

Highlights nella leucemia linfatica cronica

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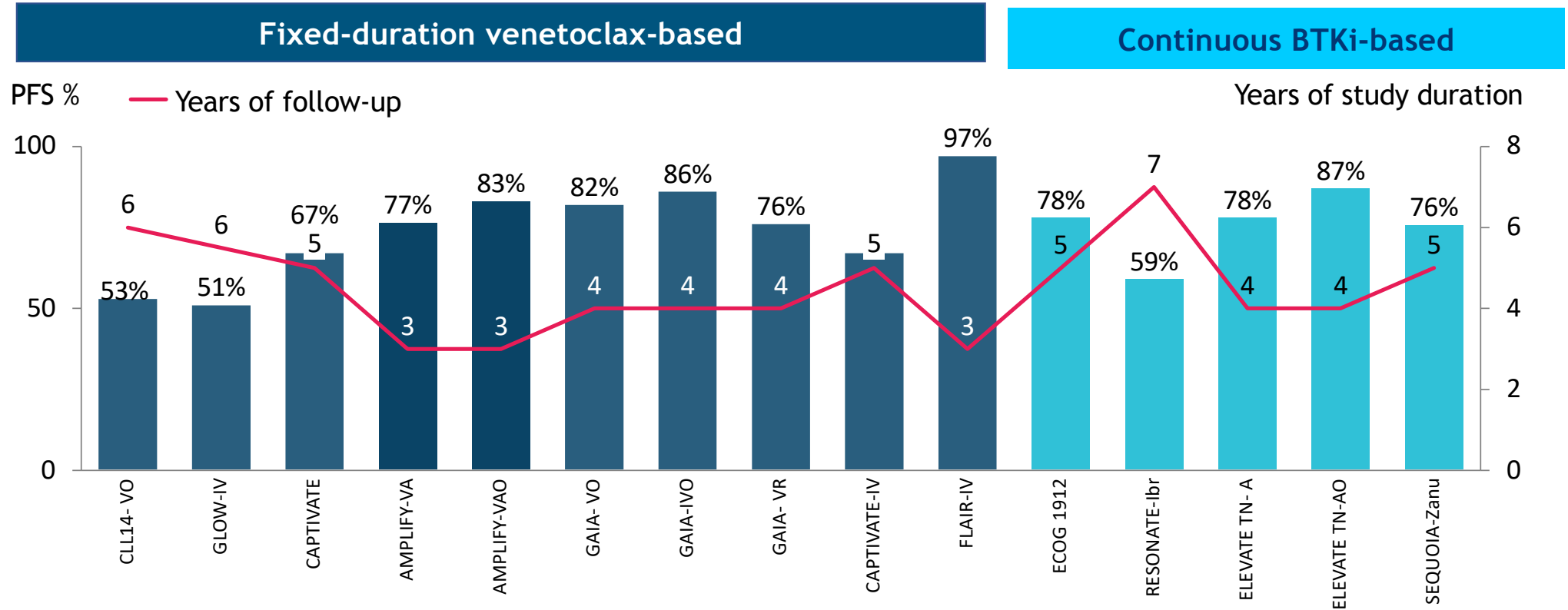
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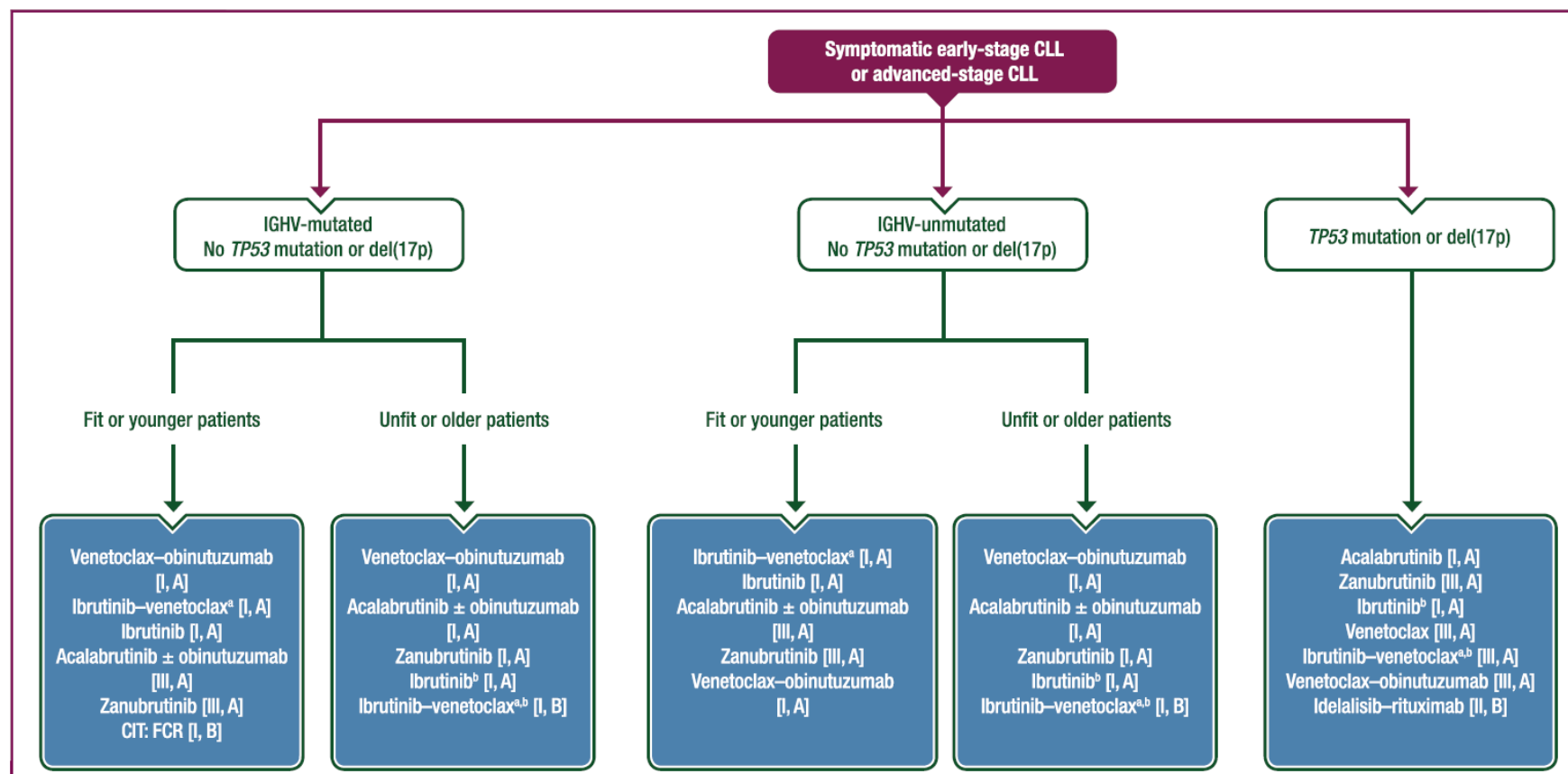
Highlights in
**EMATO
LOGIA**

Key 1L treatments for CLL: PFS

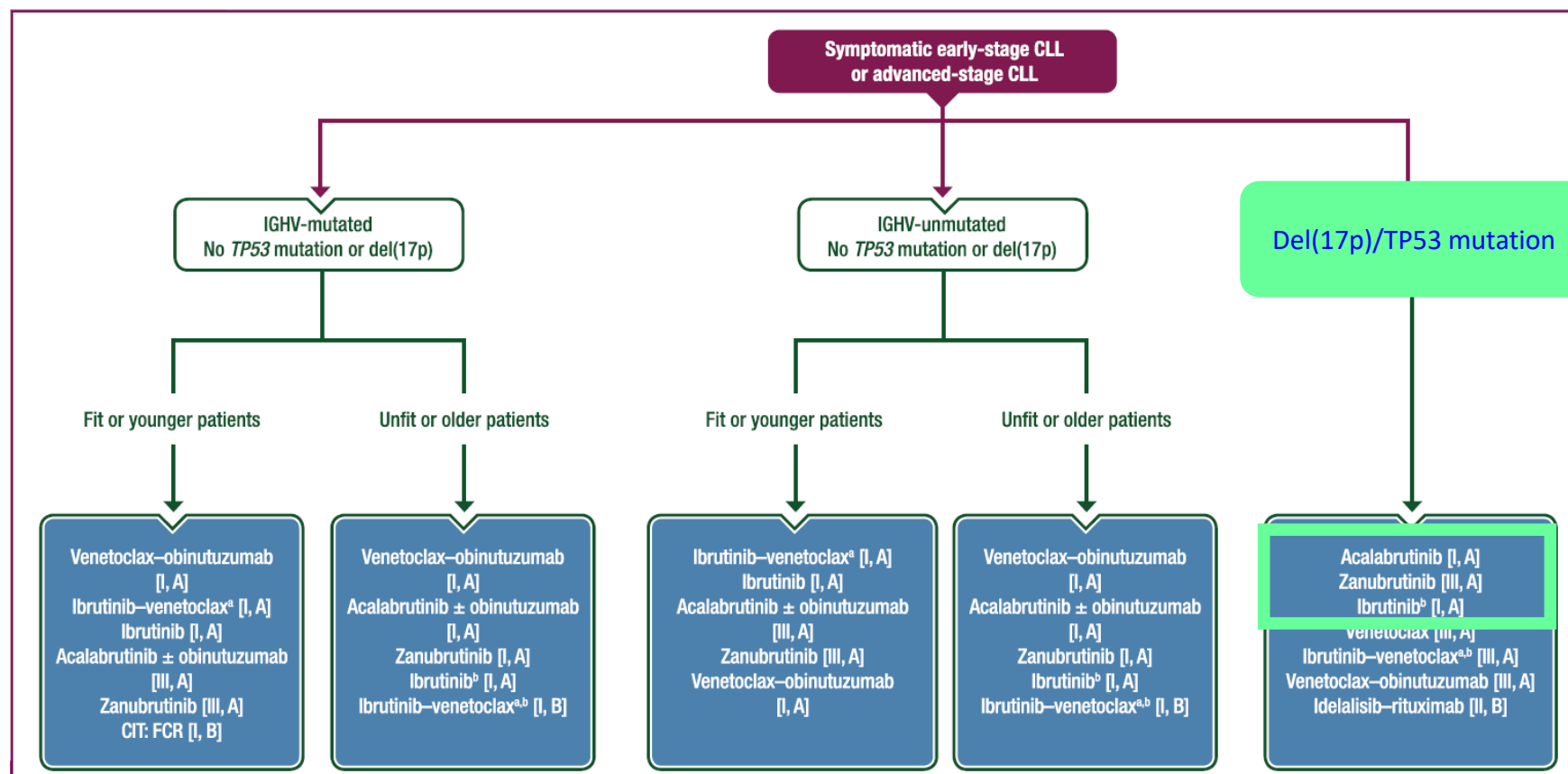


Al-Sawaf O, et al. Nat Commun 2023; Niemann CU, et al. ASH 2024, #1871; Wierda WG, et al. J Clin Oncol 2024; Brown JR, et al. N Engl J Med 2025; Fürstenau M, et al. Lancet Oncol 2024; Hillmen P, et al. ASH 2023, #631; Shanafelt T, et al. Blood 2022; Barr PM, et al. Blood Adv 2022; Sharman JP, et al. Leukemia 2022; Shadman M, et al. ASH 2024 #3249

2024 ESMO Treatment guidelines: 1L treatment for CLL



2024 ESMO Treatment guidelines: 1L treatment for CLL



BTKi-based treatment in patients with CLL

IBRUTINIB OR IBRUTINIB PLUS RITUXIMAB IN PATIENTS WITH CLL: 10-YEAR FOLLOW-UP OF A
Jan Burger et al,
EHA abstr#1570

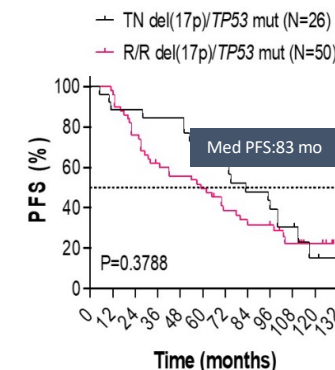
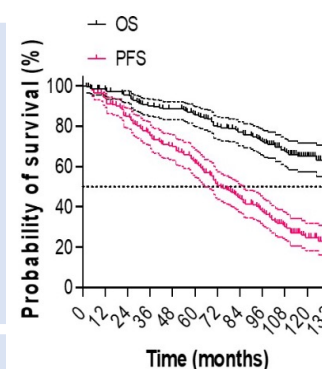
2025
EHA

181 R/R pts
27 TN pts with 17p aberr.

randomized Txt:
Ibr vs. Ibr+R

Survival: Ibr=Ibr+R:
Med. PFS: 74 months
10-year OS: 65%

TN vs. R/R pts patients with TP53 aberration: higher med PFS (83 mo vs.59 mo.).



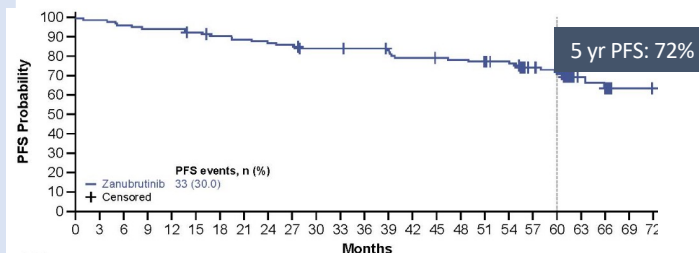
5-YEAR FOLLOW-UP OF THE SEQUOIA ARM C: FRONTLINE ZANUBRUTINIB IN PATIENTS WITH DEL(17P) AND TN CLL/SLL
Mazyar Shadmanet al,
EHA abstr. #1565

2025
EHA

111 TN patients with del(17p)

Zanubrutinib single agent

ORR: 97.3%
60-month PFS 72.2%
60-month OS rate was 85.1%



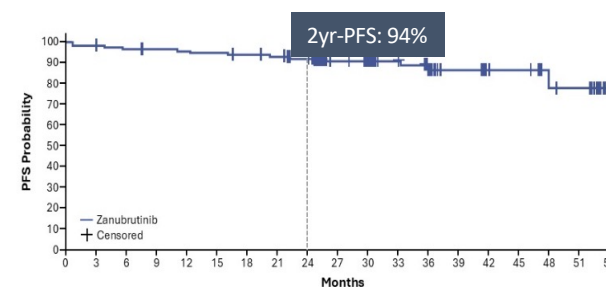
SEQUOIA ARM D: ZANUBRUTINIB + VENETOCLAX FOR TN CLL/SLL
Mazyar Shadmanet al,
EHA abstr#1566

2025
EHA

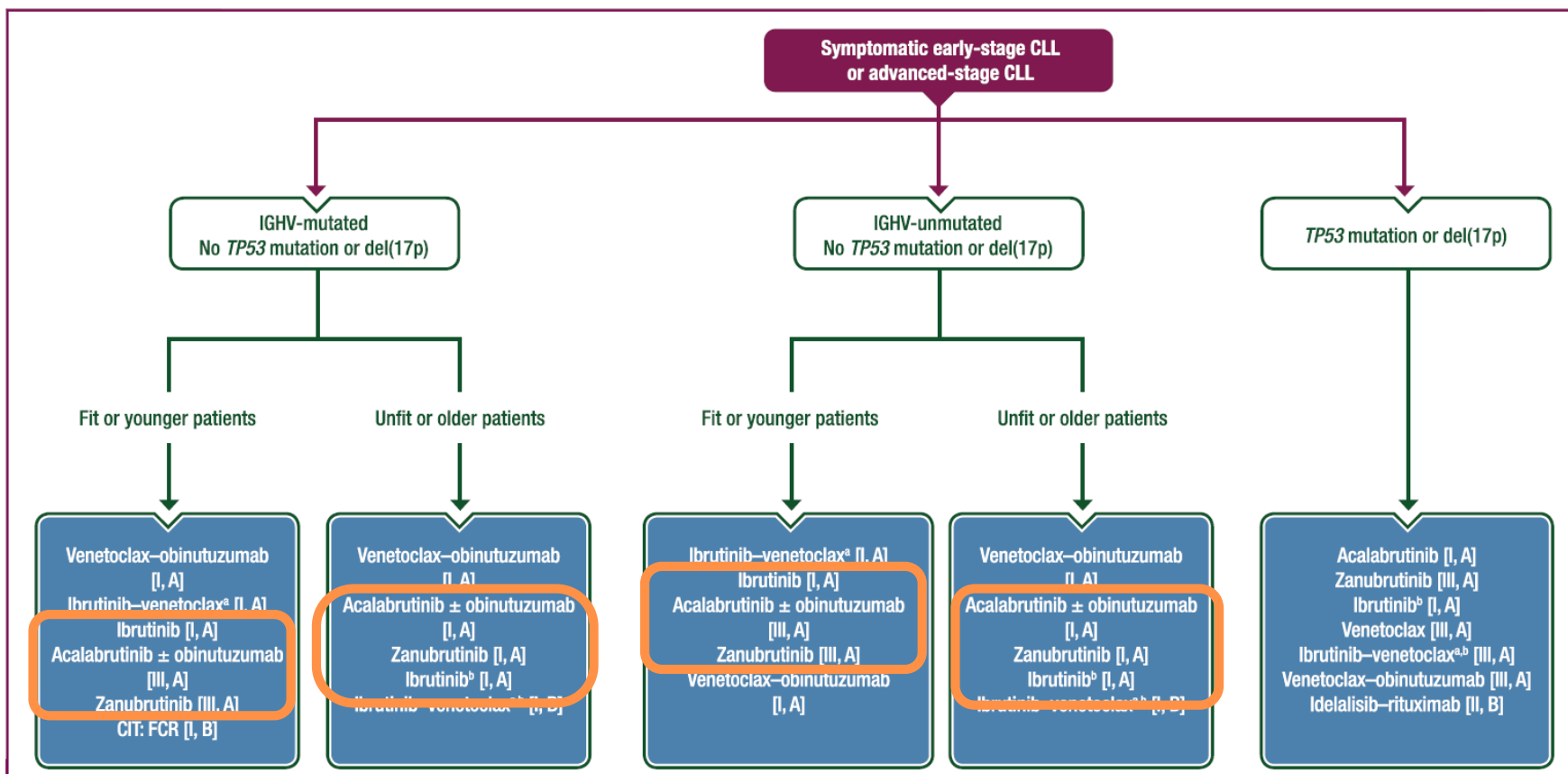
114 TN pts
58% TP53 aberr.
41% without TP53 aberr.
Zanubrutinib+ venetoclax

total population
24-month PFS: 92%
PB uMRD: 59%.

TP53 aberr. population
24-month PFS: 94%
PB uMRD: 59%



2024 ESMO Treatment guidelines: 1L treatment for CLL



Priority to
Time-Limited Therapy
for CLL patients
without *TP53* disruption

1

Efficacy

- uMRD
- PFS
- Treatment-free interval

2

Reduced risk in BTK and BCL2 mutations
Potential retreatment

3

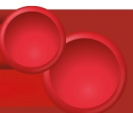
Reduced risk of long term toxicities

4

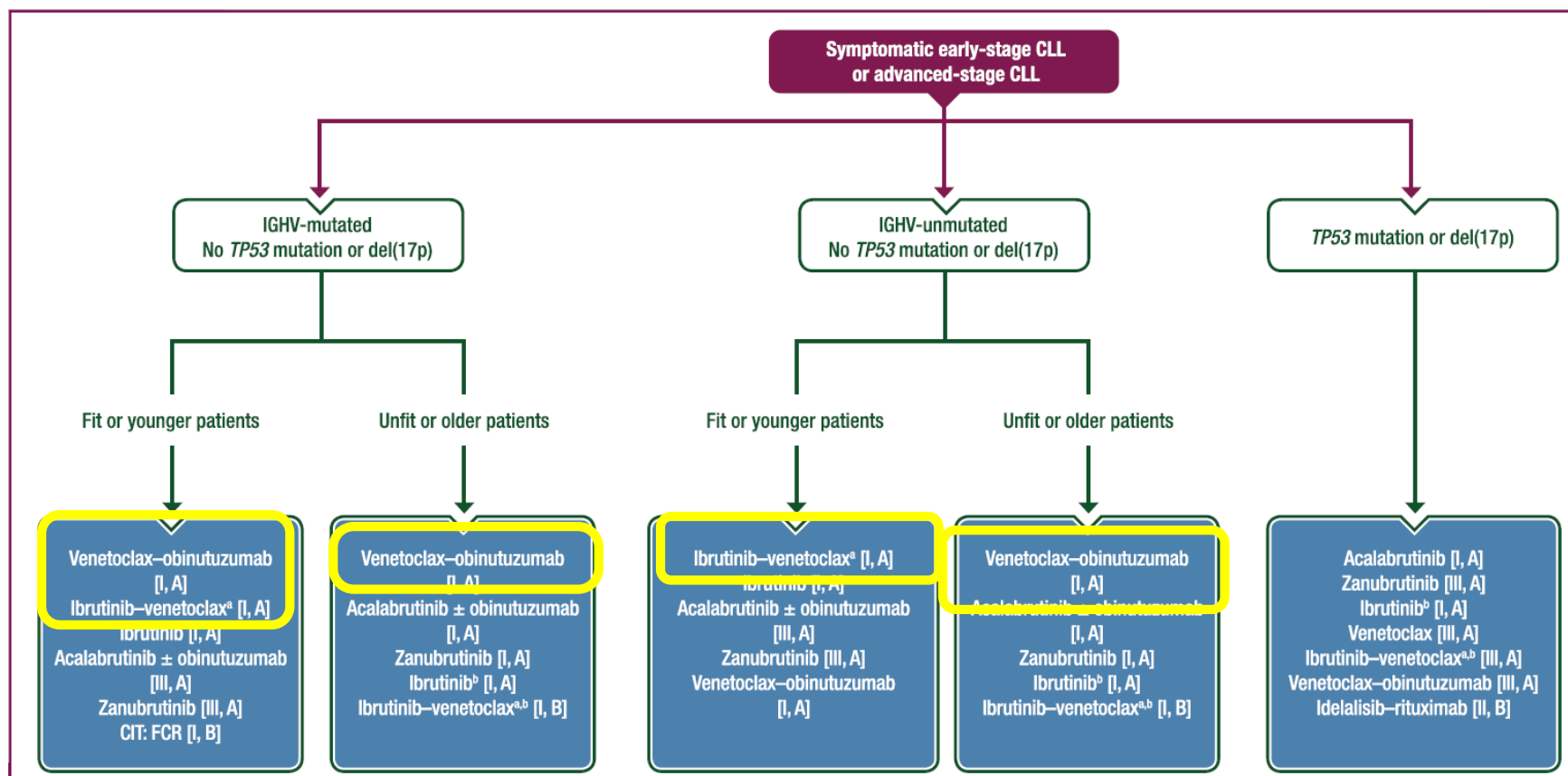
Reduced costs

5

Patient preference

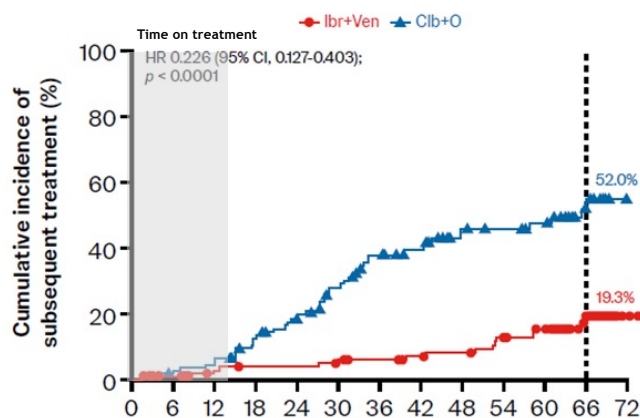


2024 ESMO Treatment guidelines: 1L treatment for CLL



1L Fixed-Duration treatment for CLL: TTNT

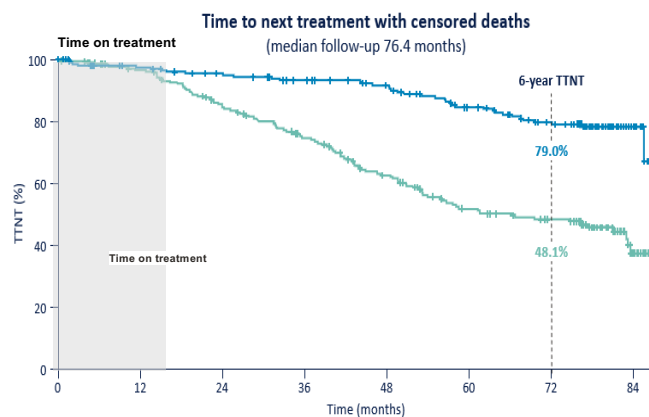
V+I - GLOW



5.5y TTNT
80,7%*

*calculated as 100 - 19,3

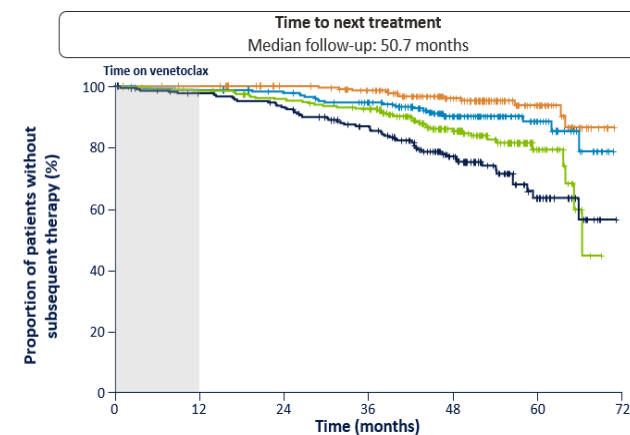
V+O - CLL14



6yTTNT
79,0%

Niemann et al. ASH 2024
Al-Sawaf O, et al. Blood 2024 Jul.
Fürstenau M, et al. Lancet Oncol 2024

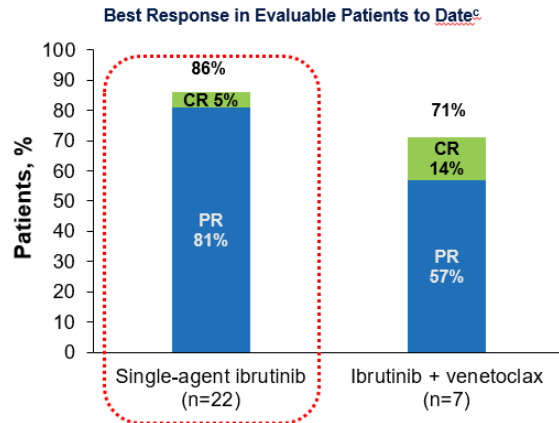
V+O - CLL13



4y TTNT
90,4%

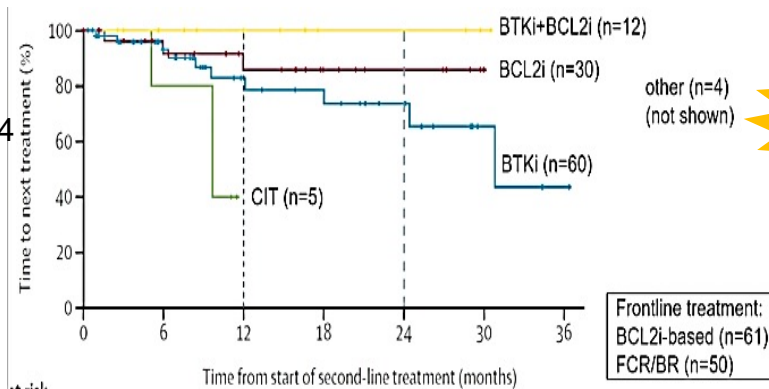
Retreatment

1L CAPTIVATE trial



Wierda et al.
ASCO. 2024

1L CLL13/GAIA trial



Fursteneau et al.
Lancet Oncol. 2024

2025
EHA

REVENGE trial

RETREATMENT WITH VenO IN PATIENTS WITH RECURRENT CLL

Eligibility Criteria	Treatment Cohorts	Endpoints
<ul style="list-style-type: none"> Relapsed CLL Completed 12 cycles of first line Ven-Obi and achieved a clinical response¹ Minimum of 1 year progression-free period after completing 1L Ven treatment PD by iwCLL criteria 	<p>COHORT 1 (n = 60)</p> <p>> 2 years between last dose of fixed duration Ven in 1L setting and PD</p> <p>Study Treatment 6 cycles Ven-Obi, then 6 cycles Ven monotherapy</p> <p>COHORT 2 (n = up to 15)</p> <p>1-2 years between last dose of fixed duration Ven in 1L setting and PD</p> <p>Study Treatment² 6 cycles Ven-Obi, then 18 cycles Ven monotherapy</p>	<p>Primary Endpoint ORR at EoCT (C6+3 months)</p> <p>Key Secondary Endpoints CR/CRi ORR at EoT DOR uMRD 10⁻⁴ PFS OS TTNT Safety</p>

.Cohort 1: at the EOCT (15 pts): ORR 100%, CR/CRi, 20%, uMRD, 85%

Dauids et al. EHA 2025, abstr.#575

AV IN CLL PATIENTS RELAPSING AFTER VEN+-ANTI CD20 HOVON 159/REVEAL trial

15 patients (prior VO, 47%; VR, 53%). Median time from prior TxT: 36 months
After cycle 26: ORR 100% (CR, 36%) with BM uMRD4: 21%
 Median follow-up: 30 mo all pts alive, 1 pt with DP.
 No events of TLS, bleeding, cardiac arrhythmia, or death.

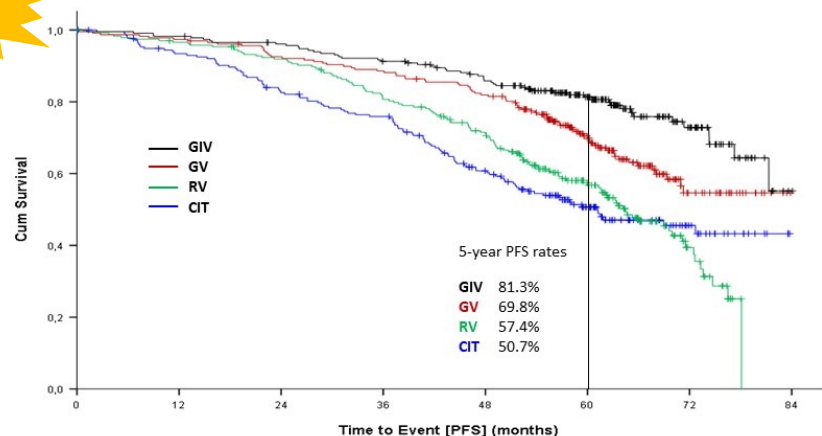
Kersting et al.. EHA 2025, abstr.#1563

2025
EHA

VENETOCLAX-IBRUTINIB-OBINUTUZUMAB PROLONGS PROGRESSION-FREE SURVIVAL COMPARED TO VENETOCLAX-CD20-ANTIBODY COMBINATIONS AND CIT IN TN CLL: FINAL ANALYSIS FROM THE PHASE 3 GAIA/CLL13 TRIAL

2025
EHA

Progression-free survival



Treatment comparisons

GIV vs CIT: HR 0.34, 97.5%CI: 0.24-0.50, *log-rank* $p < 0.001$
 GIV vs RV: HR 0.35, 97.5%CI: 0.24-0.51, *log-rank* $p < 0.001$
 GIV vs GV: HR 0.61, 97.5%CI: 0.41-0.91, *log-rank* $p = 0.0046$

GV vs RV: HR 0.59, 97.5%CI: 0.42-0.81, *log-rank* $p < 0.001$
 GV vs CIT: *log-rank* $p < 0.001$; proportional hazards assumption not satisfied
 RV vs CIT: *log-rank* $p = 0.53$; proportional hazards assumption not satisfied

GIV prolongs PFS compared to the widely used standard of GV (benefit likely driven by the difference in pts with unmutatedIGHV)

buttolerability, quality of life and OS have to be considered when comparing GIV and GV.

Patients at risk

	0	12	24	36	48	60	72	84
CIT	229	198	174	159	119	67	21	
RV	237	227	214	187	160	89	20	
GV	229	223	210	201	185	109	25	
GIV	231	227	219	207	189	126	44	

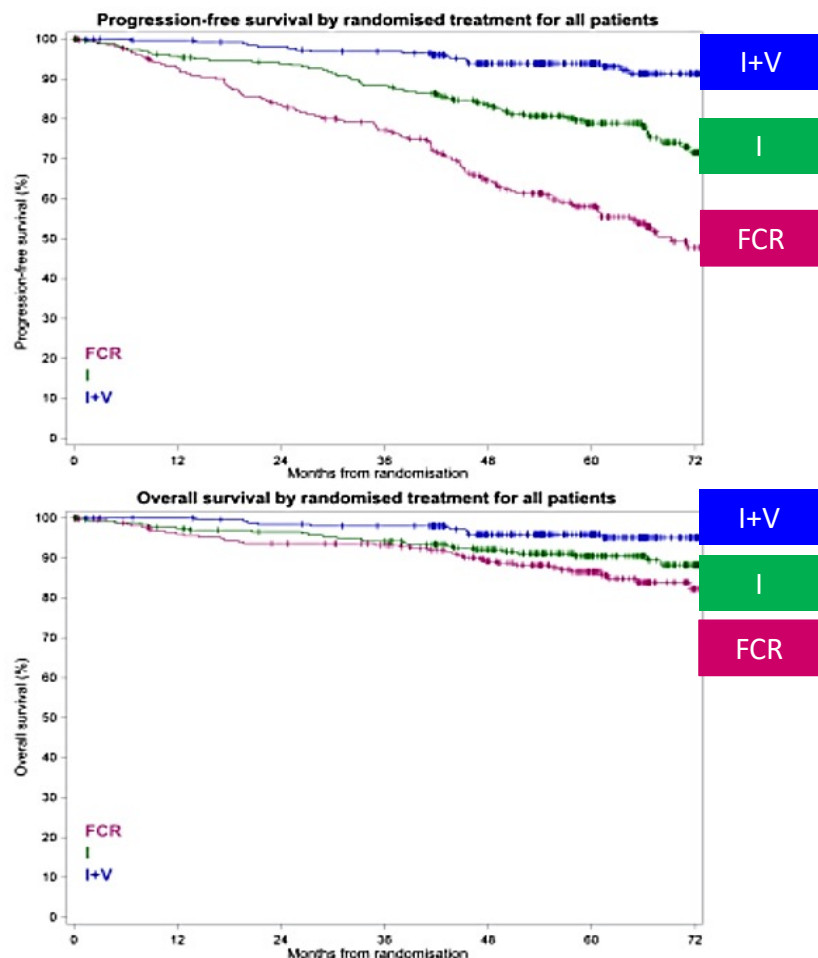
	% 5 yr-PFS			% 2L Txt
	All pts	U-IGHV	M-IGHV	
CIT	50.7	33.6	75.3	7.4
RV	57.4	48.3	71	12.5
GV	69.8	59	82.3	22.9
GIV	81	75.9	89.1	32.9

No difference in OS

IGHV independent prognostic factor for shorter PFS

Fürstenau et al., EHA 2025; S191

BRUTINIB PLUS VENETOCLAX WITH MRD-GUIDED DURATION OF TREATMENT IS SUPERIOR TO BOTH CONTINUOUS IBRUTINIB AND FCR FOR TN CLL: REPORT OF THE PHASE III UK FLAIR STUDY



	% pts with BM-uMRD at 9 mo	% 5yr PFS	% 5yr OS
I+V*	33.1	94.4	96
I	0	80.6	91.3
FCR	40.7	62.4	88.2

2025
EHA

- Rate of pts with uMRD increased over time
- 15 pts had sudden or cardiac deaths: 4 FCR, I, 8; I+V,3)

MRD stopping rules resulted in **44%** patients stopping at 2 years, **10%** at 3 years and **5%** at 4 years

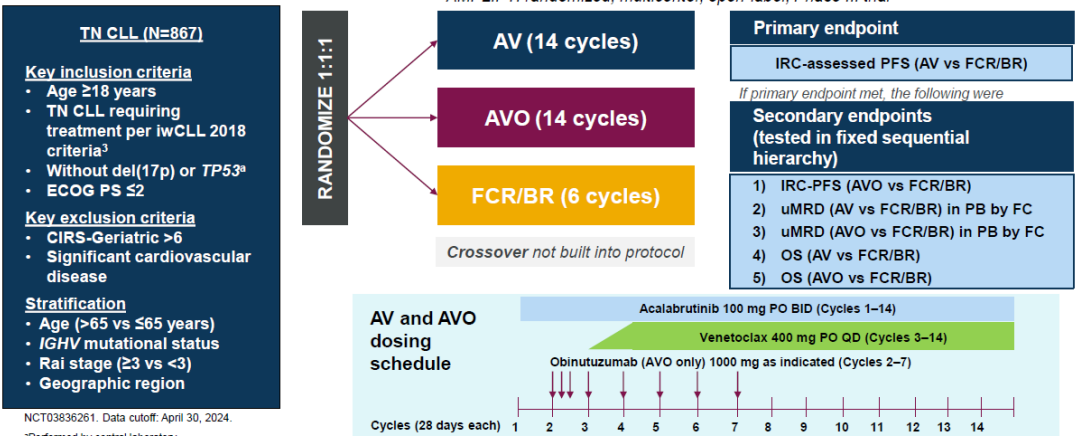
786 pts randomised to FCR, I, and I+V from 96 UK Centres

I+V significantly improved uMRD, PFS and OS rates compared to I monotherapy and FCR in untreated CLL.

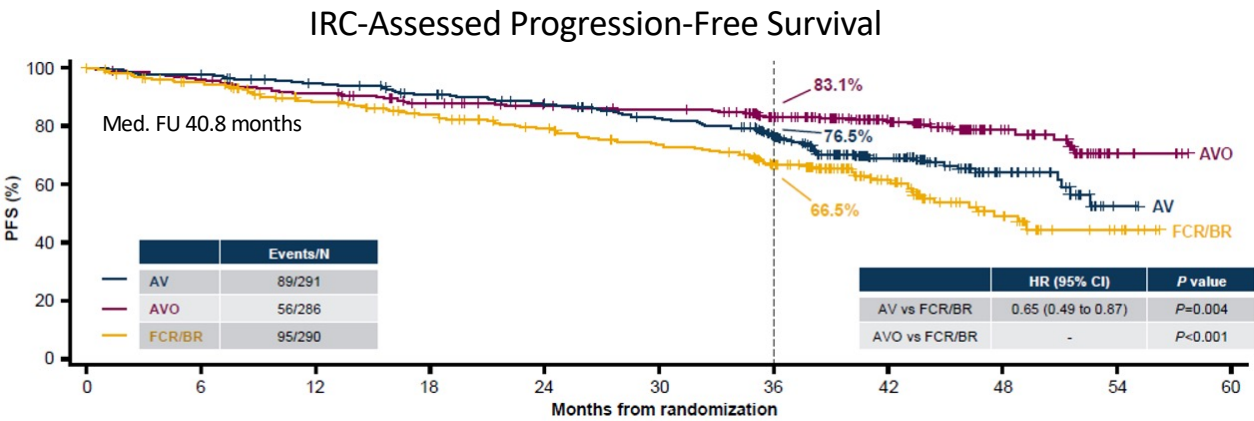
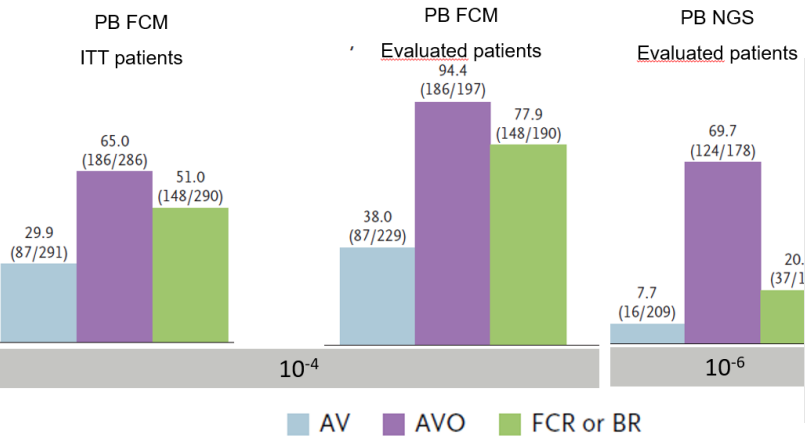
These results further substantiates the use of risk adapted approach in untreated CLL patients to optimise outcomes

Munir et al EHA 2025, abstr.155

AMPLIFY: 1L Fixed-Duration Acalabrutinib + Venetoclax ± Obinutuzumab vs CIT in CLL



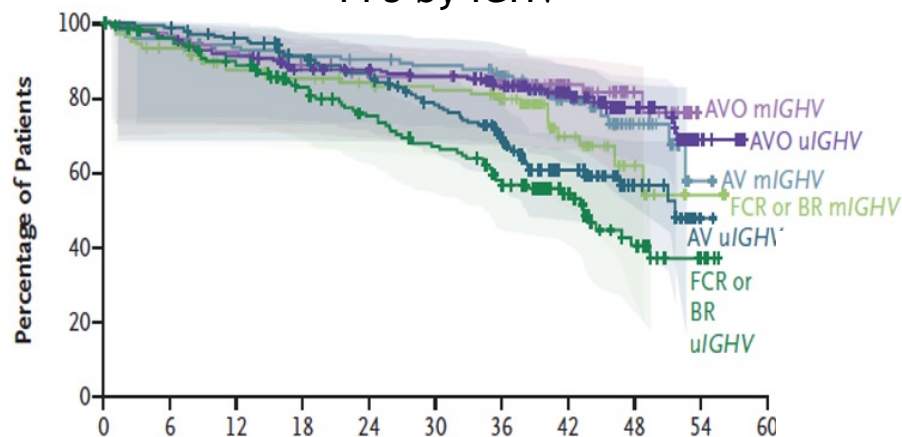
Characteristic	AV (n = 291)	AVO (n = 286)	FCR/BR (n = 290)
Median age, yr (range)	61 (31-84)	61 (29-81)	61 (26-86)
ECOG PS 2, n (%)	28 (9.6)	14 (4.9)	26 (9.0)
Rai stage			
▪ 0-II	154 (52.9)	170 (59.4)	163 (56.2)
▪ III-IV	137 (47.1)	116 (40.6)	127 (43.8)
del(11q) present	51 (17.5)	56 (19.6)	46 (15.9)
Unmutated IGHV	167 (57.4)	169 (59.1)	172 (59.3)



Brown et al., NEJM 2025

AMPLIFY: 1L Fixed-Duration Acalabrutinib + Venetoclax ± Obinutuzumab vs CIT in CLL

PFS by IGHV



Months since Randomization

	No. of Events/ Total No. of Patients	Median Progression- free Survival mo	Progression- free Survival at 36 Months %
AV mIGHV	28/124	NC	86.0
AV uIGHV	61/167	51.5	68.9
AVO mIGHV	20/117	NC	83.6
AVO uIGHV	36/169	NC	82.8
FCR or BR mIGHV	28/118	NC	79.9
FCR or BR uIGHV	67/172	43.3	56.8

AEs of Clinical Interest

AEs of Clinical Interest, n (%)	AV (n = 291)		AVO (n = 284)		FCR/BR (n = 259)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any	222 (76.3)	136 (46.7)	242 (85.2)	188 (66.2)	185 (71.4)	141 (54.4)
Cardiac events	27 (9.3)	5 (1.7)	34 (12.0)	7 (2.5)	9 (3.5)	3 (1.2)
▪ Atrial fibrillation	2 (0.7)	1 (0.3)	6 (2.1)	2 (0.7)	2 (0.8)	2 (0.8)
▪ Ventricular tachyarrhythmias	2 (0.7)	0	3 (1.1)	0	0	0
Hypertension	12 (4.1)	8 (2.7)	11 (3.9)	6 (2.1)	7 (2.7)	2 (0.8)
Hemorrhage	94 (32.3)	3 (1.0)	86 (30.3)	6 (2.1)	11 (4.2)	1 (0.4)
▪ Major hemorrhage	3 (1.0)	3 (1.0)	8 (2.8)	6 (2.1)	2 (0.8)	1 (0.4)
Neutropenia	108 (37.1)	94 (32.3)	143 (50.4)	131 (46.1)	132 (51.0)	112 (43.2)
Infections	148 (50.9)	36 (12.4)	153 (53.9)	67 (23.6)	82 (31.7)	26 (10.0)
Secondary primary malignancy	15 (5.2)	5 (1.7)	12 (4.2)	5 (1.8)	2 (0.8)	0
▪ Excluding nonmelanoma skin cancer	8 (2.7)	5 (1.7)	7 (2.5)	4 (1.4)	1 (0.4)	0
TLS	1 (0.3)	1 (0.3)	1 (0.4)	1 (0.4)	8 (3.1)	8 (3.1)

2025
EHA

Munir et al.
I+V vs A+V.
abstr. 587
[I+V>AV]

2025
EHA

Munir et al.
A+V vs. zanubrutinib.
abstr. 1581
[Zanu>AV]

2025
EHA

Woyach et al.
COVID-19 in AV-treated patients
abstr.

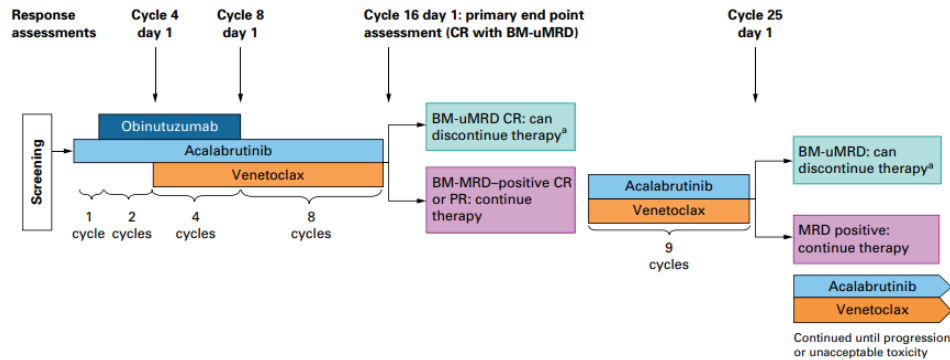
2025
EHA

Kersting et al. .
A+V in RR CLL
abstr. 1563

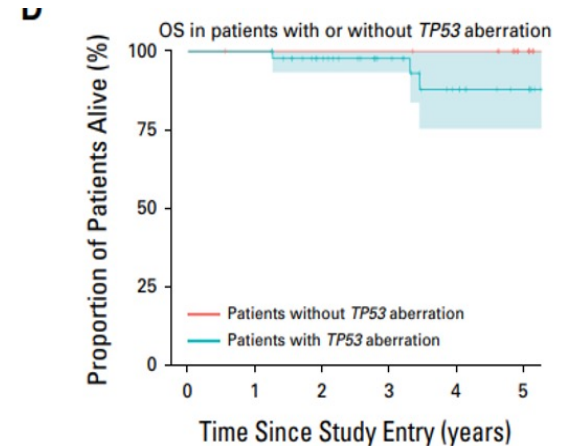
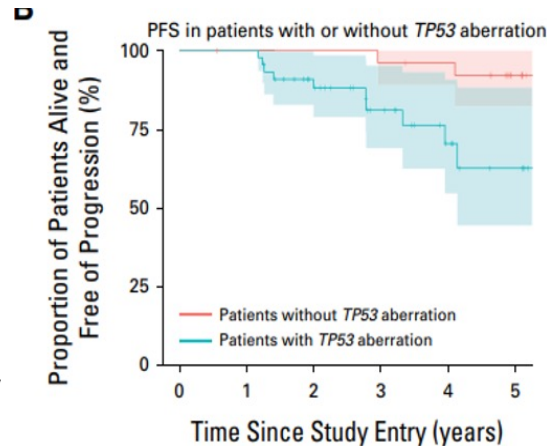
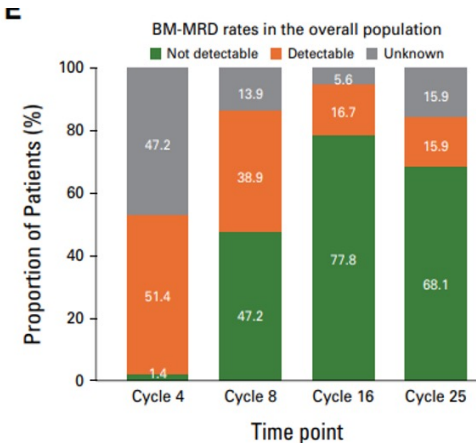
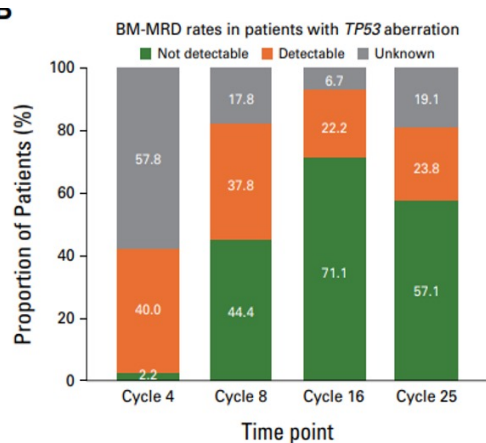
Brown et al., NEJM 2025

Acalabrutinib, Venetoclax, and Obinutuzumab in TN CLL patients with High-Risk Disease

TN patients with CLL enriched for high-risk CLL, defined by TP53 aberration



Characteristic	All Participants (N = 72)	TP53 Aberration (n = 45)
Age, years, median (range)	63 (36-80)	65 (36-80)
Cytogenetics		
TP53 aberration	45 (62.5)	45 (100.0)
Del(17p) with TP53 mutation	31 (43.1)	31 (68.9)
Del(17p) without TP53 mutation or TP53 unknown	3 (4.2)	3 (6.7)
TP53 mutation without del(17p) or del(17p) unknown	11 (15.3)	11 (24.4)
Del(13q)	33 (45.8)	19 (42.2)
Del(11q)	17 (23.6)	7 (15.6)
Trisomy 12	14 (19.4)	11 (24.4)
Del(6q)	4 (5.6)	2 (4.4)
IGHV status, unmutated	54 (75.0)	37 (82.2)
NOTCH1 mutation	12 (16.7)	8 (17.8)
SF3B1 mutation	13 (18.0)	11 (24.4)



Dauids et al. JCO 2025

Highlights in **EMATOLOGIA**

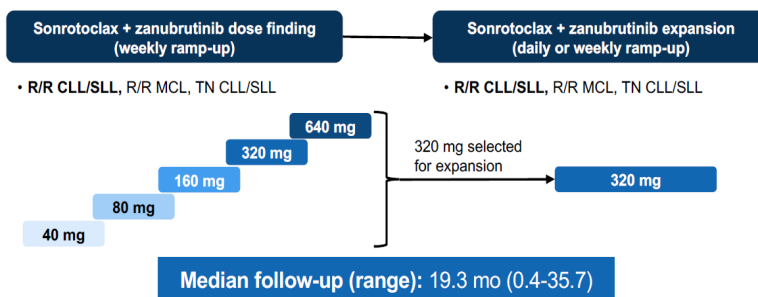
RENDE (CS)
23-24 MAGGIO 2025

Sonrotoclax and Zanubrutinib as 1L Treatment for CLL

Ongoing Phase 1/1b Study BGB-11417-101

Sonrotoclax: potent and selective BCL2 inhibitor with short half life (4 hours)

BCL2 Member Kinase	IC ₅₀ (nM)	
	Venetoclax	Sonrotoclax
BCL2	0.20 ± 0.015	0.014 ± 0.0021
BCL-xL	65 ± 9.1	28 ± 3.6
BCL-W	2730 ± 250	1803 ± 83
MCL1	>10000	>10000
BCL2A1	>10000	>10000

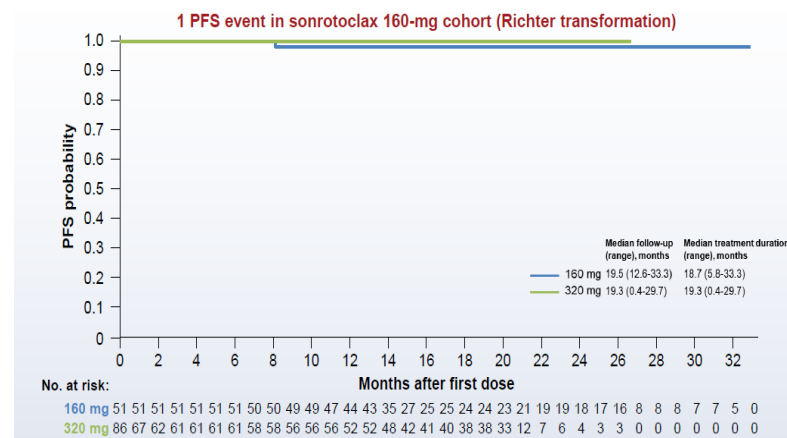
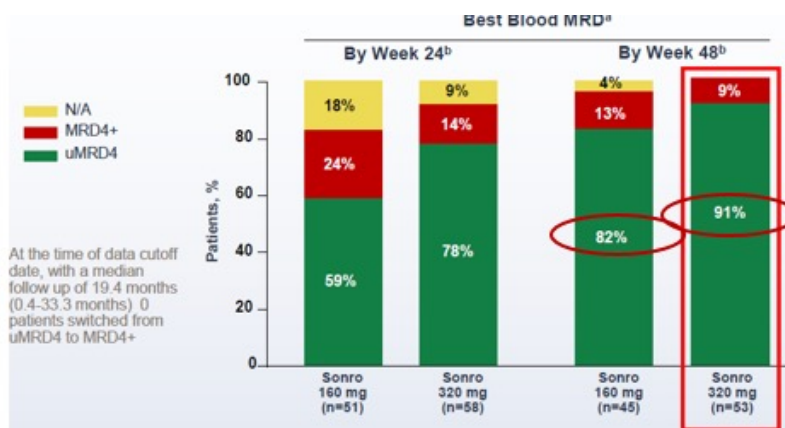


TN patients
zanubrutinib treatment
x 8-12 weeks

zanubrutinib combined with
sonrotoclax daily ramp-up to
160 mg or 320 mg

Characteristics	Sonro 160 mg + zanu (n=51)	Sonro 320 mg + zanu (n=86)	All Patients (N=137)
Study follow-up, median (range), months	19.5 (12.6-33.3)	19.3 (0.4-29.7)	19.4 (0.4-33.3)
Age, median (range), years	63 (38-82)	61 (32-84)	62 (32-84)
Risk status, n/tested (%)			
del(17p)	5/45 (11.1)	6/77 (7.8)	11/122 (9.0)
TP53 muta	11/47 (23.4)	13/62 (21.0)	24/109 (22.0)
del(11q)	10/45 (22.2)	11/77 (14.3)	21/122 (17.2)
IGHV status, n/tested (%)			
Unmutated IGHV	32/47 (68.1)	32/60 (53.3)	64/107 (59.8)
High tumor bulk ^a at baseline, n/tested (%)	22/51 (43.1)	17/82 (20.7)	39/133 (29.3)

Sonrotoclax		
	120 mg	320 mg
ORR	100%	
CR	41%	42%



No TLS
The most common grade ≥3 TEAE: neutropenia

2025
EHA

Sonrotoclax and zanubrutinib
in R/R patients with CLL
Cheah et al. . abst. S159

Soumerai et al. abstract #1012

Highlights in **EMATOLOGIA**

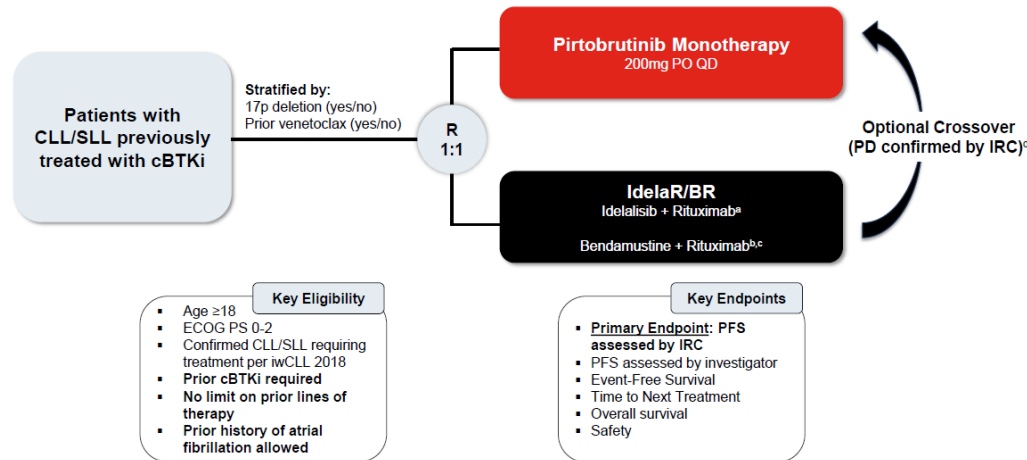
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BRUIN CLL-321: Randomized phase 3 Trial of Pirtobrutinib vs. Idelalisib + Rituximab or BR in BTK Inhibitor Pretreated CLL/SLL



Jaypirca as monotherapy is indicated for the treatment of adult patients with relapsed or refractory CLL who have been previously treated with a BTK inhibitor.

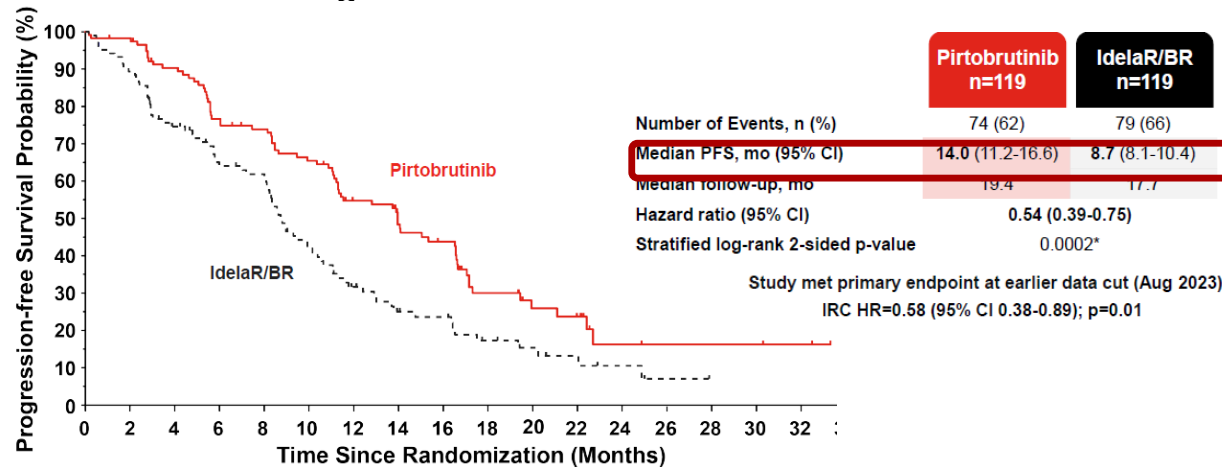
Jaypirca as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma who have been previously treated with a Bruton's tyrosine kinase (BTK) inhibitor.



Baseline Characteristics

Characteristic	Pirtobrutinib (n = 119)	IdelaR/BR (n = 119)
Median age, yr (range)	66 (42-90)	68 (42-85)
High-risk features, n/N (%)		
▪ 17p del and/or TP53 mut	51/94 (54)	53/98 (54)
▪ IGHV unmut	90/97 (93)	74/93 (80)
▪ Complex karyotype	53/74 (72)	44/75 (59)
BTK C481S, n/N (%)	37/99 (37)	36/94 (38)
PI3Cγ2, n/N (%)	15/99 (15)	11/94 (12)
Median lines prior systemic therapy, n (range)	3 (1-13)	3 (1-11)
Prior therapy, n (%)		
▪ cBTKi	119 (100)	119 (100)
▪ Ibrutinib	100 (84)	106 (89)
▪ Acalabrutinib	17 (14)	20 (17)
▪ Zanubrutinib	10 (8)	7 (6)
▪ Other	5 (4)	3 (3)
▪ ≥1 prior cBTKi	17 (14)	18 (15)
▪ BCL-2 inhibitor	60 (50)	62 (52)
▪ Chemotherapy	81 (68)	83 (70)

IRC-Assessed Progression-free Survival

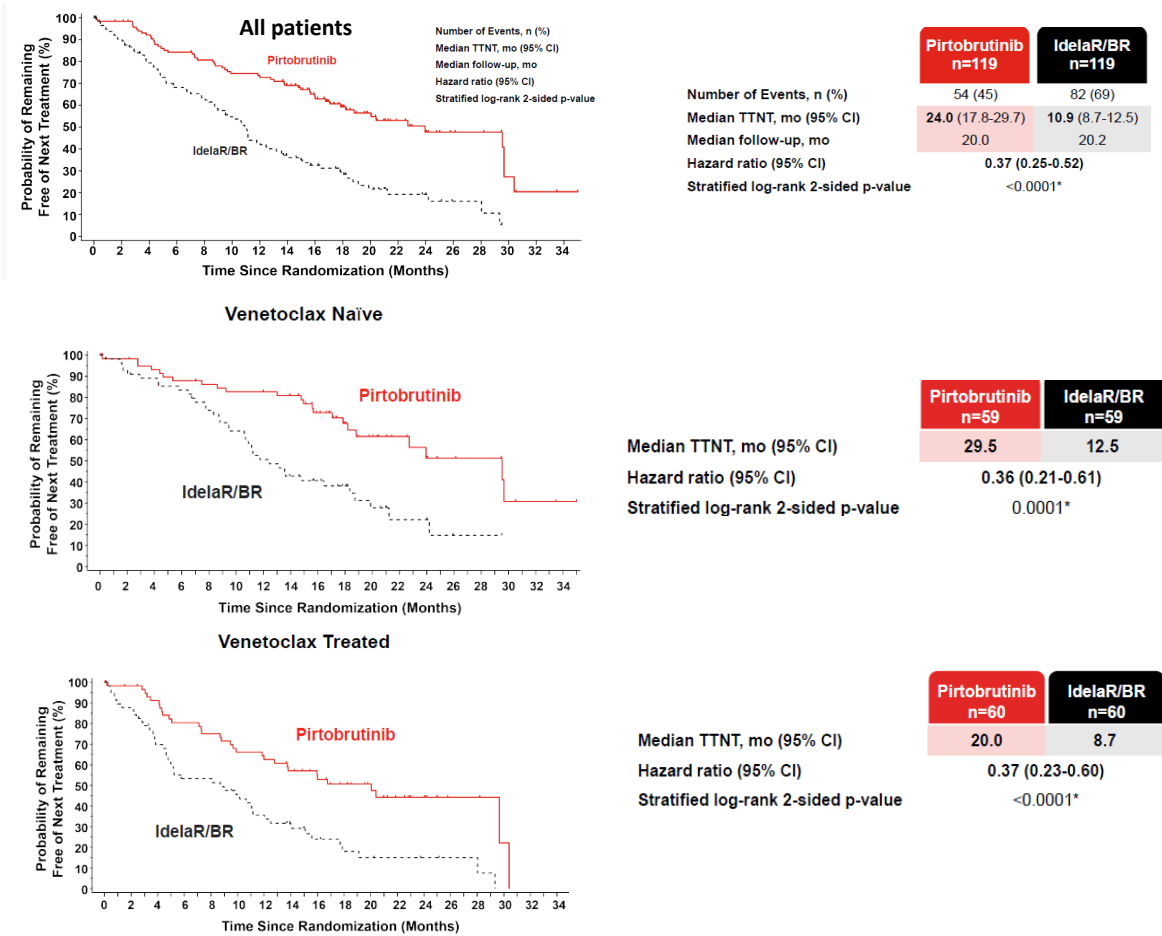


Benefit in PFS seen in patients across all key risk-factor

Sharman et al., 2024 ASH, abstract #886

BRUIN CLL-321: Randomized phase 3 Trial of Pirtobrutinib vs. Idelalisib + Rituximab or BR in BTK Inhibitor Pretreated CLL/SLL

Time to Next Treatment or Death

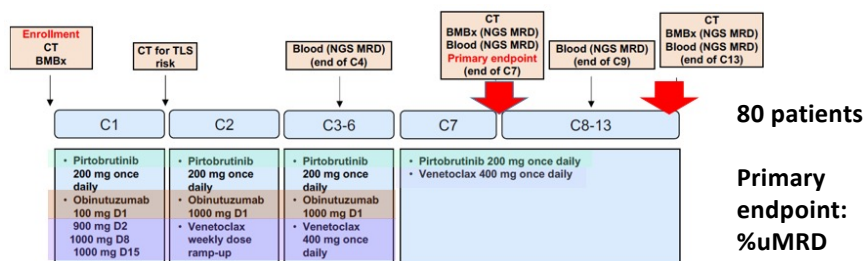


Adverse Events of Interest ^a (AEI)	Pirtobrutinib (n=116)	
	Any grade n (%)	Grade 3+ n (%)
Bleeding	25 (21.6)	4 (3.4)
Bruising	9 (7.8)	1 (0.9)
Petechiae and purpura	6 (5.2)	1 (0.9)
Hemorrhage	18 (15.5)	3 (2.6)
Anemia	24 (20.7)	13 (11.2)
Neutropenia	31 (26.7)	24 (20.7)
Thrombocytopenia	11 (9.5)	9 (7.8)
Infection	74 (63.8)	34 (29.3)
Infection without Covid-19	67 (57.8)	30 (25.9)
Atrial fibrillation and atrial flutter	3 (2.6) ^a	2 (1.7)
Hypertension	8 (6.9)	3 (2.6)

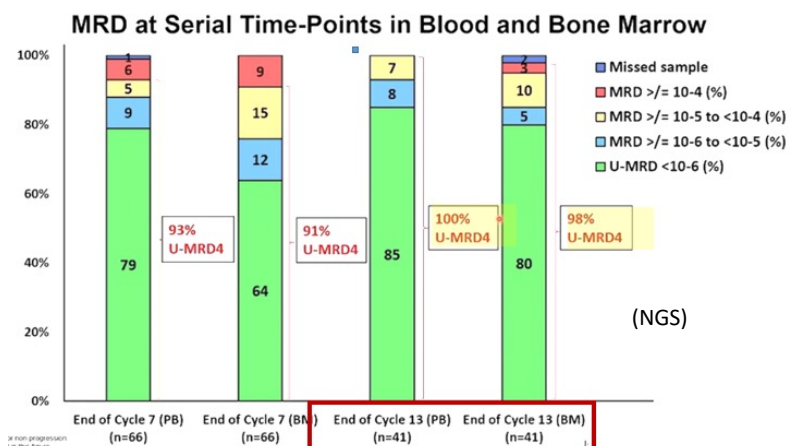
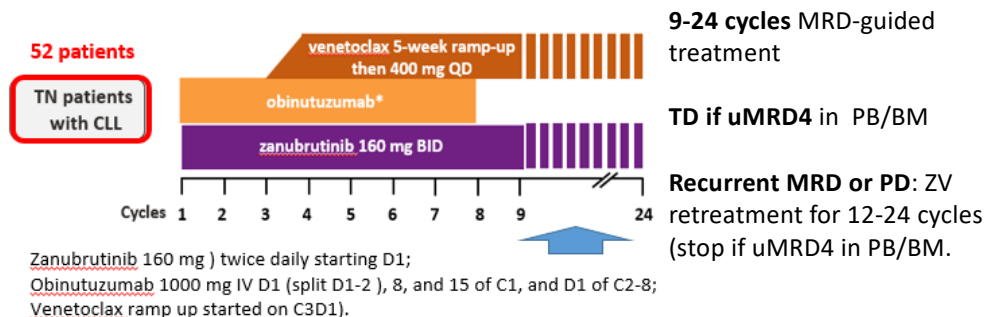
^a2 of 3 patients with atrial fibrillation had a past medical history of atrial fibrillation

Sharman et al., 2024 ASH, abstract #886

Pirtobrutinib, Venetoclax, and Obinutuzumab (PVO) In TN patients with CLL



Zanubrutinib, Obinutuzumab, and Venetoclax (BOVen) in TN patients with CLL

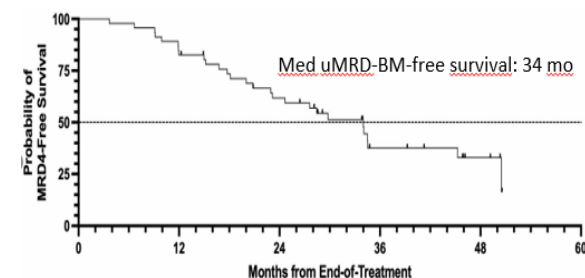


Higher 12m uMRD rate than I+V: 98% vs 52%
 With a median FU of 11.9m no patient has progressed

Best uMRD4 at EOT



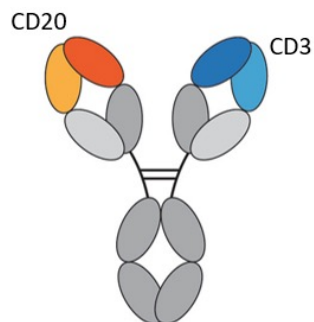
uMRD4BM -Free Survival



Jain et al., 2024 ASH, abstract #1867

Soumerai et al., 2024 ASH, abstract #1867

EPCORE CLL1 Expansion and Cycle 1 Optimization Cohorts

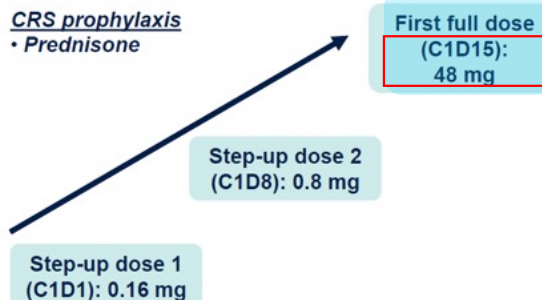


Key inclusion criteria

- CD20⁺ R/R CLL
- **≥2 prior lines of systemic therapy**
- ECOG PS 0–2
- Measurable disease with $\geq 5 \times 10^9/L$ B lymphocytes (expansion only)
- No prior allogeneic HSCT

Expansion (EXP; N=23)

CRS prophylaxis
• Prednisone

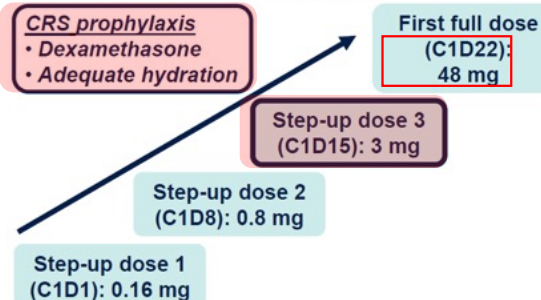


Data cutoff: May 28, 2024

Median follow-up: 22.8 months

Cycle 1 Optimization (C1 OPT; N=17)

CRS prophylaxis
• Dexamethasone
• Adequate hydration



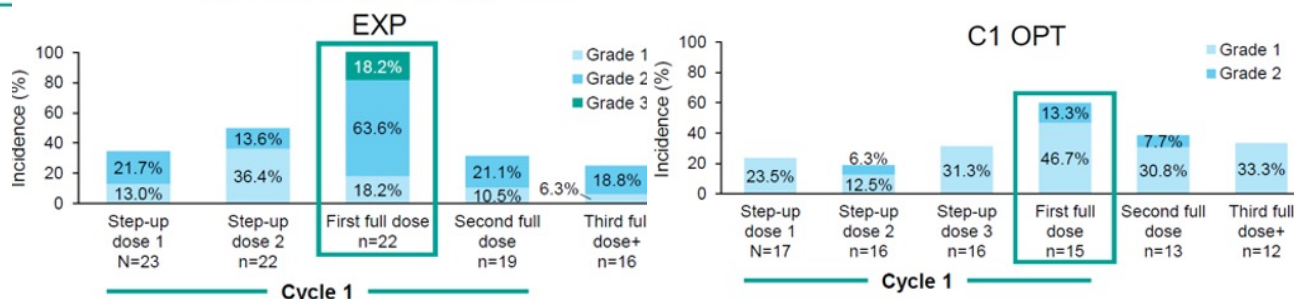
Data cutoff: May 28, 2024

Median follow-up: 2.9 months

Response, n (%)	EXP mFU: 22.8 months					C1 OPT mFU: 2.9 months
	Full Analysis Set N=23	Response Evaluable n=21	TP53 Aberration n=15	IGHV Unmutated n=16	Double Exposed ^a n=19	Response Evaluable n=10
Overall response ^b	14 (61)	14 (67)	10 (67)	10 (63)	10 (53)	6 (60)
Complete response	9 (39)	9 (43)	5 (33)	7 (44)	7 (37)	1 (10)

EXP MRD Negativity, n/n (%) ^c	uMRD ^d	uMRD ^d
Overall response ^b	9/12 (75)	8/12 (67)
Complete response	7/7 (100)	6/7 (86)
Partial response	2/5 (40)	2/5 (40)
Full analysis set	9/23 (39)	8/23 (35)

CRS Events by Dosing Period



Danilov et al., 2024 ASH, abstract #883

Highlights in **EMATOLOGIA**

RENDE (CS)
23-24 MAGGIO 2025

Efficacy and Safety of the BTK Degraders in patients with R/R CLL

BTK Degradar **NX-5948** in 60 Patients with R/R CLL

(Phase 1 NX-5948 Study)

Shah et al., 2024 ASH, abstr. #885

N= 60 patients

Med prior Txt=4
BTK/PLCG2/BCL2 mutated ~50%

ORR at 16 weeks: 84.2%

CR: 0%

Response duration
>6months: 26.5%

BTK Degradar **BGB-16673** in Patients with R/R CLL/SLL.

(Phase 1 CaDAnCe-101 Study)

Thompson et al., 2024 ASH, abstr. #885
Scarfò et al. EHA 2025, abstr. #158

N=66 patients

Med prior Txt=4
BTK/PLCG2 mutated ~48%

TP53 aberr.: 65%
Triple exposed:58%

ORR: 80.3% - CR: 2%

- at 200 mg): 94%
- triple exposed pts:75%
- BTK mutated: 70.8%
- TP53 disrupted:76.7%

Med. FU: 13 mo.
Med PFS: NR

2025
EHA

Transcend CLL 004 Study

Lisocabtagene Maraleucel Combined with Ibrutinib for Patients with R/R CLL)/SLL

Eligibility criteria

- 1) receiving BTKi with PD at entry
- 2) HR-disease and < CR after ≥ 6 mo on BTKi
- 3) *BTK/PLC2* mutation ± ibr PD
- 4) prior BTKi with no contraindications to ibr
- 5) PD on BTKi and received prior venetoclax.

Lymphodepletion

**Fludarabine 30 mg/m² +
Cyclophosphamide 300 mg/m²
x 3 days**

Dose Escalation

**Liso-cel DL1 or DL2 +
Ibrutinib 420 mg**

Liso-cel
(2-7 d after FLU/CY)
DL1: 50 × 10⁶ CAR T cells
DL2: 100 × 10⁶ CAR T cells

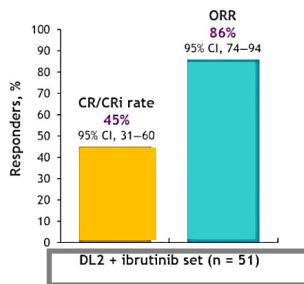
Dose Expansion

**Liso-cel DL2 +
Ibrutinib 420 mg**

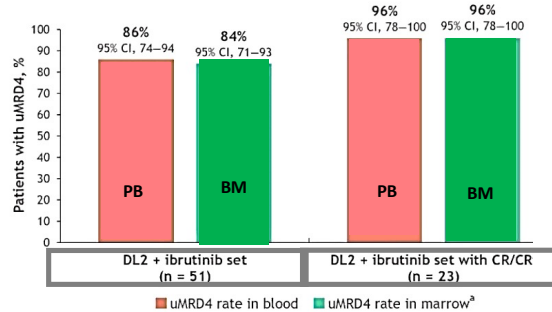
56 received ibr + liso-cel
(DL1, n = 5; DL2, n = 51)

**24 mos follow-up on study
and long-term follow-up up to 15 yrs**

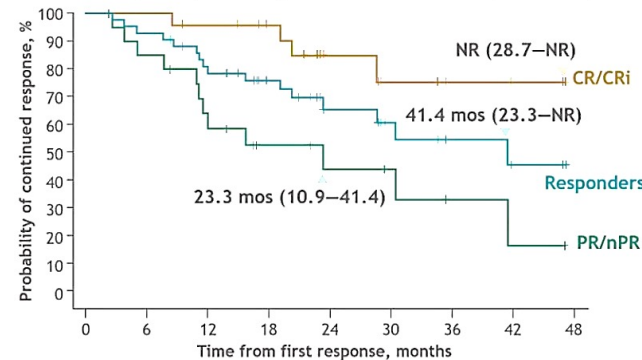
Response by INV



uMRD4



Duration of response



Safety

No TAES-related mortality
CRS 80% (Gr ≥3: 4%)
NE: 41% (Gr ≥3: 11%).

Gr3 HTN: 7% ; AF: 2%

Prolonged cytopenias:45%

Median (IQR) on-study follow-up (including LTFU): 24.8 months (14.2–34.6)
Median (range) time to first response: 1 month (0.9–6.0)
Median (range) time to first CR/CRi: 3 months (0.9–12.1)
Liso-cel showed rapid expansion (median t_{max} 10 d) and was detected up to 42 mo after infusion.

Liso-cel + IBR: higher ORR/CR rate and lower gr ≥ 3 CRS/NE rates vs liso-cel monotherapy

Wierda et al. ASH 2024. Abstract #887.

Highlights in **EMATOLOGIA**

RENDE (CS)
23-24 MAGGIO 2025

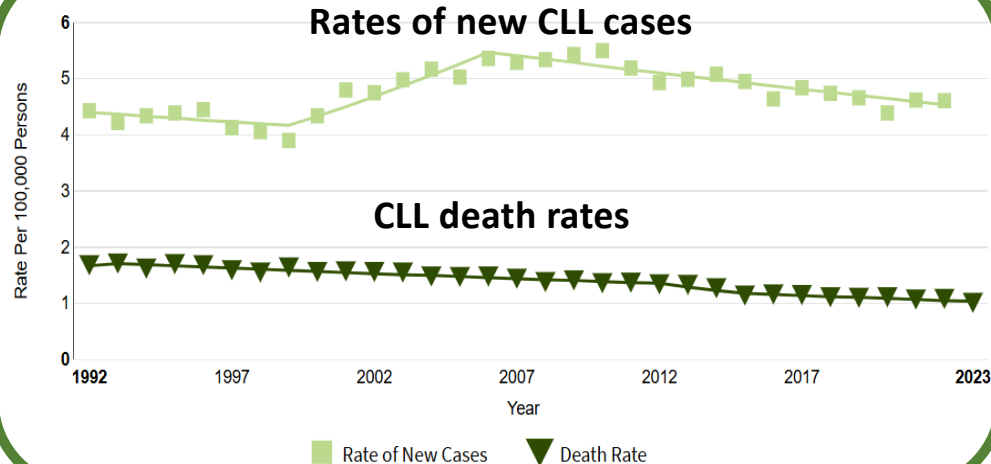
Cancer Stat Facts: Leukemia — Chronic Lymphocytic Leukemia (CLL)



NATIONAL CANCER INSTITUTE

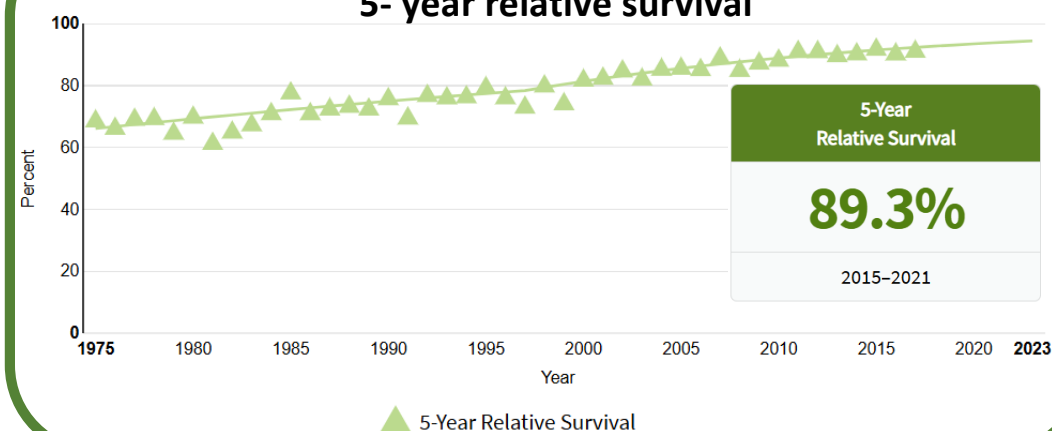
Surveillance, Epidemiology, and End Results Program

Rates of new CLL cases



Approximately 0.6 percent of men and women will be diagnosed with CLL at some point during their lifetime, based on 2018–2021 data, excluding 2020 due to COVID.

5- year relative survival



Age-adjusted death rates have been falling on average 1.9% each year over 2014–2023.