe, venetoclax plus obinutuzumab and ibrutinib; GVe, venetoclax plus Obinutuzumab; HR, hazard ratio; PFS, progression-free survival; RVe, venetoclax plus rituximab; uIGHV, unmutated immunoglobulin heavy chain variable.

Furstenau M *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 346).

First-line high-risk CLL: Acalabrutinib, venetoclax, obinutuzumab





63/68 (93%) PFS
at 35 months
median follow-up

BCL-2, B-cell lymphoma 2; BM, bone marrow; CR, complete remission; CLL, chronic lymphocytic leukemia; D-MRD, detectable MRD; iwCLL, international workshop on CLL; MRD, minimal residual disease; ORR, overall response rate; PB, peripheral blood; PFS, progression-free survival; PR, partial remission; U-MRD, undetectable MRD.

Ryan CE *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 344).

ALPINE: Study design

R/R CLL/SLL with ≥1 prior treatment

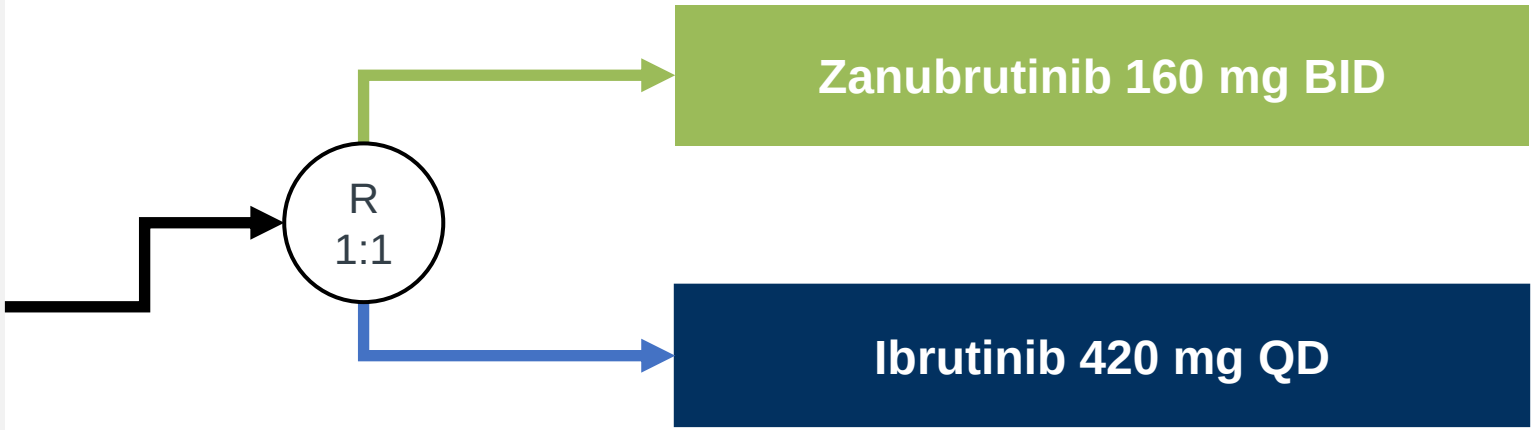
(Planned N=600, actual N=652)

Key inclusion criteria

- R/R to ≥1 prior systemic therapy for CLL/SLL
- Measurable lymphadenopathy by CT or MRI

Key exclusion criteria

- Prior BTK inhibitor therapy
- Treatment with warfarin or other vitamin K antagonists



Stratification factors:

- Age
- Geographic region
- Refractoriness
- del(17p)/*TP53*

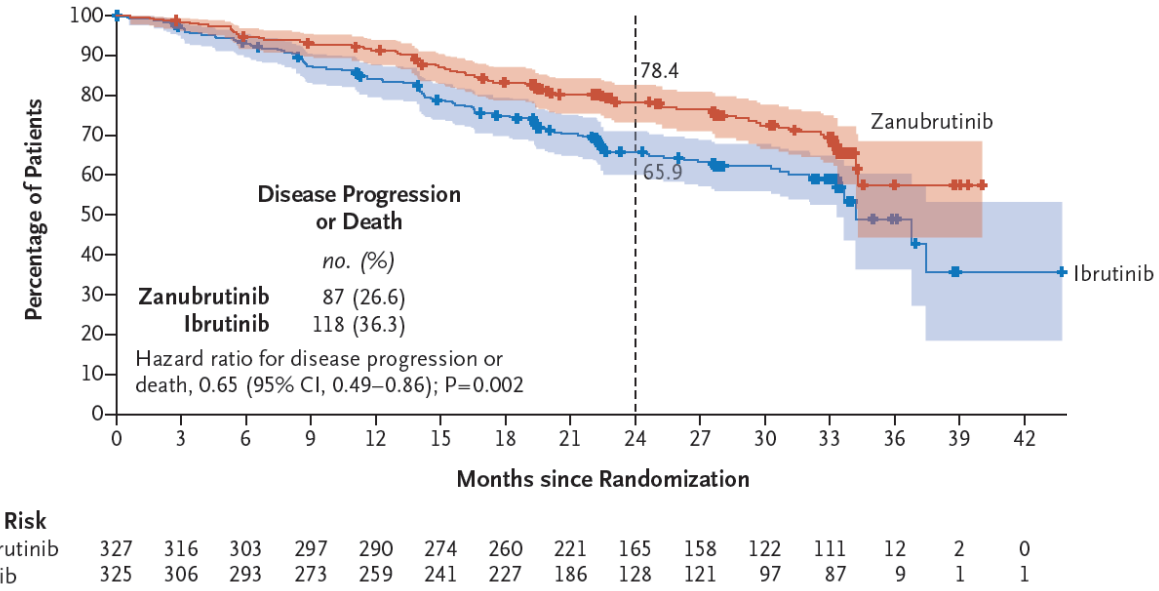
Treatment until disease progression or unacceptable toxicity

BID, twice a day; CLL, chronic lymphocytic leukemia; CT, computed tomography; del, deletion; QD, once a day; LBA, late-breaking abstract; MRI, magnetic resonance imaging; R, randomization; R/R, relapsed/refractory; SLL, small lymphocytic lymphoma.

Brown J *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract LBA–6).

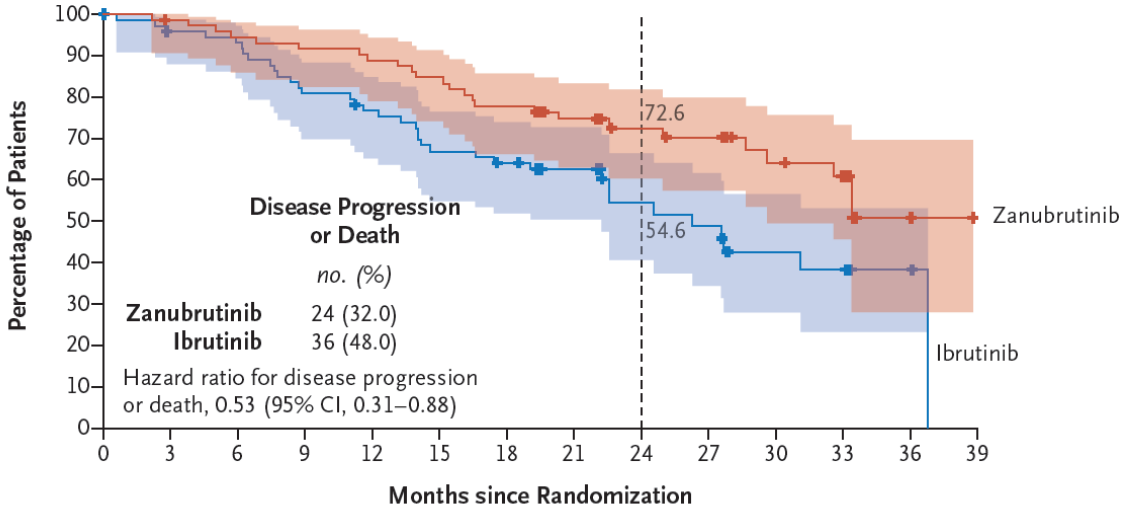
Zanubrutinib vs. ibrutinib for R/R CLL: What is high-risk?

PFS in the ITT population



No. at Risk														
Zanubrutinib	327	316	303	297	290	274	260	221	165	158	122	111	12	2	0
Ibrutinib	325	306	293	273	259	241	227	186	128	121	97	87	9	1	1

PFS in the population with one or both of del(17p) / *TP53*^{mut}

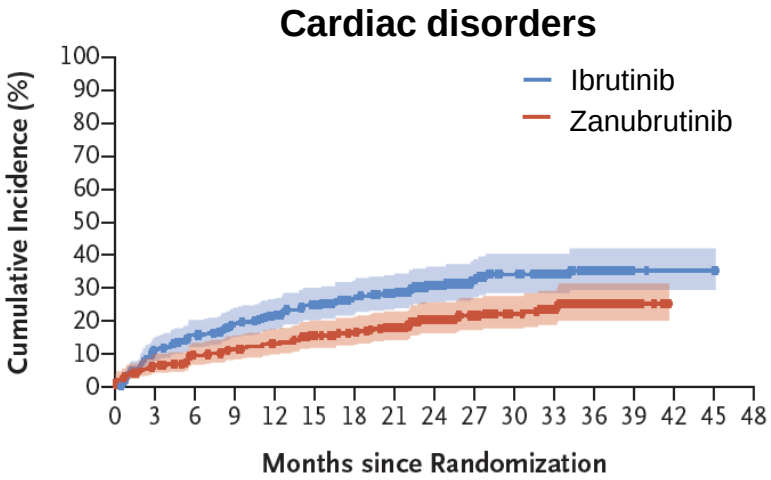


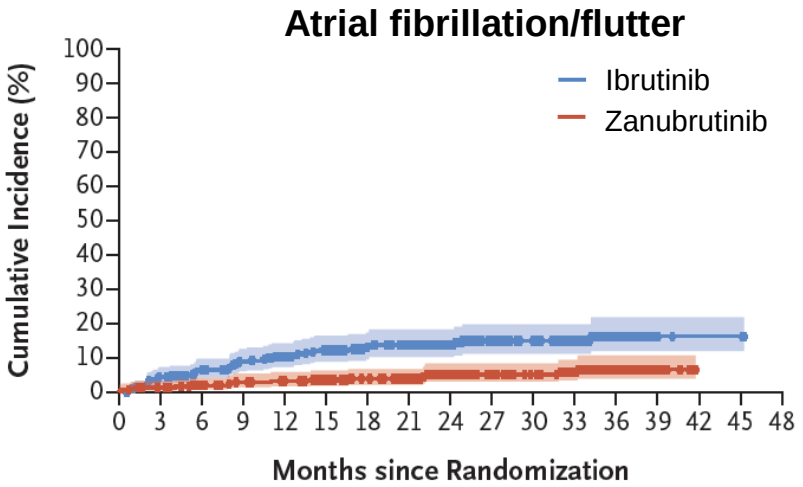
No. at Risk														
Zanubrutinib	75	71	68	66	64	61	56	47	32	30	21	18	3	0
Ibrutinib	75	70	68	59	55	48	45	34	19	17	10	9	2	0

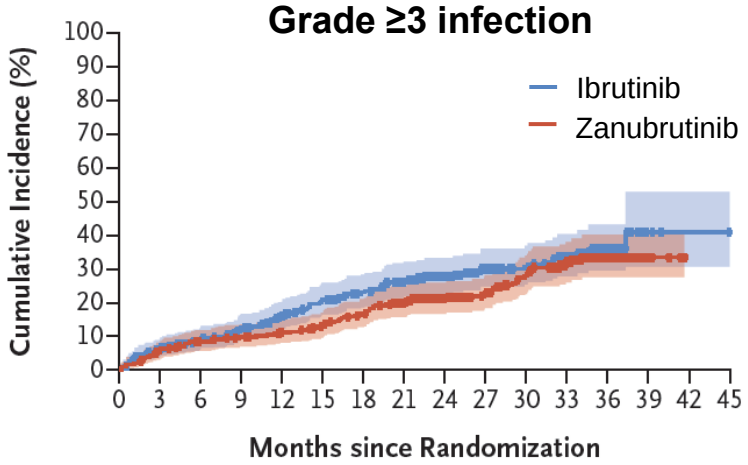
CI, confidence interval; CLL, chronic lymphocytic leukemia; ITT, intention-to-treat; PFS, progression-free survival; R/R, relapsed/refractory.

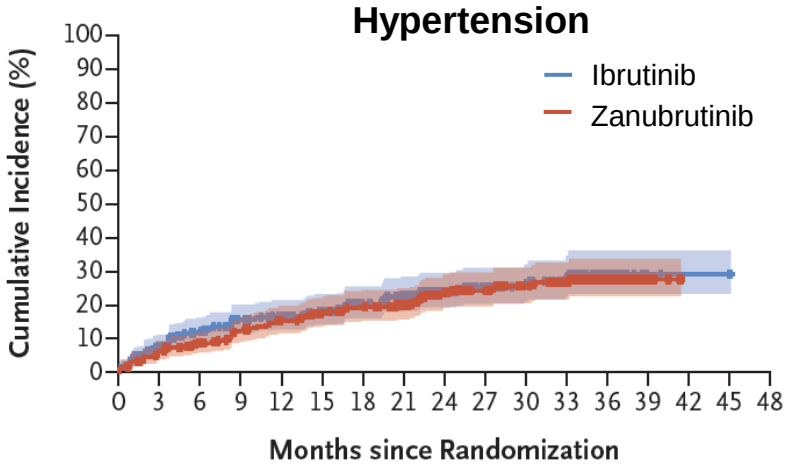
Brown JR *et al. N Engl J Med* 2023; 388 (4): 319–332.

Zanubrutinib vs. ibrutinib for R/R CLL: Different adverse events









CLL, chronic lymphocytic leukemia; R/R, relapsed/refractory.
Brown JR *et al*. *N Engl J Med* 2023; 388 (4): 319–332.

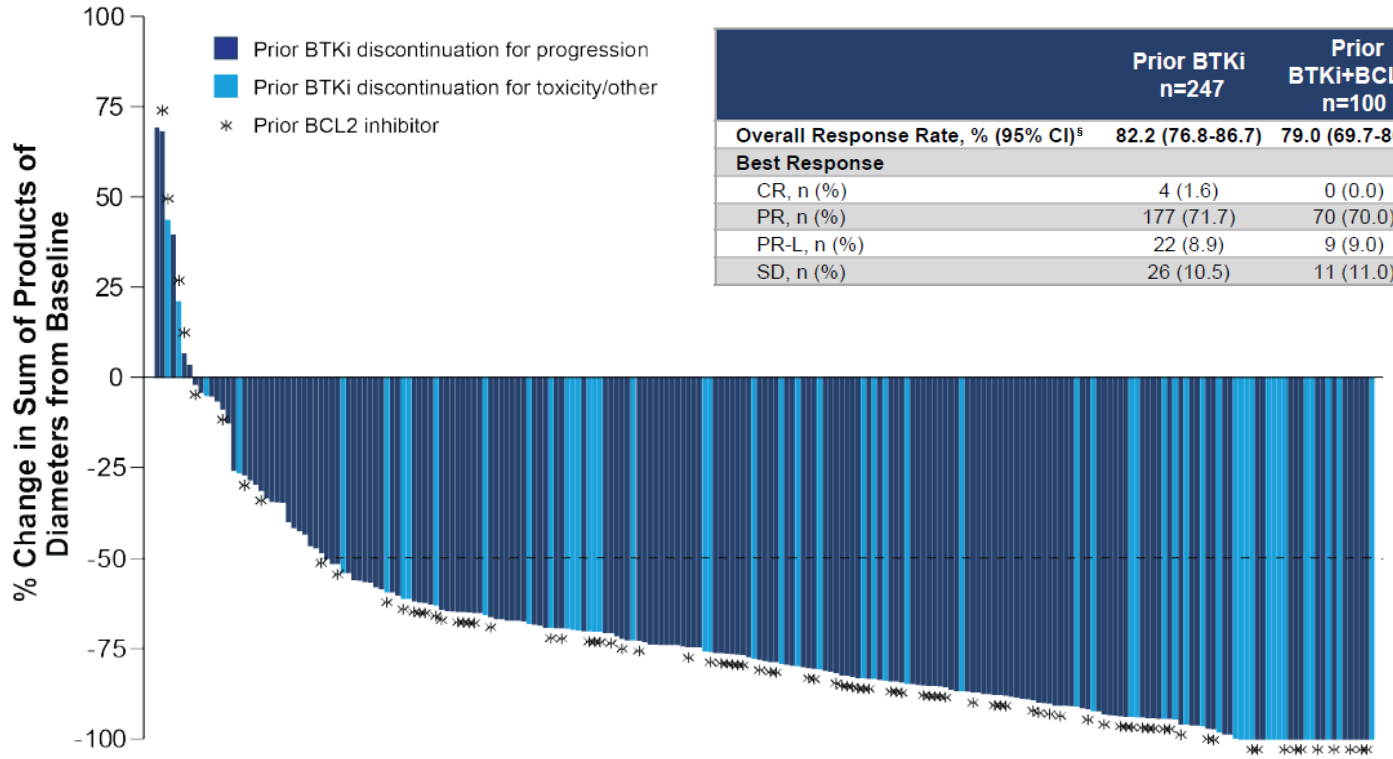
Pirtobrutinib for BTK inhibitor exposed R/R CLL

Characteristics	n=247
Median age, years (range)	69 (36-88)
Male, n (%)	168 (68)
Histology	
CLL	246 (>99)
SLL	1 (<1)
Rai staging*	
0-II	131 (53)
III-IV	102 (41)
Bulky Disease ≥5 cm, n (%)	78 (32)
ECOG PS, n (%)	
0	133 (54)
1	97 (39)
2	17 (7)
Median number of prior lines of systemic therapy, n (range)	3 (1-11)
Prior therapy, n (%)	
BTK inhibitor	
Anti-CD20 antibody	
Chemotherapy	
BCL2 inhibitor	
PI3K inhibitor	
CAR-T	
Allogeneic stem cell transplant	
Median time from diagnosis to first dose,	

Baseline Molecular Characteristics†	
Mutation status, n/n available (%)	
BTK C481-mutant	84/222 (38)
BTK C481-wildtype	138/222 (62)
PLCG2-mutant	18/222 (8)
PLCG2-wildtype	204/222 (92)
High Risk Molecular Features, n/n available (%)	
17p deletion	51/176 (29)
TP53 mutation	87/222 (39)
17p deletion and/or *TP53* mutation	90/193 (47)
Both 17p deletion and *TP53* mutation	48/170 (28)
IGHV unmutated	168/198 (85)
Complex Karyotype	24/57 (42)
11q deletion	44/176 (25)

Reason for prior BTKi discontinuation‡, n (%)	
Progressive disease	190 (77)
Toxicity/Other	57 (23)

Pirtobrutinib efficacy in CLL/SLL patients previously treated with a BTKi



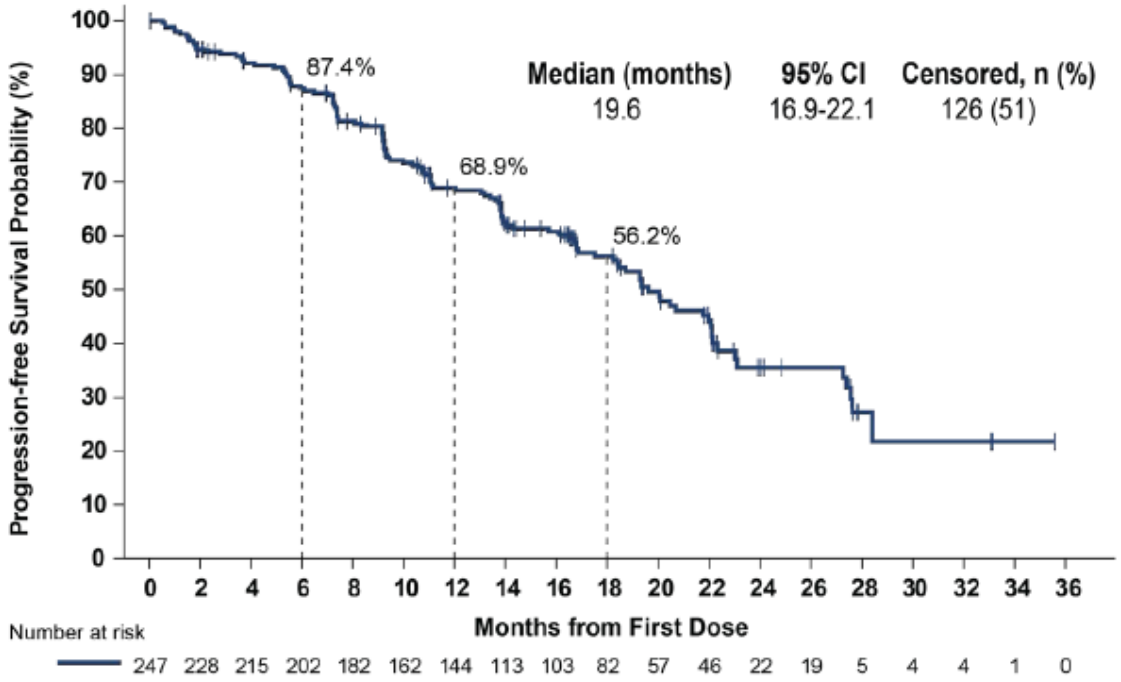
	Prior BTKi n=247	Prior BTKi+BCL2i n=100
Overall Response Rate, % (95% CI)§	**82.2 (76.8-86.7)**	**79.0 (69.7-86.5)**
Best Response		
CR, n (%)	4 (1.6)	0 (0.0)
PR, n (%)	177 (71.7)	70 (70.0)
PR-L, n (%)	22 (8.9)	9 (9.0)
SD, n (%)	26 (10.5)	11 (11.0)

*14 patients had missing data for Rai staging data. †Molecular characteristics were determined centrally and are presented based on data availability in those patients with sufficient sample to pass assay quality control. ‡In the event that more than one reason was noted for discontinuation, disease progression took priority. §ORR includes patients with a best response of CR, PR, and PR-L.

BTK, BTK inhibitor; CLL, chronic lymphocytic leukemia; CR, complete remission; ECOG, Eastern Cooperative Oncology Group; PR-L, partial remission with lymphocytosis; PR, partial remission; PS, performance status; R/R, relapsed/refractory; SD, stable disease; SLL, small lymphocytic lymphoma. Mato AR *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 961).

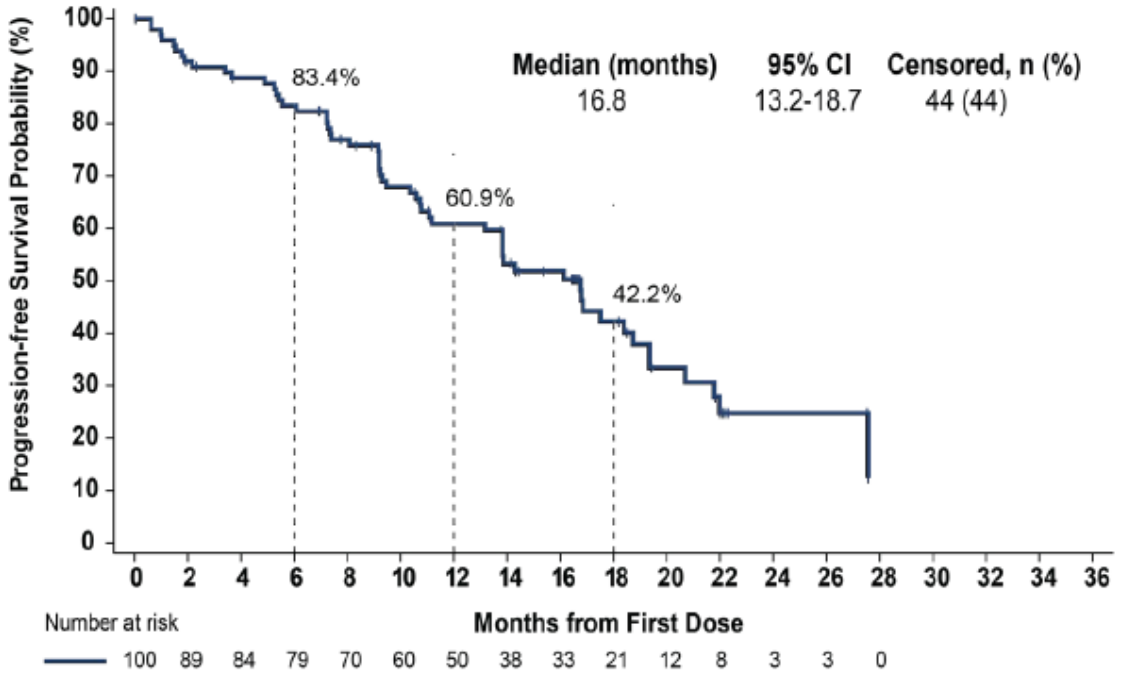
Pirtobrutinib for BTK inhibitor exposed R/R CLL:
A single agent is not the solution!

All prior BTKi patients
Median prior lines = 3



Median follow-up of 19.4 months for patients who received prior BTKi

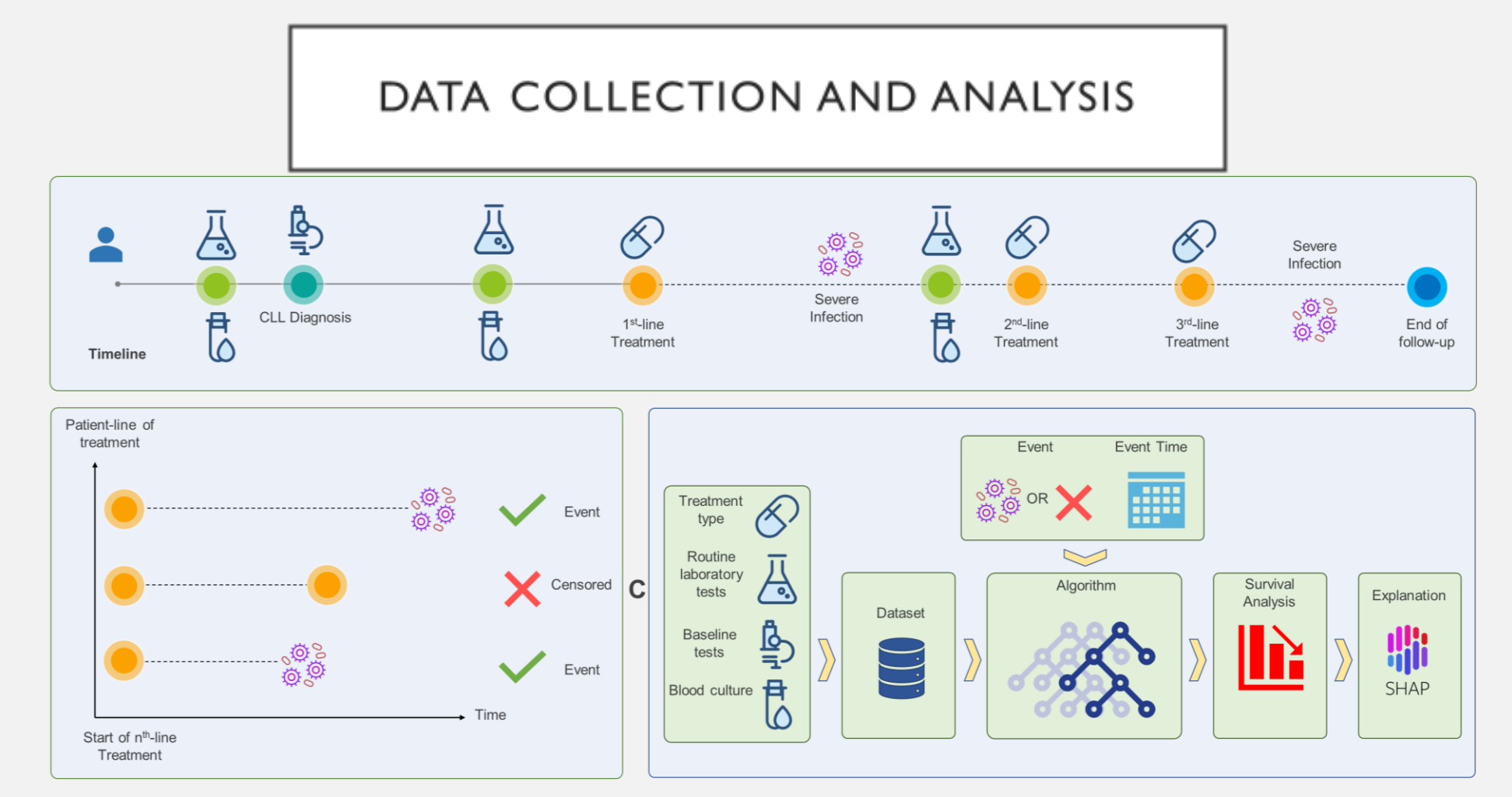
Prior BTKi and BCL2i patients
Median prior lines = 5



Median follow-up of 18.2 months for patients who received prior BTKi and BCL2i

BCL2i, BCL2 inhibitor; BTKi, BTK inhibitor; CI, confidence interval; CLL, chronic lymphocytic leukemia; R/R, relapsed/refractory.
Mato AR *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 961).

Data driven modelling of risk of infection upon CLL treatment



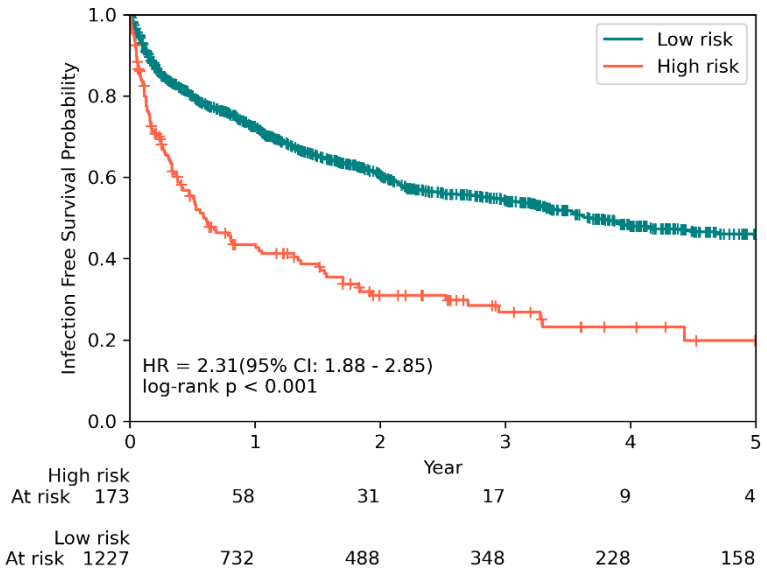
CLL, chronic lymphocytic leukemia; SHAP, SHapley Additive exPlanations.
Parviz M *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 3126).

Infection-free survival

Kaplan-Meier curves of infection-free survival estimated from the start of treatment*

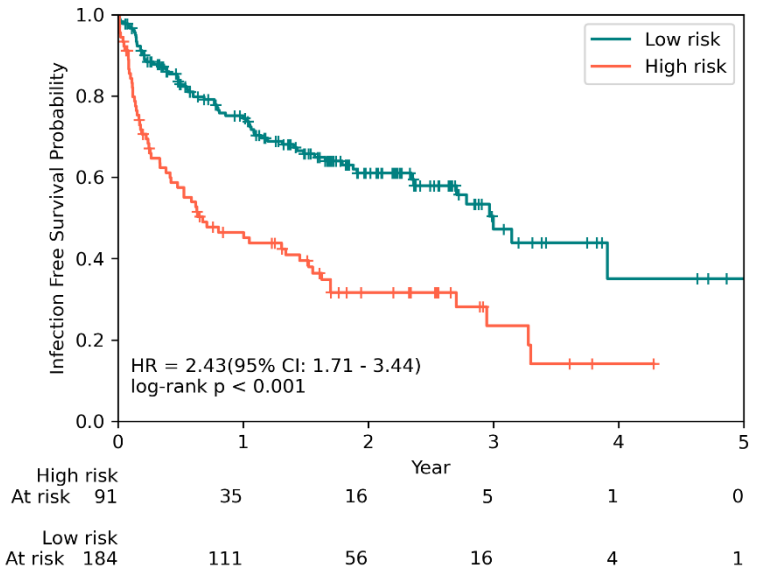
All treatment types

(A) C-index (95% CI): 0.687 (0.649–0.725)



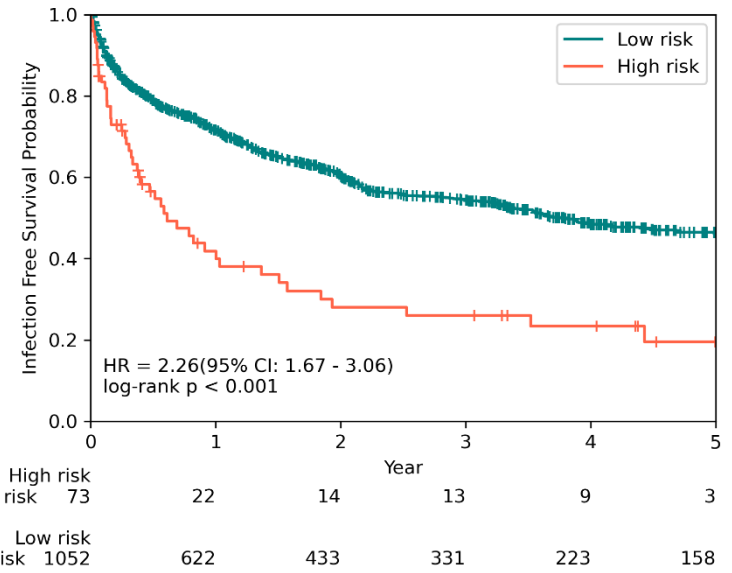
Ibrutinib treatment

(B) C-index (95% CI): 0.672 (0.647–0.696)



Other treatments

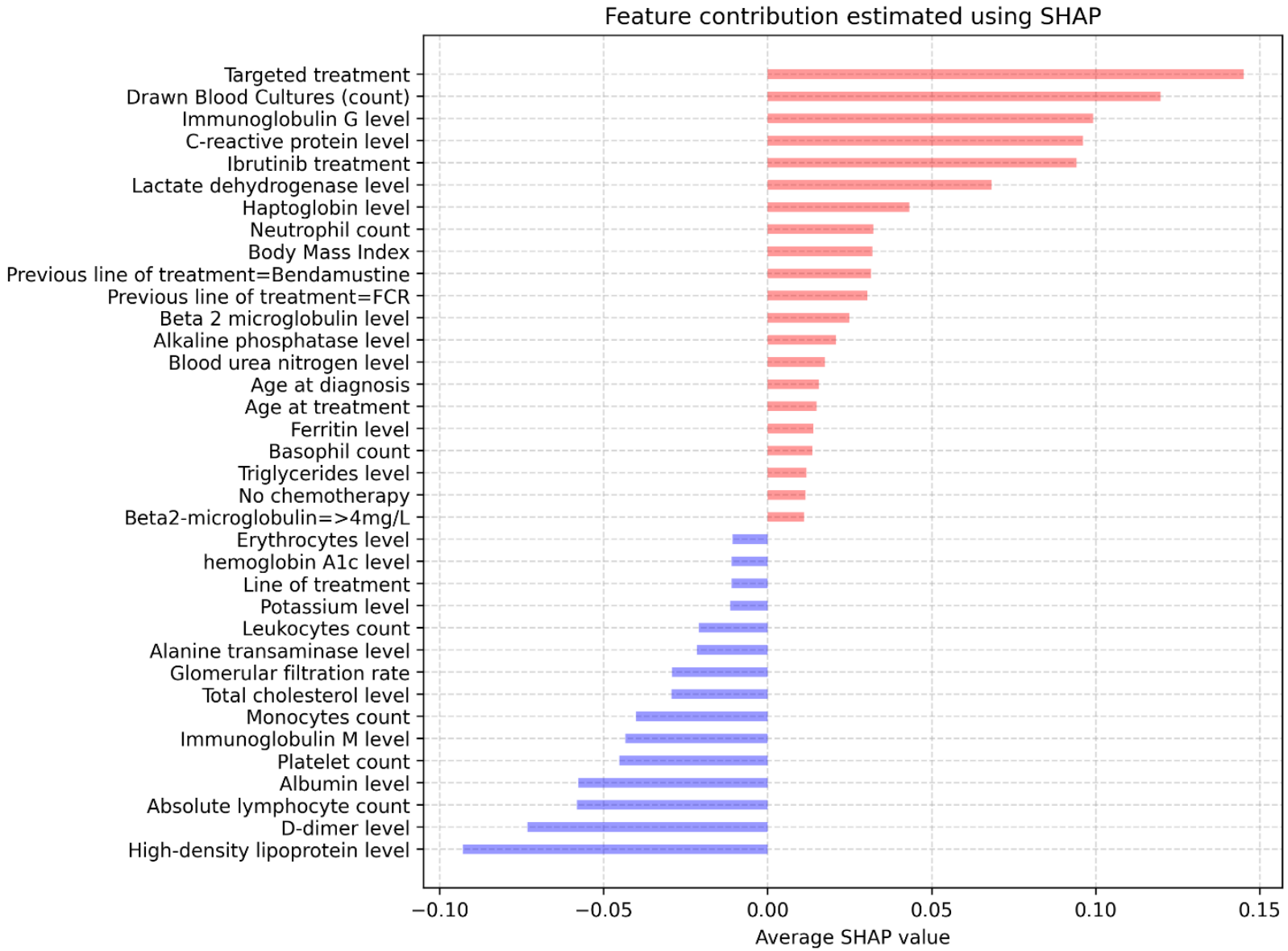
(C) C-index (95% CI): 0.659 (0.597–0.721)



*A high-risk and low-risk group were identified with 57% and 28% estimated risk of a severe infection within one year of treatment initiation, respectively.
CI, confidence interval; HR, hazard ratio.
Parviz M *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 3126).

Feature contributions

- Targeted therapy including ibrutinib treatment correlated with increased risk of infection
- Targeted therapy was primarily used for patients with aggressive CLL
  - *TP53* aberration and/or relapsed/refractory CLL
- Important features:
  - The number of blood cultures drawn prior to treatment
  - Routine laboratory tests measuring immunoglobulin G, c-reactive protein, and high-density lipoprotein levels



CLL, chronic lymphocytic leukemia; FCR, fludarabine, cyclophosphamide and rituximab; SHAP, SHapley Additive exPlanations.
Parviz M *et al*. Oral presentation at ASH 2022; New Orleans, LA, USA, December 10–13, 2022 (Abstract 3126).

ASH 2022: Take home messages for CLL

- **GLOW study**: First-line overall survival benefit of ibrutinib-venetoclax for frail patients[1]
- Early toxicity for (some) BTK inhibitors[2] – unmet need to identify risk groups
- MRD in CLL – need to consider treatment and molecular subgroup[1,4,5]
- Pattern of molecular findings needed to identify high risk upon venetoclax-based combinations[6,7]
- Mortality and morbidity from infections – we are starting to identify risk groups[8]
- Fixed-duration combination regimens, not continuous monotherapies, are needed[1,2,9]

BTK, Bruton tyrosine kinase; CLL, chronic lymphocytic leukemia; MRD, minimal residual disease.

1. Niemann CU *et al*. Abstract 93. 2. Huber H *et al*. Abstract 343. 3. Slot M *et al*. Abstract 893. 4. Jain N *et al*. Abstract 95. 5. Munir T *et al*. Abstract 94. 6. Tausch E *et al*. Abstract 345. 7. Furstenau M *et al*. Abstract 346. 8. Parviz M *et al*. Abstract 3126. 9. Eichhorst B *et al*. Abstract LB2365. All references were oral presentations at ASH 2022; New Orleans, LA, USA, December 10–13, 2022.

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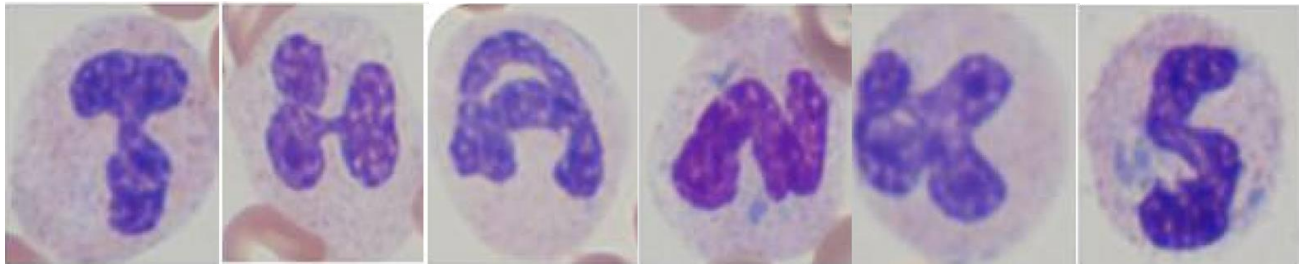

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novo nordisk fonden

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