


Kompetenznetz
Maligne Lymphome

Lymphom Kompetenz KOMPAKT



KML KONGRESSE

Expert:innen berichten zu
Lymphomen & Leukämien



EHA2023 HYBRID



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Innere Medizin I | Uniklinik Köln

Chronische lymphatische Leukämie (CLL)

Offenlegung potentieller Interessenskonflikte

LymphomKompetenz KOMPAKT – EHA2023 HYBRID wird in Kooperation mit sieben unterstützenden Firmen durchgeführt.
Meine persönlichen Disclosures betreffen:

Anstellungsverhältnis, Führungsposition	-
Beratungs-/ Gutachtertätigkeit	Janssen, AbbVie, AstraZeneca, Beigene
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Patent, Urheberrecht, Verkaufslizenz	-
Honorare	Janssen, AbbVie, AstraZeneca, Beigene
Finanzierung wissenschaftlicher Untersuchungen	Janssen
Andere finanzielle Beziehungen	-
Immaterielle Interessenkonflikte	-

Kapitel 1

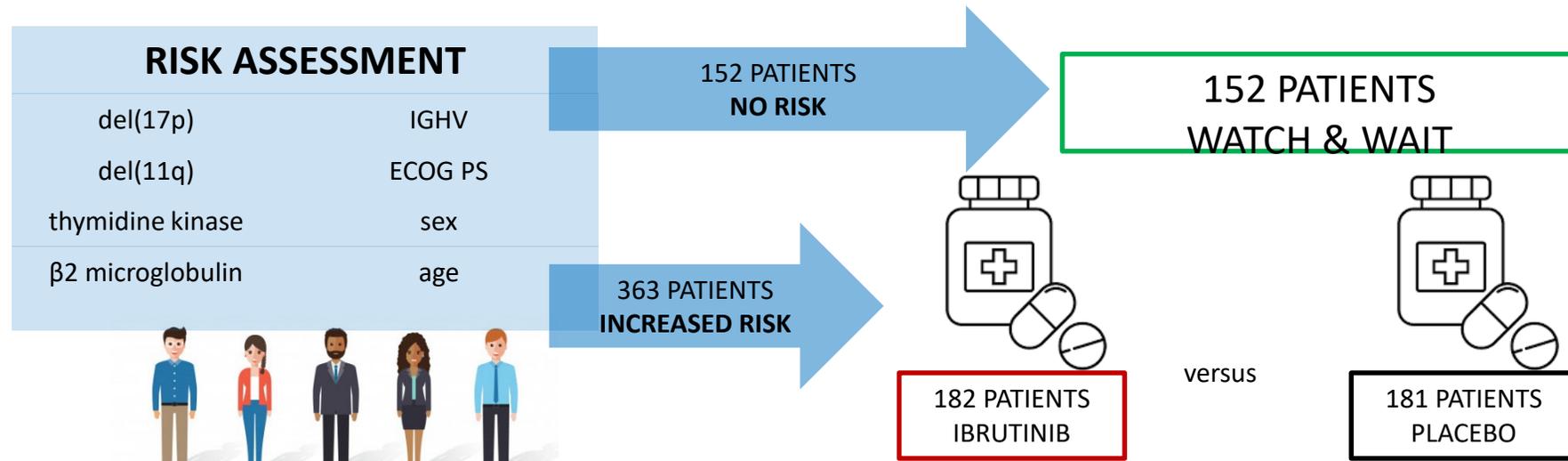
Zielgerichtete Therapie mit Ibrutinib im Frühstadium

CLL12: Ibrutinib versus placebo in patients with asymptomatic, treatment-naive early stage CLL

S200

Petra Langerbeins

Studiendesign



Primary endpoint analysis demonstrated superior EFS for the ibrutinib group.¹

Overall survival was not analyzed due to a lacking number of events.

The final analysis is performed at a median observation time of 69.3 (0 - 93.4) months.

¹Langerbeins P. et al. Blood. 2022 Jan 13;139(2):177-187.

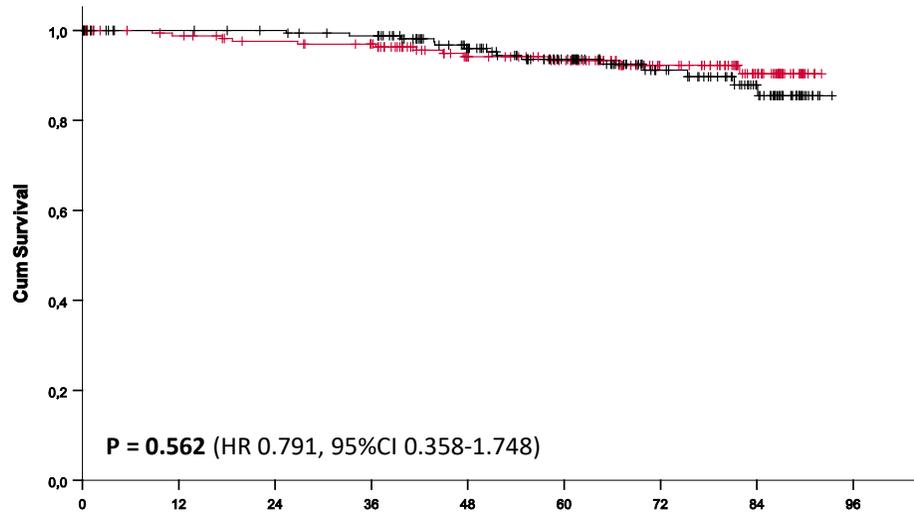
CLL12

Death cases (N=32)

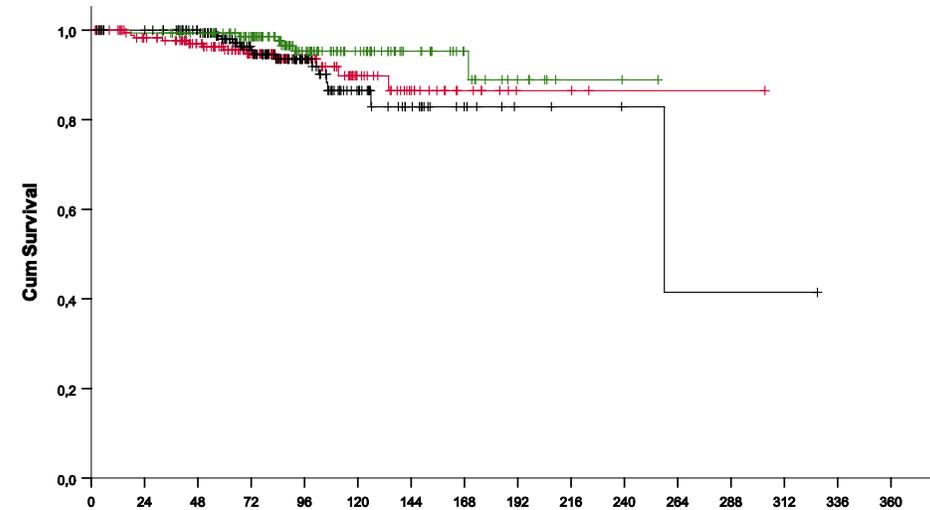
	Ibrutinib N=182	Placebo N=181	Watch & wait N=152
All death cases, N (%)	12 (6.6)	14 (7.7)	6 (3.9)

CLL12

Overall survival



OS	Pts, N	Events, N (%)	Median months	1-year Survival, %	2-year Survival, %	3-year Survival, %	4-year Survival, %	5-year Survival, %
All patients [ITT]	363	26 (7.2)						
Ibrutinib	182	12 (6.6)	NR	98.8	97.6	97.0	94.1	93.3
Placebo	181	14 (7.7)	NR	100.0	100.0	98.8	96.0	93.6



OS from diagnosis	Pts, N	Events, N (%)	Median months	2-year Survival, %	4-year Survival, %	6-year Survival, %	8-year Survival, %	10-year Survival, %
All patients [ITT]	515	32 (6.2)						
Ibrutinib	182	12 (6.6)	NR	98.2	97.0	94.7	93.6	89.8
Placebo	181	14 (7.7)	258.0	100.0	100.0	96.4	93.5	86.5
Watch & Wait	152	6 (3.9)	NR	99.3	99.3	98.6	95.3	95.3

Kapitel 2

Zeitlich begrenzte Erstlinientherapie mit Venetoclax plus Obinutuzumab

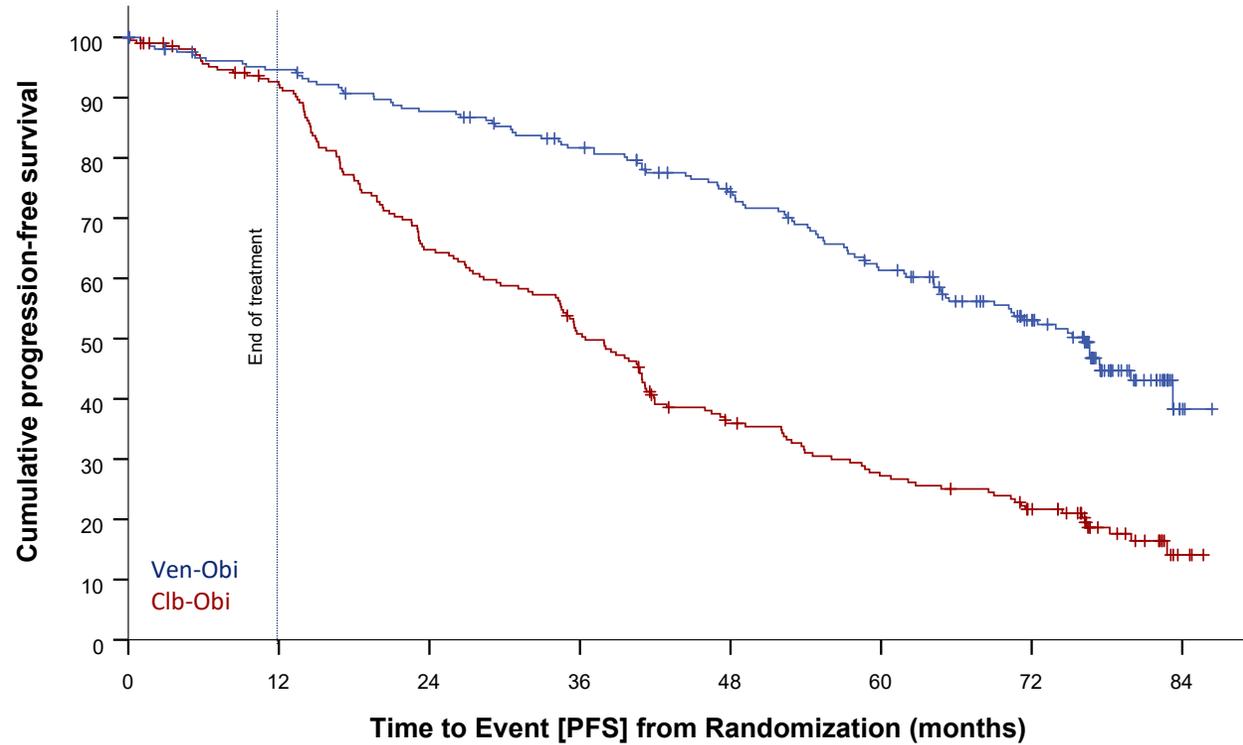
CLL14: Venetoclax-Obinutuzumab for previously untreated CLL

S145

Othman Al-Sawaf

PROGRESSION-FREE SURVIVAL

Median observation time 76.4 months



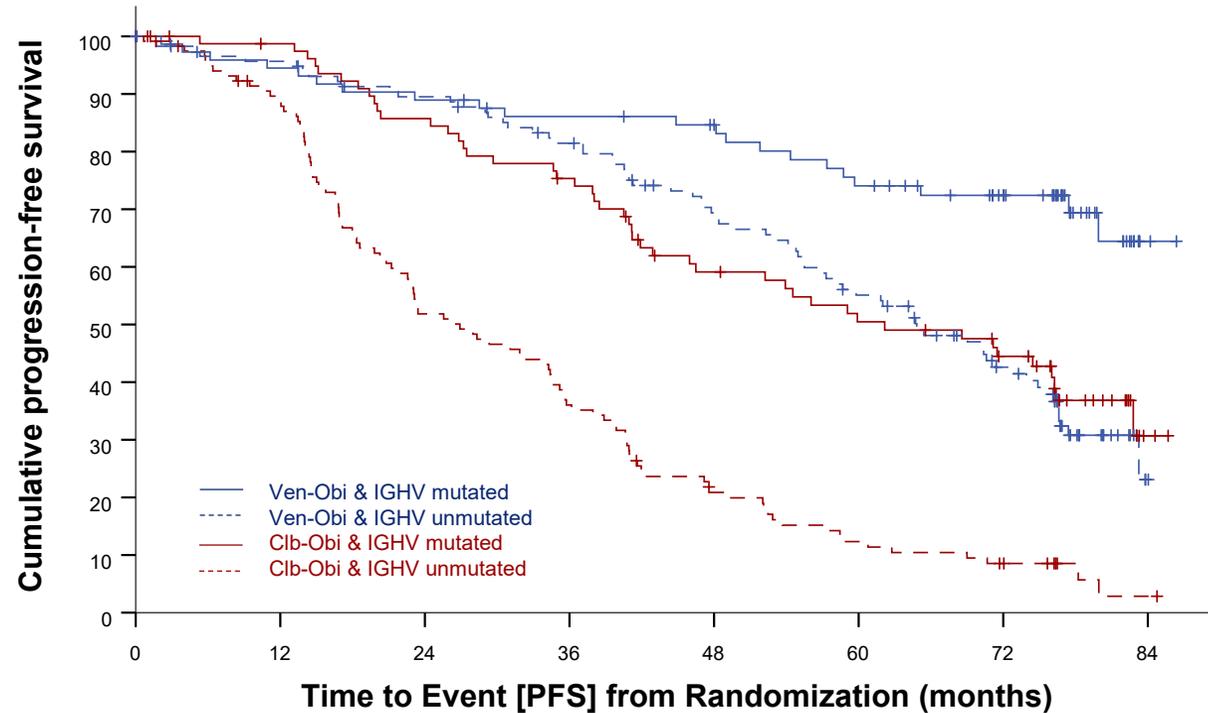
	0	12	24	36	48	60	72	84
Ven-Obi	216	193	177	160	139	112	79	3
Clb-Obi	216	185	130	101	67	50	36	3

Median PFS
 Ven-Obi: 76.2 months
 Clb-Obi: 36.4 months

6-year PFS rate
 Ven-Obi: 53.1%
 Clb-Obi: 21.7%

HR 0.40, 95% CI [0.31-0.52]
 P<0.0001

PROGRESSION-FREE SURVIVAL – IGHV status



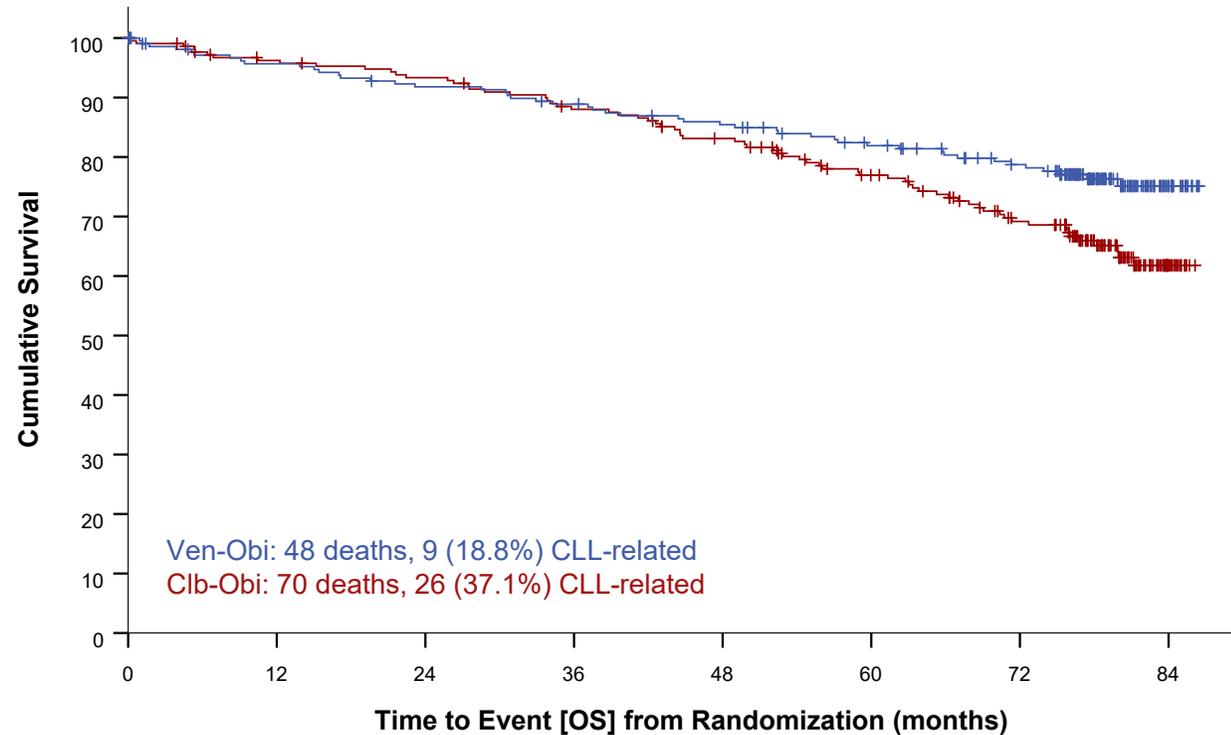
Median PFS
 Ven-Obi & IGHVmut: NR
 Ven-Obi & IGHVunmut: 64.8 m
HR 0.38, 95%CI [0.23-0.61], p<0.001

Clb-Obi & IGHVmut: 62.2 m
 Clb-Obi & IGHVunmut: 26.9 m
HR 0.33, 95% CI [0.23-0.47], p<0.001

Ven-Obi & IGHV mutated	76	68	64	60	57	49	39	2
Ven-Obi & IGHV unmutated	121	110	101	90	73	57	37	1
Clb-Obi & IGHV mutated	83	76	66	57	42	35	28	2
Clb-Obi & IGHV unmutated	123	101	59	41	22	13	8	1

OVERALL SURVIVAL

Median observation time 76.4 months



Ven-Obi	216	198	189	182	173	160	144	23
Clb-Obi	216	201	194	181	167	144	118	16

Median OS
 Ven-Obi: not reached
 Clb-Obi: not reached

6-year OS rate
 Ven-Obi: 78.7%
 Clb-Obi: 69.2%

HR 0.69, 95% CI [0.48-1.01],
 p=0.052

Kapitel 3

Zeitlich begrenzte Rezidivtherapie mit Venetoclax plus Rituximab

FINAL 7-YEAR FOLLOW UP AND RETREATMENT SUBSTUDY ANALYSIS OF MURANO

S201

Arnon Kater

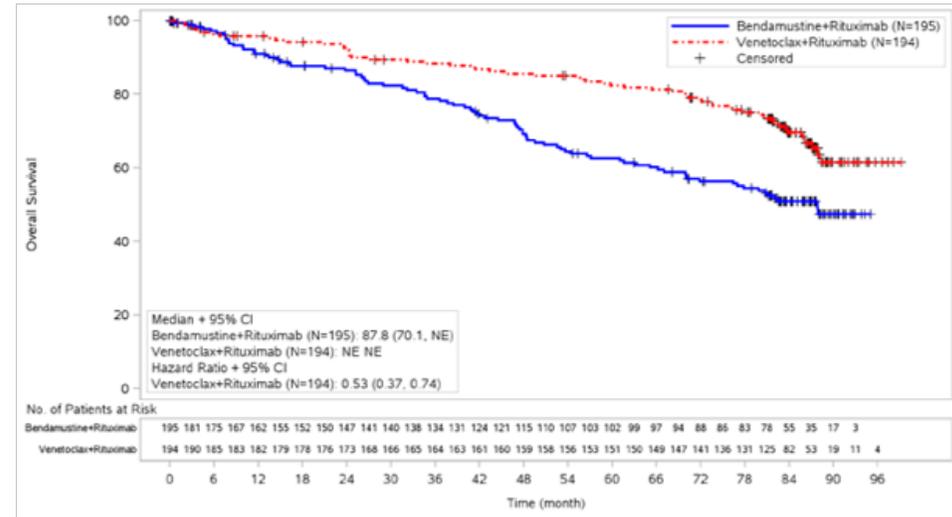
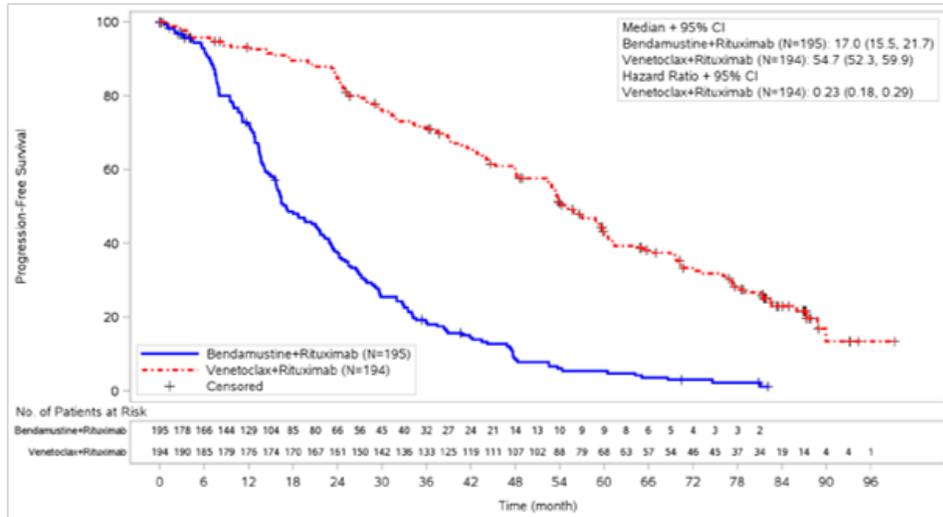
PFS and OS at 7 years

	Median PFS (95% CI), months	HR* (95% CI)	7-year PFS (%)
VenR (n=194)	54.7 (52.3–59.9)	0.23 (0.18–0.29)	23.0
BR (n=195)	17.0 (15.5–21.7)	<0.0001†	NE

Stratified P-value <0.0001†

	Median OS (95% CI), months	HR‡ (95% CI)	7-year OS (%)
VenR (n=194)	NE	0.53 (0.37–0.74)	69.6
BR (n=195)	87.8 (70.1–NE)	<0.0002†	51.0

Stratified P-value <0.0002†



- No new safety signals were identified since the 5-year data cut¹ and patients are outside of the AE reporting window[§]

*Stratified HR is presented, unstratified HR=0.25. †P-values are descriptive only. ‡Stratified HR is presented, unstratified HR=0.54. §All AEs were reported until 28 days after the last dose of venetoclax or 90 days after last dose of rituximab, whichever was longer. After this, only deaths, serious AEs or AEs of concern that were believed to be venetoclax-related were reported.

1. Seymour JF, et al. Blood 2022;140(8):839–850.

MURANO

Retreatment / crossover substudy

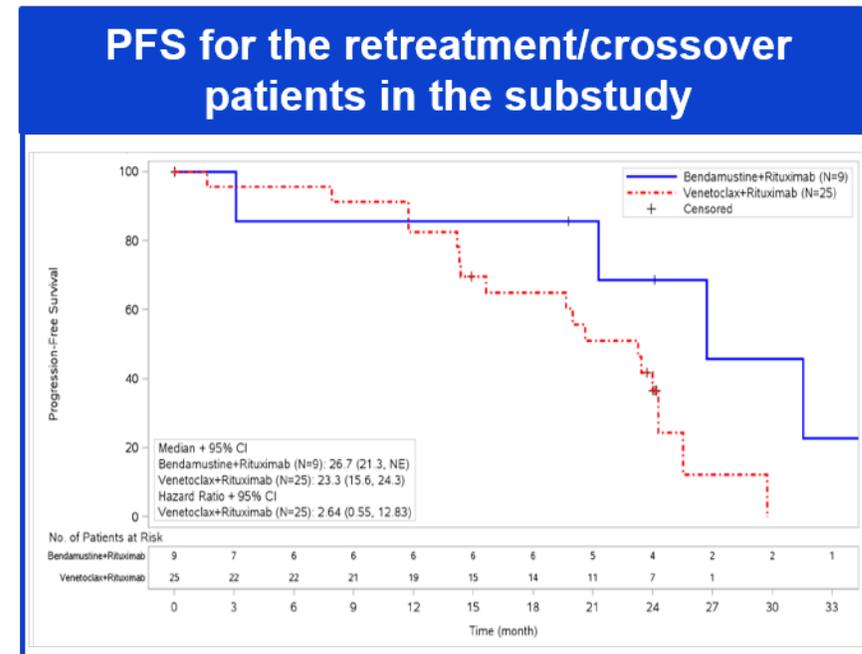


- In total, 34 patients with PD entered the substudy, 25 were retreated with VenR and 9 crossed over from BR to VenR
 - For retreated patients, median (range) time between the last Ven dose in the main study and Ven ramp-up in the substudy was 2.3 (1.2–3.1) years

PFS for retreatment / crossover

Clinical outcomes indicate that VenR is a viable option for pretreated patients

- Median PFS (95% CI) was:
 - 23.3 months (15.6–24.3) for retreated patients
 - 26.7 months (21.3–NE) for crossover patients
- Best ORR was high for both retreated patients (72.0%) and crossover patients (88.9%)
- Median duration of response (95% CI) was:
 - 15.5 months (11.5–NE) for retreated patients
 - 22.5 months (12.7–NE) for crossover patients
- Median OS was not reached for either the retreatment or crossover patients



CLL12-Studie

watch & wait bleibt der Standard bei CLL im frühen Stadium – unabhängig von klinischen, genetischen oder laborchemischen Risikofaktoren

CLL14-Studie

5 Jahre nach Therapieende sind >50% der PatientInnen unter Venetoclax-Obinutuzumab ohne Progress – noch zeigt sich kein Überlebensvorteil...

MURANO-Studie

Eine erneute Behandlung mit Venetoclax-Rituximab kann zu einem hohen Ansprechen bis hin zur MRD-negativen Remission führen.

Die Kurzpräsentationen sind online unter

www.lymphome.de/eha2023

Für den Inhalt verantwortlich:

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Uniklinik Köln

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