Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

KML-Experten berichten

EHA2021 VIRTUAL

Kompetenznetz Maligne Lymphome

Lymphom Kompetenz KOMPAKT

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Klinik für Innere Medizin | Universitätsklinikum des Saarlandes

Chronische lymphatische Leukämie (CLL)

Offenlegung potentieller Interessenskonflikte

LymphomKompetenz KOMPAKT – EHA2021 wird in Kooperation mit sechs unterstützenden Firmen durchgeführt.
Meine persönlichen Disclosures betreffen:

Anstellungsverhältnis, Führungsposition	-
Beratungs-/ Gutachtertätigkeit	AbbVie, Amgen, AstraZeneca, Celgene, Gilead, GSK, Hoffmann-La Roche, Janssen, Novartis, Sunesis
Besitz von Geschäftsanteilen, Aktien oder Fonds	-
Patent, Urheberrecht, Verkaufslizenz	-
Honorare	AbbVie, Amgen, AstraZeneca, Celgene, Gilead, GSK, Hoffmann-La Roche, Janssen, Novartis, Sunesis
Finanzierung wissenschaftlicher Untersuchungen	AbbVie, Amgen, AstraZeneca, Celgene, Gilead, GSK, Hoffmann-La Roche, Janssen, Novartis, Sunesis
Andere finanzielle Beziehungen	-
Immaterielle Interessenkonflikte	-

ELEVATE-RR Trial:

First Results of a Head-to-Head Trial of Acalabrutinib versus Ibrutinib in Previously Treated Chronic Lymphocytic Leukemia

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Hillmen *et al.* ELEVATE-RR, S145, EHA 2021.

ELEVATE-RR: Phase 3 Randomized Non-inferiority Open-Label Trial

Patients (N=533)

Key Inclusion Criteria

- Adults with previously treated CLL requiring therapy (iwCLL 2008 criteria[1])
- Presence of del(17p) or del(11q)[a]
- ECOG PS of ≤2

Stratification

- del(17p) status (yes or no)
- ECOG PS (2 vs ≤1)
- No. prior therapies (1–3 vs ≥4)

RANDOMIZE 1:1

- **Acalabrutinib[b] 100 mg PO BID**
- **Ibrutinib[b] 420 mg PO QD**

Primary endpoint

- Non-inferiority on IRC-assessed PFS[c]

Secondary endpoints (hierarchical order):

- Incidence of any grade atrial fibrillation/flutter
- Incidence of grade ≥3 infection
- Incidence of Richter transformation
- Overall survival

Key exclusion criteria: Significant CV disease; concomitant treatment with warfarin or equivalent vitamin K antagonist; prior treatment with ibrutinib, a BCR inhibitor, (eg, BTK , PI3K, or Syk inhibitors) or a BCL-2 inhibitor (eg, venetoclax)

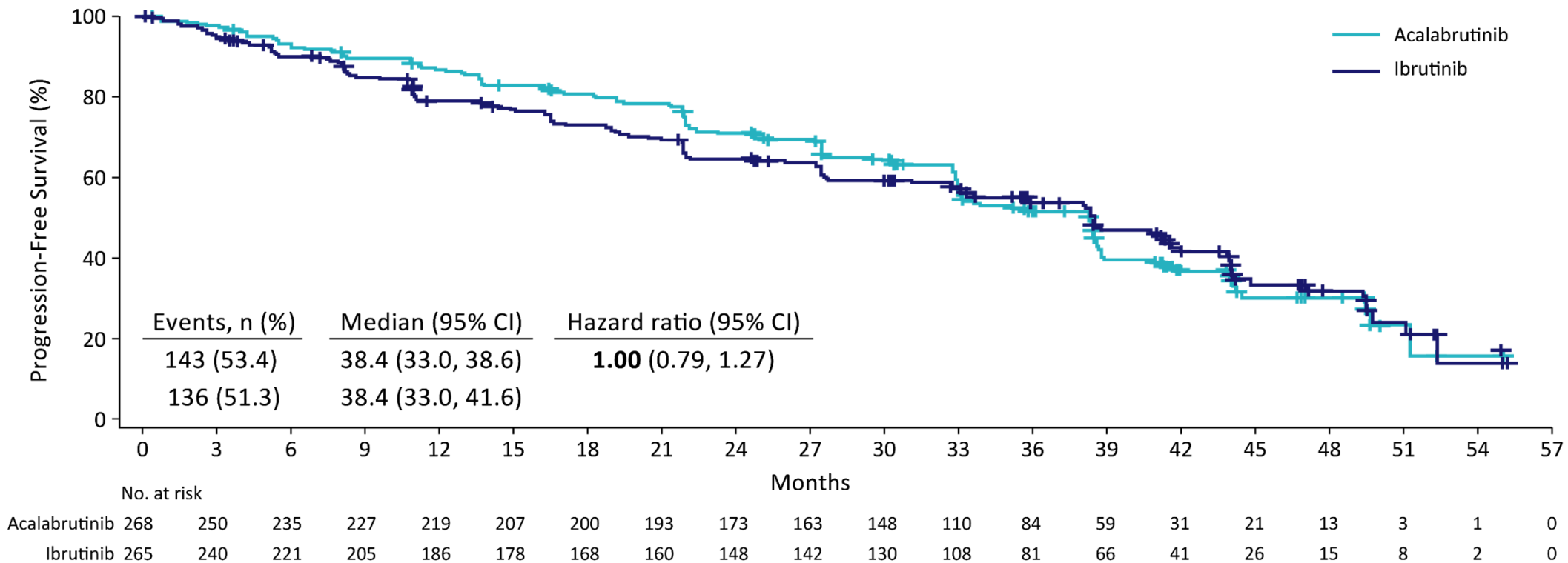
NCT02477696 (ACE-CL-006).

[a]By central laboratory testing; [b]continued until disease progression or unacceptable toxicity; [c]conducted after enrollment completion and accrual of ~250 IRC-assessed PFS events.

Afib/flutter, atrial fibrillation/flutter; BCL-2, B-cell leukemia/lymphoma-2; BCR, B-cell receptor; BID, twice daily; BTK, Bruton tyrosine kinase; CLL, chronic lymphocytic leukemia; CV, cardiovascular; ECOG PS, Eastern Cooperative Oncology Group performance status; IRC, independent review committee; iwCLL, International Workshop on CLL; PFS, progression-free survival; PI3K, phosphatidylinositol 3-kinase; PO, orally; QD, once daily.

1. Hallek M, et al. *Blood*. 2008;111:5446-56.

Primary Endpoint: Non-inferiority Met on IRC-Assessed PFS



Median follow-up: 40.9 months (range, 0.0–59.1).

CI, confidence interval; IRC, independent review committee; PFS, progression-free survival.

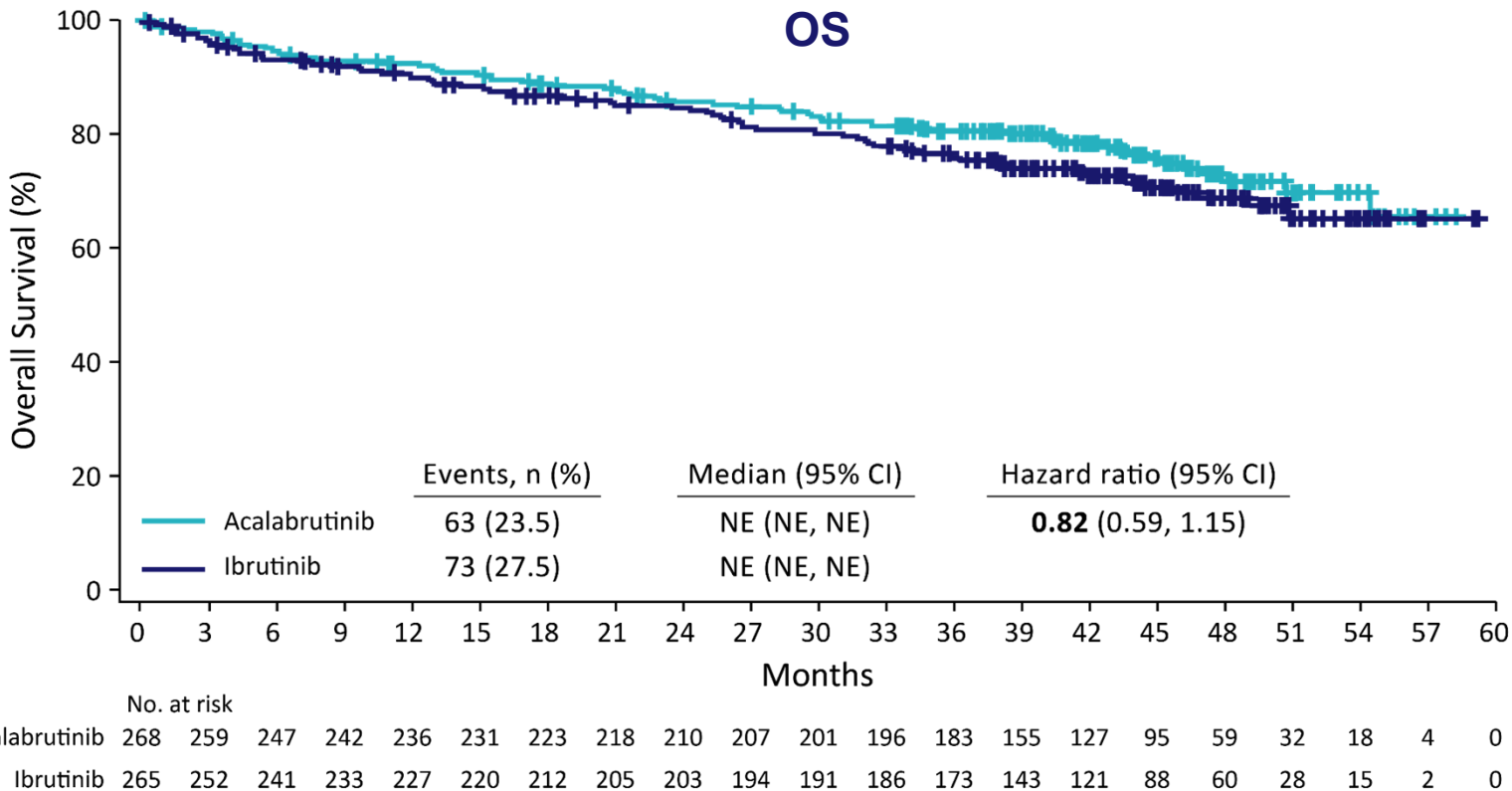
Adverse Events of Clinical Interest

Events, n (%)	Any grade		Grade ≥3	
	Acalabrutinib (n=266)	Ibrutinib (n=263)	Acalabrutinib (n=266)	Ibrutinib (n=263)
Cardiac events	64 (24.1)	79 (30.0)	23 (8.6)	25 (9.5)
Atrial fibrillation[a]*	25 (9.4)	**42 (16.0)**	13 (4.9)	10 (3.8)
Ventricular arrhythmias[b]	0	3 (1.1)	0	1 (0.4)
Bleeding events*	101 (38.0)	**135 (51.3)**	10 (3.8)	12 (4.6)
Major bleeding events[c]	12 (4.5)	14 (5.3)	10 (3.8)	12 (4.6)
Hypertension[d]*	25 (9.4)	**61 (23.2)**	11 (4.1)	**24 (9.1)**
Infections[e]	208 (78.2)	214 (81.4)	82 (30.8)	79 (30.0)
ILD/pneumonitis*	7 (2.6)	**17 (6.5)**	1 (0.4)	2 (0.8)
SPMs excluding NMSC	24 (9.0)	20 (7.6)	16 (6.0)	14 (5.3)

Higher incidence indicated in **bold red** for terms with statistical differences.
*Two-sided P-value for event comparisons <0.05 without multiplicity adjustment.
[a]Includes events with preferred terms atrial fibrillation and atrial flutter.
[b]Includes events with preferred terms torsade de pointes, ventricular arrhythmia, ventricular extrasystoles, ventricular fibrillation, ventricular flutter, ventricular tachyarrhythmia, and ventricular tachycardia.
[c]Defined as any hemorrhagic event that was serious, grade ≥3 in severity, or a central nervous system hemorrhage (any severity grade).
[d]Included events with the preferred terms of hypertension, blood pressure increased, and blood pressure systolic increased.
[e]Most common grade ≥3 infections were pneumonia (acalabrutinib, 10.5%; ibrutinib, 8.7%), sepsis (1.5% vs 2.7%, respectively), and UTI (1.1% vs 2.3%).
ILD, interstitial lung disease; NMSC, nonmelanoma skin cancer; SPMs, second primary malignancies; UTI, urinary tract infection.

Additional Secondary Endpoints: Gr≥3 Infection, Richter's Transformation, Overall Survival

- Comparable incidence of Gr≥3 infection (*P*=0.8777):
  - Acalabrutinib: n=82 (30.8%)
  - Ibrutinib: n=79 (30.0%)
- Comparable incidence of RT:
  - Acalabrutinib: n=10 (3.8%)
  - Ibrutinib: n=13 (4.9%)



CI, confidence interval; Gr, grade; HR, hazard ratio; OS, overall survival; RT, Richter transformation.

ALPINE TRIAL:
FIRST INTERIM ANALYSIS OF ALPINE STUDY: RESULTS OF A PHASE 3 RANDOMIZED STUDY OF ZANUBRUTINIB VS IBRUTINIB IN PATIENTS WITH RELAPSED/REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA/ SMALL LYMPHOCYTIC LYMPHOMA

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Hillmen *et al.* ALPINE; LB1900, EHA 2021.

ALPINE: Phase 3, Randomized Study of Zanubrutinib vs Ibrutinib in Patients With Relapsed/Refractory CLL or SLL

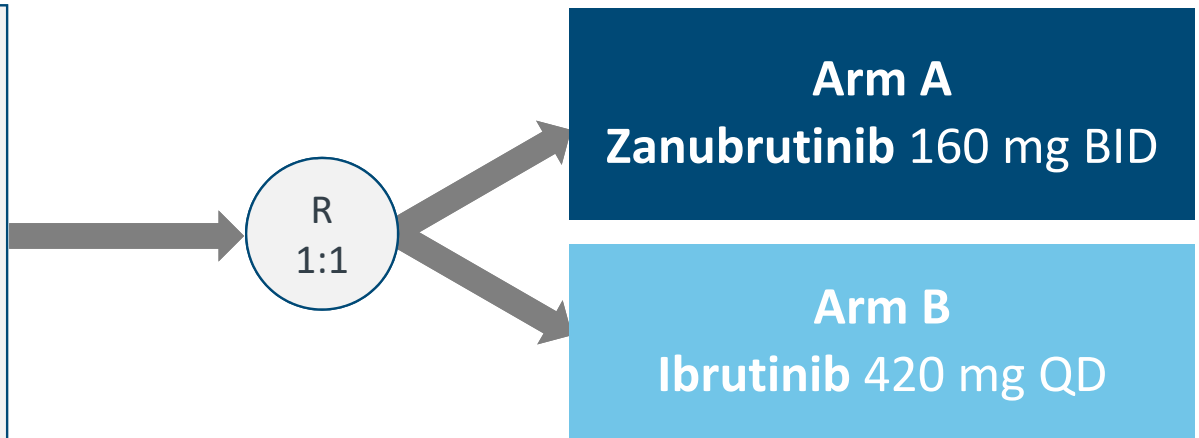
R/R CLL/SLL with ≥ 1 prior treatment
(Planned N=600, Actual N=652)

Key Inclusion Criteria

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

Key Exclusion Criteria

- Current or past Richter's transformation
- Prior BTK inhibitor therapy
- Treatment with warfarin or other vitamin K antagonists



Stratification Factors

- Age
- Geographic region
- Refractory status
- Del(17p)/*TP53* mutation status

Primary endpoint

- PR+CR noninferiority and superiority investigator assessed

Secondary endpoints:

- safety
- DOR, PFS, OS

BID, twice daily; BTK, Bruton tyrosine kinase CLL, chronic lymphocytic leukemia; CT, computed tomography; MRI, magnetic resonance imaging; QD, once daily; R, randomized; R/R, relapsed/refractory; SLL, small lymphocytic lymphoma.

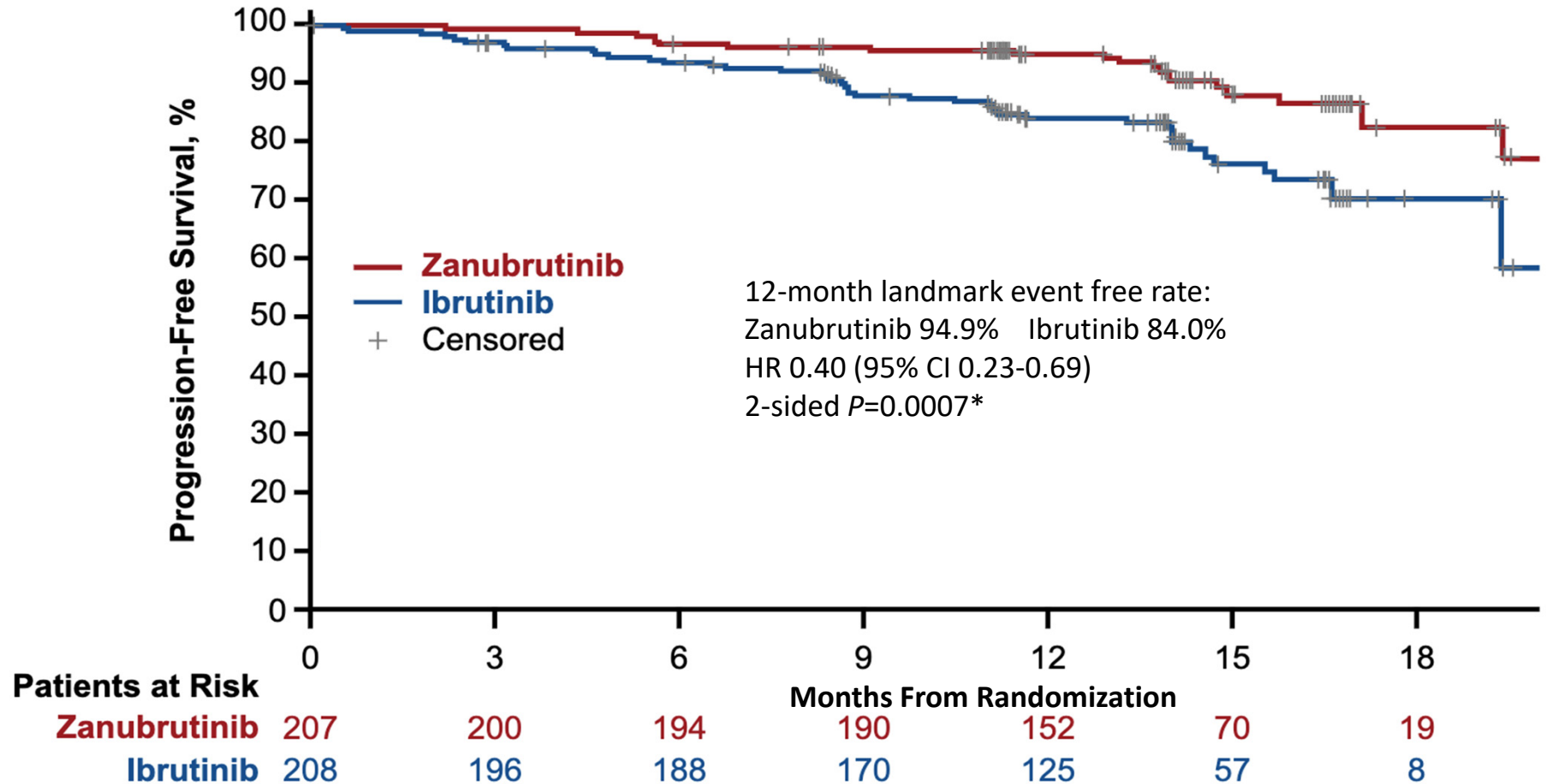
ORR by Investigator Assessment

	Zanubrutinib (n=207), n (%)	Ibrutinib (n=208), n (%)
Primary endpoint: ORR (PR+CR)	162 (**78.3**) 95% CI: 72.0, 83.7	130 (**62.5**) 95% CI: 55.5, 69.1
	Superiority 2-sided *P*=0.0006 compared with pre-specified alpha of 0.0099	
CR/CRi	4 (1.9)	3 (1.4)
nPR	1 (0.5)	0
PR	157 (75.8)	127 (61.1)
ORR (PR-L+PR+CR)	*183 (88.4)*	*169 (81.3)*
PR-L	21 (10.1)	39 (18.8)
SD	17 (8.2)	28 (13.5)
PD	1 (0.5)	2 (1.0)
Discontinued or new therapy prior to 1st assessment	6 (2.9)	9 (4.3)

	del(17p) (n=24), n (%)	del(17p) (n=26), n (%)
ORR (PR+CR)	20 (83.3)	14 (53.8)

CR, complete response; CRi, complete response with incomplete bone marrow recovery; D/C, discontinuation; DOR, duration of response; NE, not evaluable; nPR, nodular partial response; ORR, overall response rate; PR, partial response; PR-L, partial response with lymphocytosis; SD, stable disease.

PFS by Investigator Assessment



*Not a prespecified analysis; formal analysis of PFS will be based on all patients when the target number of events are reached.
Median PFS follow-up was 14.0 months for both zanubrutinib and ibrutinib arms by reverse KM method.
PFS, progression-free survival.

AEs of Special Interest

Safety Analysis Population	Zanubrutinib (n=204), n (%)		Ibrutinib (n=207), n (%)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Cardiac disorders[a]	28 (13.7)	5 (2.5)	52 (25.1)	14 (6.8)
Atrial fibrillation and flutter (key 2º endpoint)	**5 (2.5)**	**2 (1.0)**	**21 (10.1)**	**4 (1.9)**
Hemorrhage Major hemorrhage[b]	73 (35.8) 6 (2.9)	6 (2.9) 6 (2.9)	75 (36.2) 8 (3.9)	6 (2.9) 6 (2.9)
Hypertension	34 (16.7)	22 (10.8)	34 (16.4)	22 (10.6)
Infections	122 (59.8)	26 (12.7)	131 (63.3)	37 (17.9)
Neutropenia[c]	58 (28.4)	38 (18.6)	45 (21.7)	31 (15.0)
Thrombocytopenia[c]	19 (9.3)	7 (3.4)	26 (12.6)	7 (3.4)
Secondary primary malignancies Skin cancers	17 (8.3) 7 (3.4)	10 (4.9) 3 (1.5)	13 (6.3) 10 (4.8)	4 (1.9) 2 (1.0)

AE, adverse events. All events are of any grade unless otherwise specified.
[a] Cardiac disorders leading to treatment discontinuation: zanubrutinib 0 patients and ibrutinib 7 (3.4%) patients.
[b] Includes hemorrhages that were serious or grade ≥3 or CNS hemorrhages of all grades.
[c] Pooled terms including neutropenia, neutrophil count decreased, and febrile neutropenia; thrombocytopenia and platelet count decreased.

GLOW TRIAL: FIXED-DURATION IBRUTINIB PLUS VENETOCLAX (I+V) VERSUS CHLORAMBUCIL PLUS OBINUTUZUMAB (CLB+O) FOR FIRST-LINE TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): PRIMARY ANALYSIS OF THE PHASE 3 GLOW STUDY

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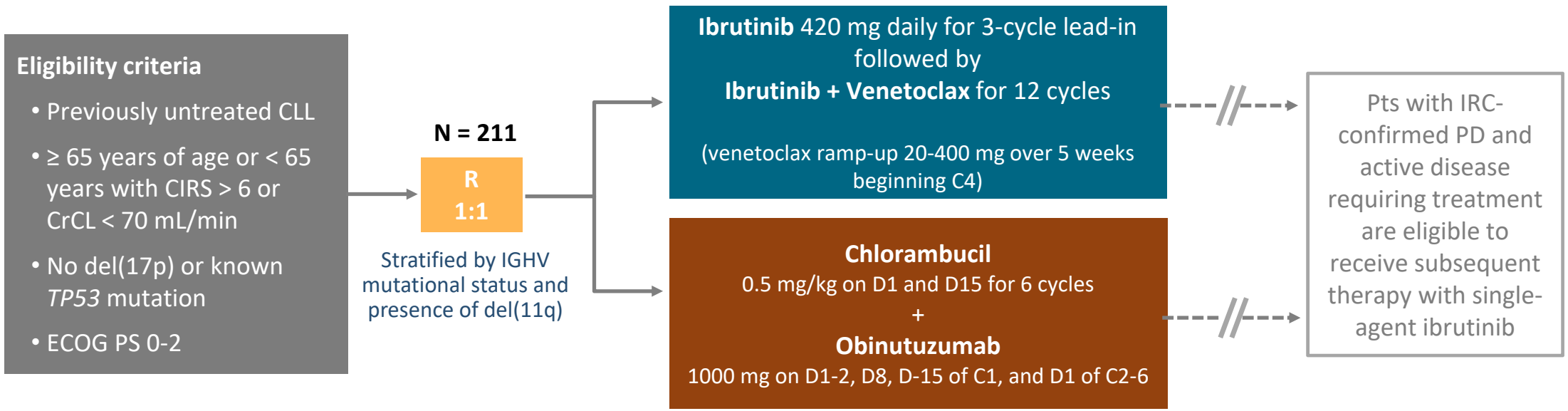
Kater *et al.* GLOW, LB1902, EHA 2021.

Phase 3 GLOW Study Design (NCT03462719)



Primary end point: Progression-free survival by independent review committee (IRC)

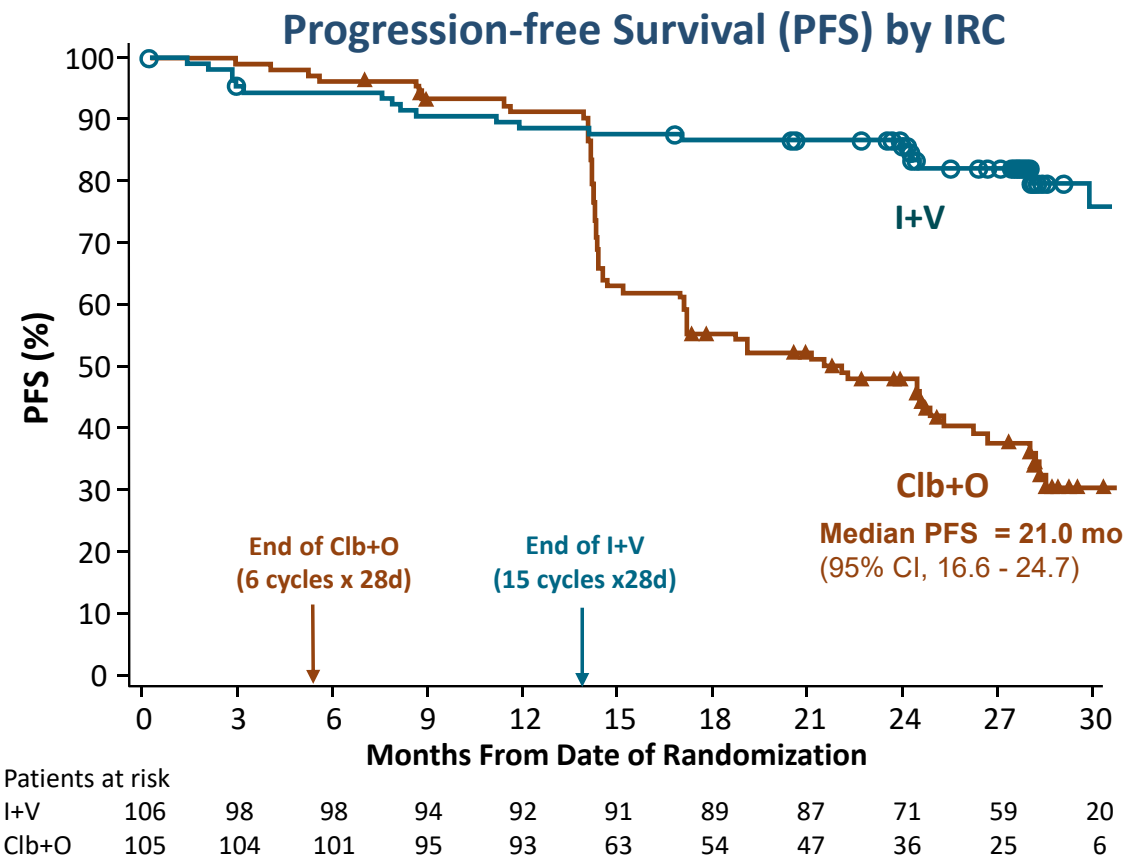
- 71 PFS events to detect an effect size with an HR = 0.5 (80% power at a 2-sided significance level of 0.05)

Key secondary end points: Undetectable MRD in BM, CR rate (IRC), ORR (IRC), OS; safety was also evaluated.

CLL, chronic lymphocytic leukemia; CIRS, Cumulative Illness Rating Scale score; CIRS, Cumulative Illness Rating Scale; CrCl, creatinine clearance; ECOG, Eastern Cooperative Oncology Group performance status; C, cycle (28 days); D, day; PD, progressive disease; PFS, progression-free survival; HR, hazard ratio; MRD, minimal residual disease; BM, bone marrow; CR, complete response; ORR, overall response rate; OS, overall survival

EHA 2021, Kater AP, et al.

I+V Significantly Improved Progression-Free Survival vs Clb+O

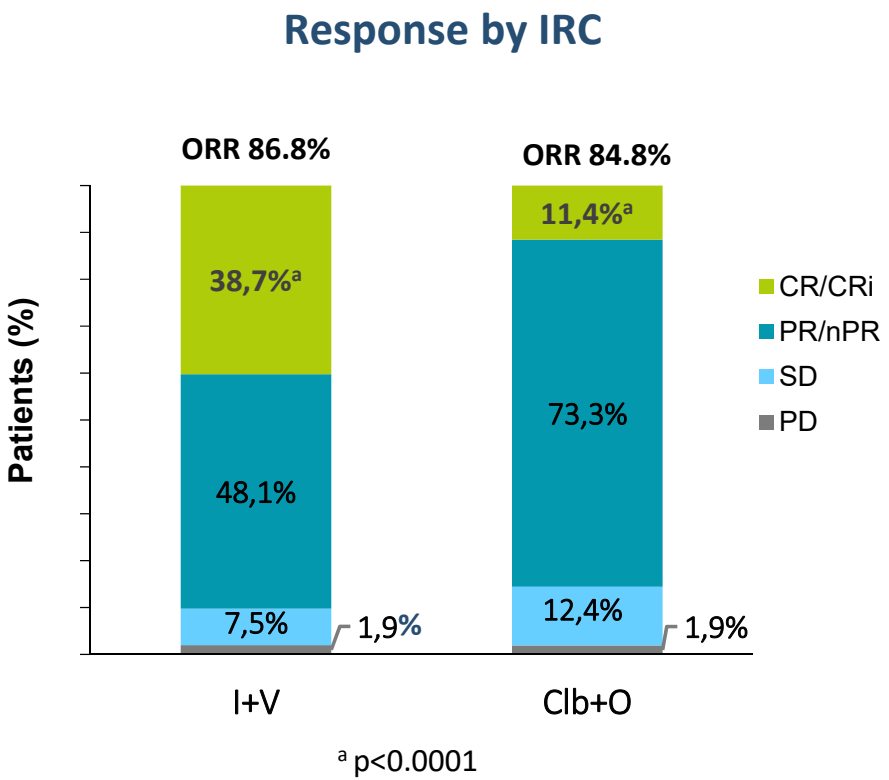


- **With a median follow up of 27.7 months, IRC-assessed PFS for I+V was superior to Clb+O**
- I+V reduced the risk of progression or death by 78% vs Clb+O
  - **HR 0.216** (95% CI, 0.131-0.357; p < 0.0001)
- PFS by INV assessment was consistent with IRC
  - **HR 0.207** (95% CI, 0.120, 0.357; p < 0.0001)

Disease evaluations per iwCLL criteria (confirmed by CT): Baseline, Cycles 3, 9, 15, and 18, then every 4 or 6 cycles until progressive disease or death; 6 cycles x 28 days = 5.5 mos and 15 cycles x 28 days = 13.8 mos; CT, computerized tomography; HR, hazard ratio; CI, confidence interval; IRC, independent review committee; INV, investigator

EHA 2021, Kater AP, et al.

CR/CRi Rate with I+V Was Significantly Higher vs Clb+O



- CR/CRi rates were significantly higher for I+V vs Clb+O by both IRC and INV assessments:
  - 38.7% vs 11.4% by IRC (p <0.0001)
  - 45.3% vs 13.3% by INV (p <0.0001)
- Responses to I+V were more durable:
  - 90% of responders in the I+V arm sustained IRC response 24 months after initial response vs 41% in Clb+O arm

CR, complete response; CRi, complete response with incomplete bone marrow recovery; PR, partial response; nPR, nodular partial response; SD, stable disease; PD, progressive disease; ORR, overall response rate; IRC, independent review committee; INV, investigator

EHA 2021, Kater AP, et al.

Summary of Safety and TLS Risk Reduction

Grade 3 or Higher AEs in ≥5% of Patients

	I+V (N = 106)	Clb+O (N = 105)
Median exposure, mos (range)	13.8 (0.7-19.5)	5.1 (1.8-7.9)
Any, %	75.5	69.5
Neutropenia[a]	34.9	49.5
Infections[b]	17.0	11.4
Thrombocytopenia	5.7	20.0
Diarrhea	10.4	1.0
Hypertension	7.5	1.9
Atrial fibrillation	6.6	0
Hyponatremia	5.7	0
TLS	0	5.7

[a]Includes 'neutrophil count decreased'; grade ≥3 febrile neutropenia: 1.9% for I+V vs 2.9% for Clb+O
[b]Includes multiple preferred terms

- After 3 cycles of ibrutinib lead-in, <2% of patients remained at risk for TLS based on high tumor burden
- 2 (1.9%) patients in I+V arm discontinued ibrutinib due to atrial fibrillation
- SAEs in ≥5% of patients for I+V vs Clb+O: Infections (12.3% vs 8.6%) and atrial fibrillation (6.6% vs 0%)
- Rate of secondary malignancies at time of analysis: 8.5% for I+V vs 10.5% for Clb+O
  - NMSC: 3.8% vs 1.9%
  - Other: 4.7% vs 8.6%

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TLS, tumor lysis syndrome; AE, adverse event; SAE, serious AE; NMSC, non-melanoma skin cancer

ELEVATE-TN TRIAL: ACALABRUTINIB ± OBINUTUZUMAB VS OBINUTUZUMAB + CHLORAMBUCIL IN TREATMENT-NAÏVE CHRONIC LYMPHOCYTIC LEUKEMIA: ELEVATE-TN 4-YEAR FOLLOW-UP

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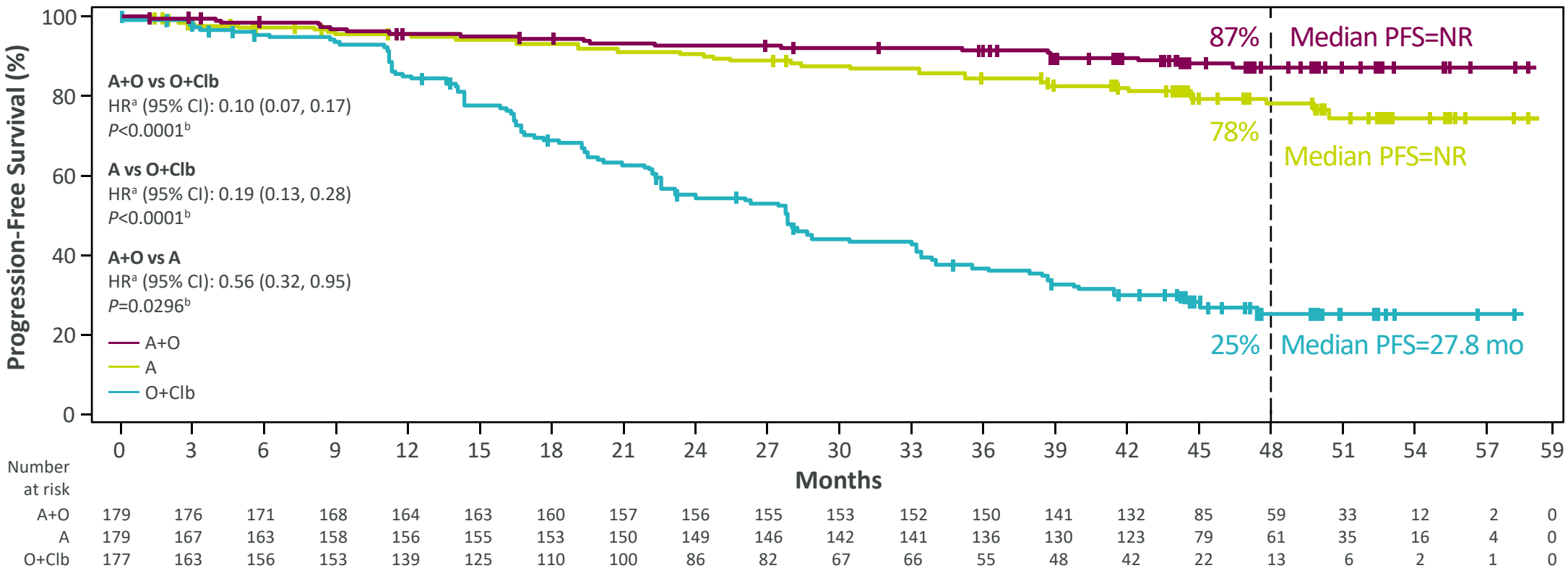
Sharman *et al.* ELEVATE-TN, S145, EHA 2021.

Investigator-assessed PFS Overall



Number at risk																				
A+O	179	176	171	168	164	163	160	157	156	155	153	152	150	141	132	85	59	33	12	2	0
A	179	167	163	158	156	155	153	150	149	146	142	141	136	130	123	79	61	35	16	4	0
O+Clb	177	163	156	153	139	125	110	100	86	82	67	66	55	48	42	22	13	6	2	1	0

[a]Hazard ratio was based on stratified Cox-Proportional-Hazards model; [b]*P*-value was based on stratified log-rank test.
A, acalabrutinib; CI, confidence interval; Clb, chlorambucil; HR, hazard ratio; NR, not reached; O, obinutuzumab; PFS, progression-free survival.

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DEUTSCHE STUDIENGRUPPE

Abstract S146

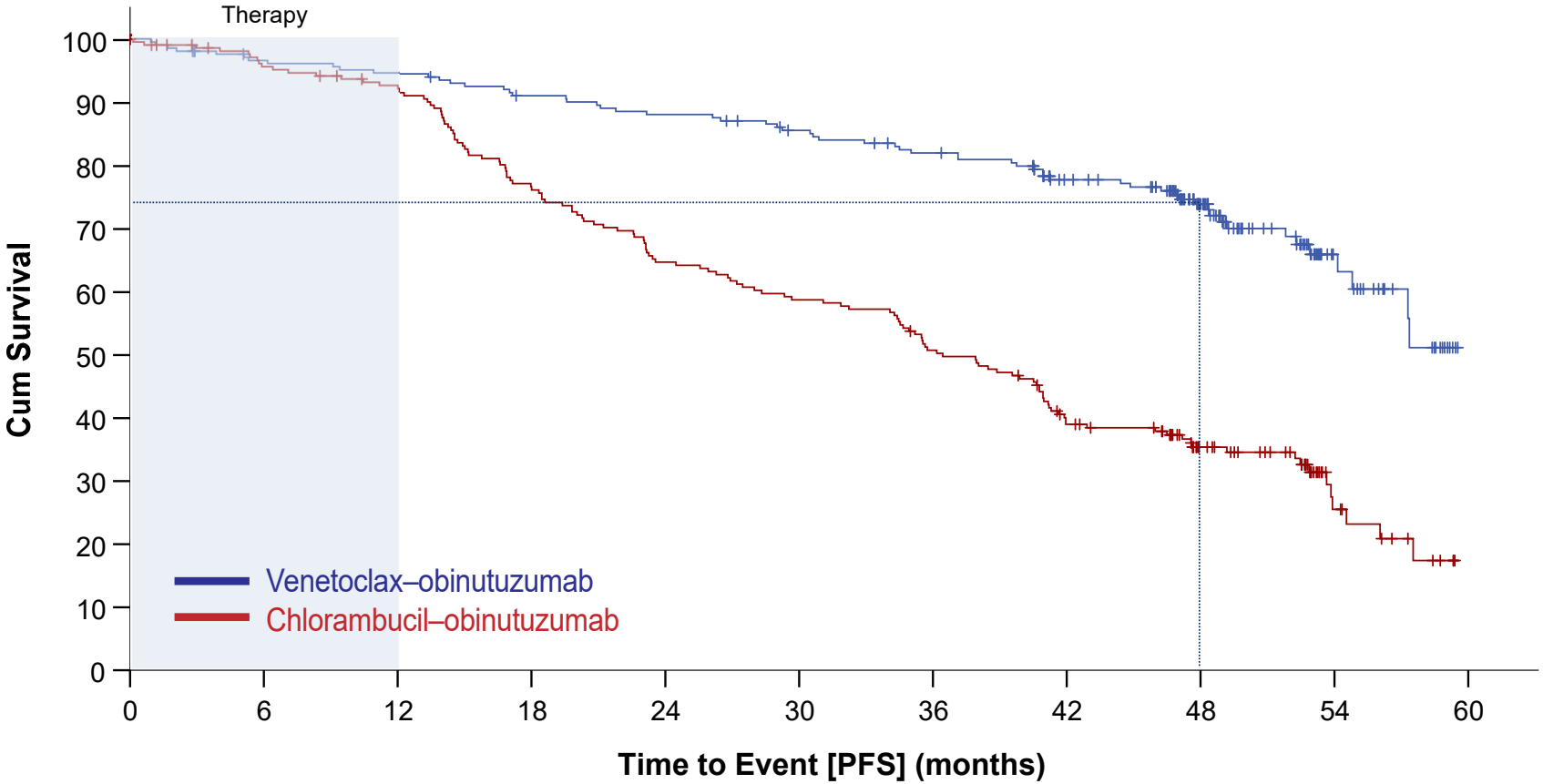
VENETOCLAX-OBINUTUZUMAB FOR PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA: 4-YEAR FOLLOW-UP ANALYSIS OF THE RANDOMIZED CLL14 STUDY

Othman Al-Sawaf, Can Zhang, Sandra Robrecht, Maneesh Tandon, Anesh Panchal, Anna-Maria Fink, Eugen Tausch, Matthias Ritgen, Karl-Anton Kreuzer, Su Young Kim, Clemens-Martin Wendtner, Barbara Eichhorst, Stephan Stilgenbauer, Yanwen Jiang, Michael Hallek, Kirsten Fischer

June 11th, 2021
Clinical trials with targeted therapies in CLL

PROGRESSION-FREE SURVIVAL

Median observation time 52.4 months



Median PFS

Ven-Obi: not reached

Clb-Obi: 36.4 months

4-year PFS rate

Ven-Obi: 74.0%

Clb-Obi: 35.4%

HR 0.33, 95% CI [0.25-0.45]

P<0.0001

Haben Sie Fragen zu diesem Thema?

Schreiben Sie uns!

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Kompetenznetz Maligne Lymphome

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Die Kurzpräsentationen sind online unter

www.lymphome.de/eha2021

Für den Inhalt verantwortlich:

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