Final Analysis of Fixed-Duration Ibrutinib + Venetoclax for Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma in the Phase 2 CAPTIVATE Study

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  - Consulting/advisory role with AbbVie, AstraZeneca, BeiGene, Bristol Myers Squibb, Janssen, Loxo/Lilly, Merck Sharp & Dohme, and Roche;
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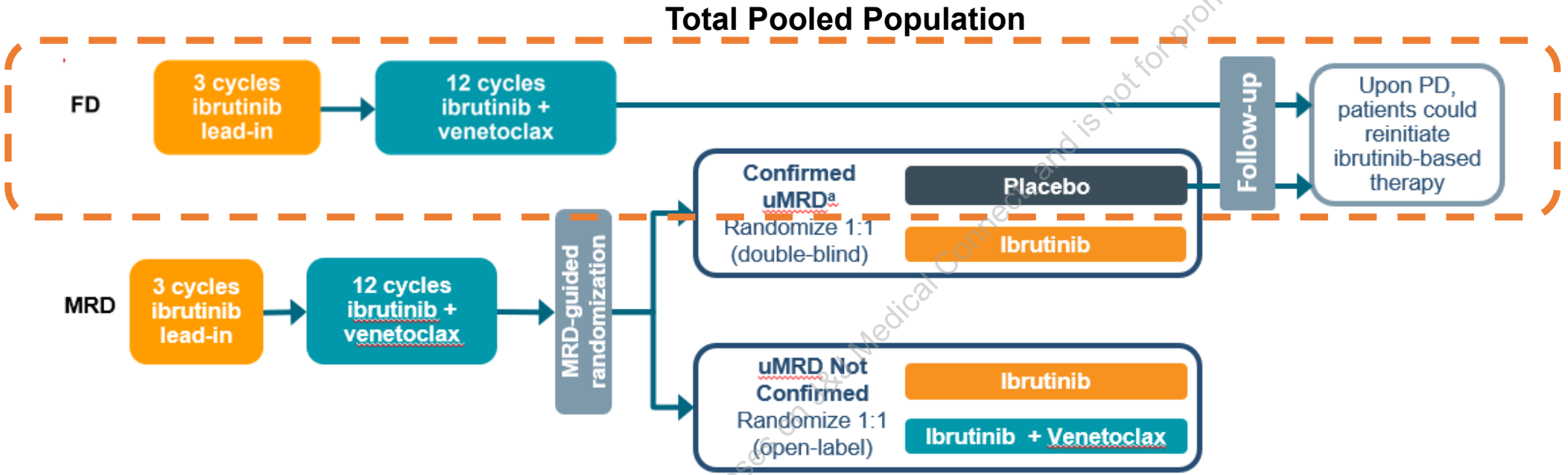
FD Ibrutinib + Venetoclax Is Effective as First-Line Treatment for CLL/SLL, Including in Patients With High-Risk Genomic Features

- First-line, all-oral, once-daily ibrutinib + venetoclax for CLL/SLL was investigated in 2 cohorts of the phase 2 CAPTIVATE study: MRD–guided randomized discontinuation (MRD cohort) and FD cohort[1,2]
- At the previous analysis with up to 5.5 years of follow-up, FD Cohort treatment with ibrutinib + venetoclax demonstrated sustained PFS at the 5-year landmark time, including in patients with high-risk genomic features[3]
- Here, we report Final Analysis results for patients treated with FD ibrutinib + venetoclax in the FD cohort and in the MRD cohort placebo arm with up to 7 years of follow-up (median 5.75 years)

CLL, chronic lymphocytic leukemia; FD, fixed-duration; MRD, minimal residual disease; PFS, progression-free survival; SLL, small lymphocytic lymphoma.

1. Wierda WG et al. *J Clin Oncol.* 2021;39:3853–3865.. 2. Tam CS et al. *Blood.* 2022;139:3278–3289. 3. Wierda WG et al. *J Clin Oncol.* 2024;42(Suppl 16):7009.

CAPTIVATE Study Design: FD Cohort and MRD Cohort Placebo Arm



- Patients aged ≤70 years with previously untreated CLL/SLL received 3 cycles of ibrutinib, then 12 cycles of ibrutinib + venetoclax (ibrutinib, 420 mg/day orally; venetoclax, 5-week ramp up to 400 mg/day orally)
  - Patients in the FD cohort received no further treatment (n=159)
  - Patients in the MRD cohort placebo arm with confirmed uMRD4 (n=43) received 1 additional cycle of ibrutinib + venetoclax during the MRD-guided randomization, then placebo treatment
- In patients with confirmed PD, on-study retreatment included single-agent ibrutinib
  - FD cohort patients with PD occurring >2 years after EOT could be retreated with FD ibrutinib + venetoclax

[a]Patients with confirmed uMRD4 (defined as uMRD $<10^{-4}$ by 8-color flow cytometry serially over ≥3 cycles in both peripheral blood and bone marrow) after 12 cycles of ibrutinib + venetoclax were randomly assigned 1:1 to receive placebo or ibrutinib; the placebo arm was included in the current analysis.
EOT, end of treatment; PD, progressive disease; uMRD, undetectable minimal residual disease.

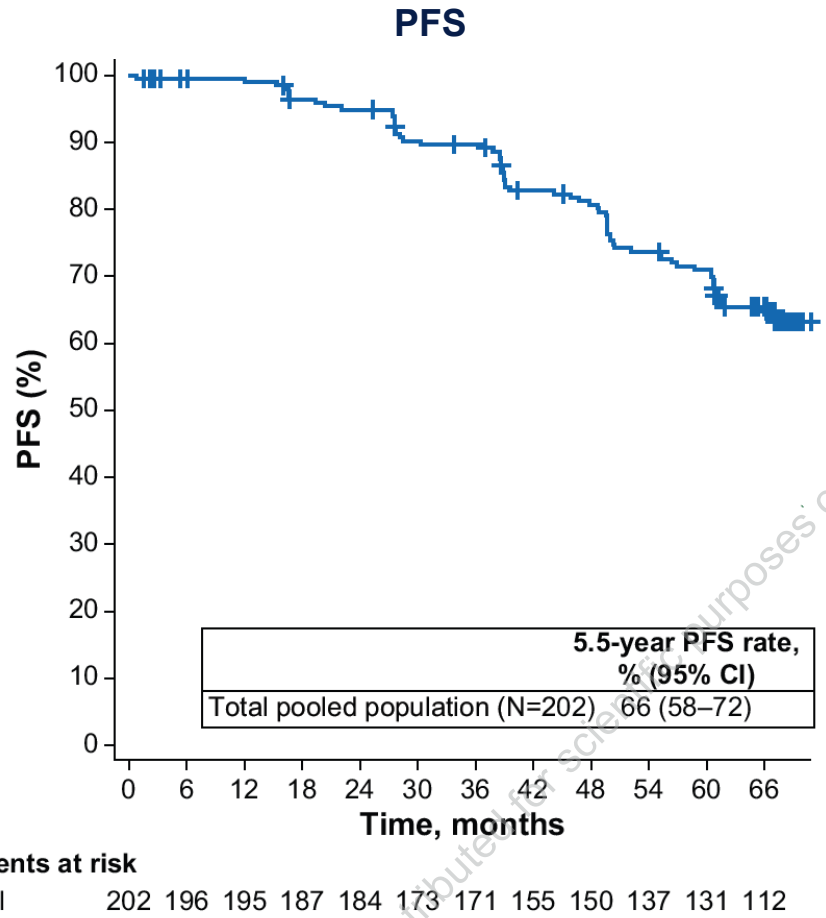
Baseline Characteristics in Patients Treated With FD Ibrutinib + Venetoclax

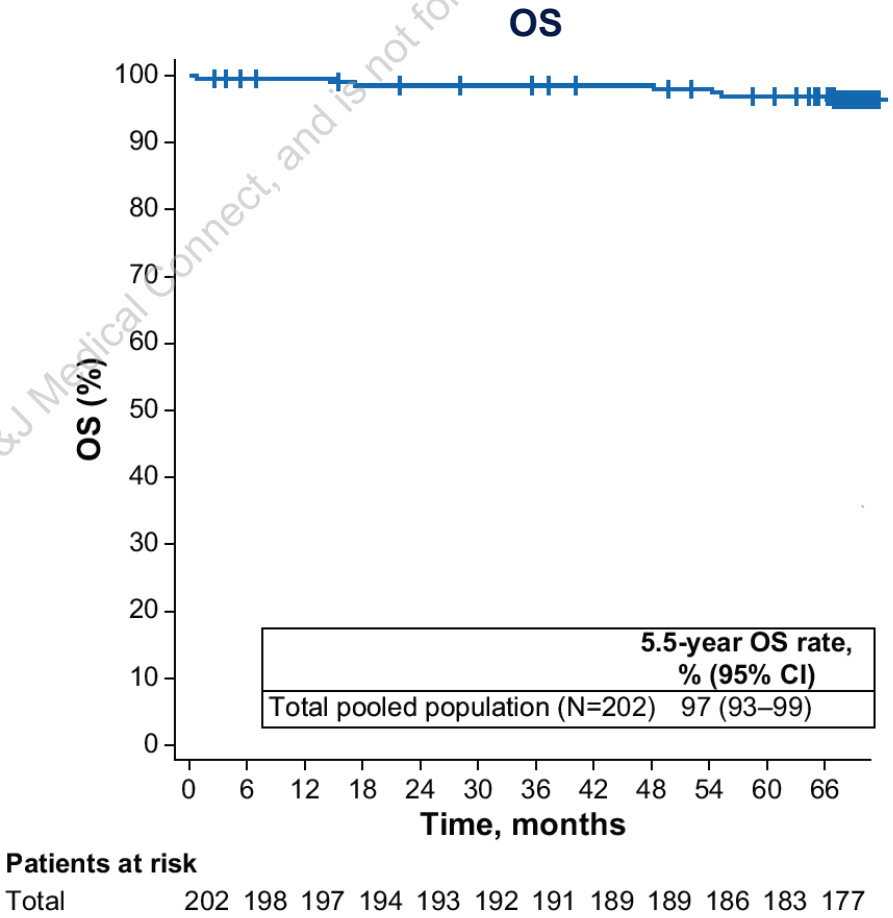
Characteristic	Total Pooled Population (N=202)	FD Cohort Only (N=159)
Median age (range), years	60.0 (33–71)	60.0 (33–71)
Male, n (%)	131 (65)	106 (67)
Rai stage III/IV, n (%)	59 (29)	44 (28)
High-risk genomic features, n (%)		
uIGHV	119 (59)	89 (56)
del(17p)/TP53	29 (14)	27 (17)
del(11q)[a]	36 (18)	28 (18)
CK (≥3 abnormalities)[b]	35 (17)	31 (20)
CK (≥5 abnormalities)[b]	19 (9)	16 (10)
Bulky LN disease, n (%)		
≥5 cm	66 (33)	48 (30)
≥10 cm	6 (3)	5 (3)

- In total, 202 patients completed FD ibrutinib + venetoclax (FD cohort, n=159; MRD cohort placebo arm, n=43)
- High-risk genomic features at baseline were similar in FD Cohort and the Total Pooled Population and enriched relative to 1L populations with CLL/SLL
- At final analysis, median follow-up was:
  - Total Pooled Population- 68.9 months (range, 0.8–83.9)
  - FD Cohort only- 69.0 months (range, 0.8–73.2)

[a]Without del(17p) per Döhner hierarchy. [b]By conventional CpG-stimulated cytogenetics; CK status was missing for 30 patients (15%).
CK, complex karyotype; LN, lymph node; uIGHV, unmutated IGHV.

Overall Median PFS and OS Were Not Reached With Up to 7 Years of Follow-up (Total Pooled Population)



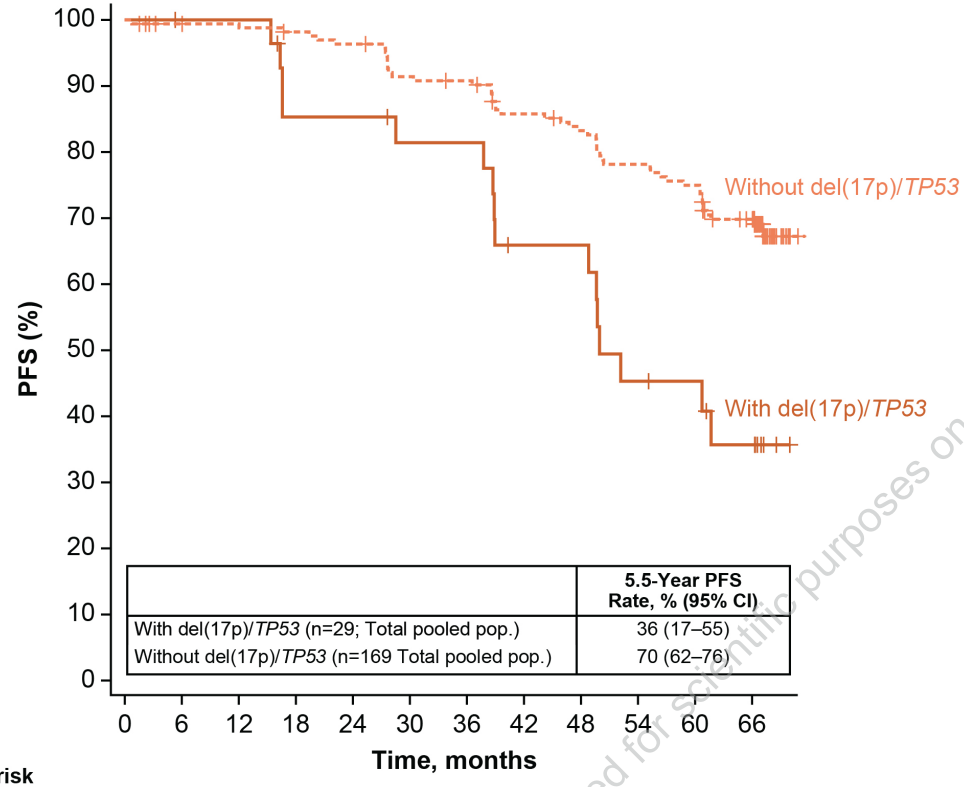


- Assessed in FD cohort patients only, 5.5-year PFS and OS rates were 60% (95% CI, 52–68) and 96% (95% CI, 91–98), respectively[a]

[a]See Supplementary Information for details. OS, overall survival.

Impact of del(17p)/mutated *TP53* and IGHV Status On Long-Term PFS (Total Pooled Population)

PFS by del(17p)/*TP53* Mutation Status



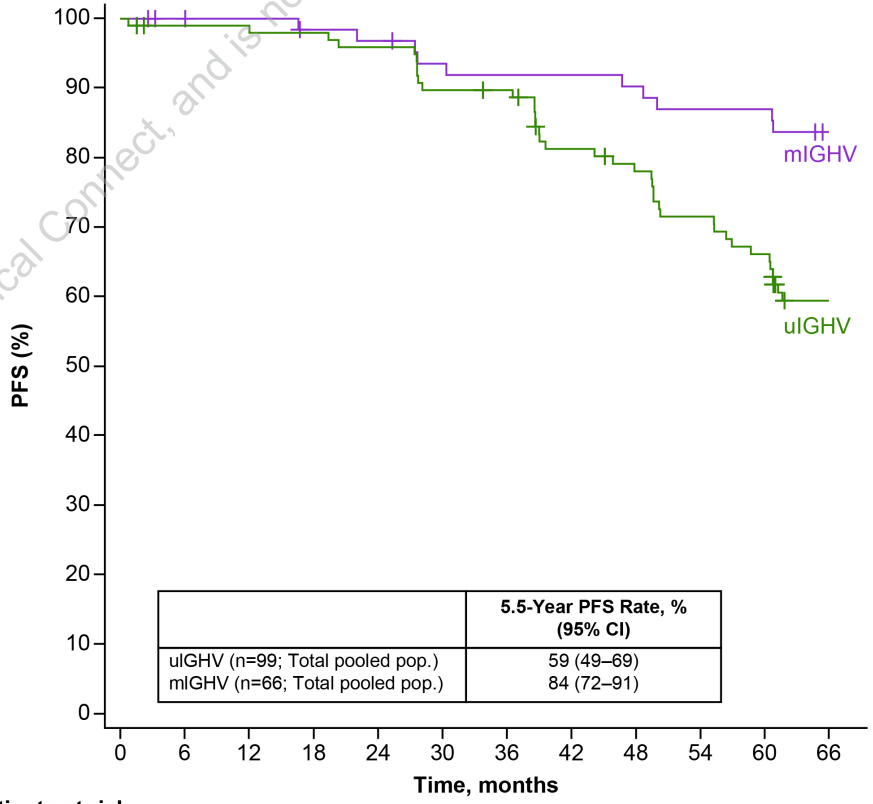
	5.5-Year PFS Rate, % (95% CI)
With del(17p)/*TP53* (n=29; Total pooled pop.)	36 (17–55)
Without del(17p)/*TP53* (n=169 Total pooled pop.)	70 (62–76)

Patients at risk

With del(17p)/*TP53*	29	28	28	23	23	21	21	16	16	11	10	7
Without del(17p)/*TP53*	169	164	163	160	157	148	146	136	131	123	118	103

FD Cohort[a]	5.5-Year PFS Rate, % (95% CI)
With del(17p)/*TP53* (n=27; FD cohort only)	30 (12–49)
Without del(17p)/*TP53* (n=129; FD cohort only)	66 (57–74)

PFS by IGHV Status in Patients Without del(17p)/mutated *TP53*



	5.5-Year PFS Rate, % (95% CI)
uIGHV (n=99; Total pooled pop.)	59 (49–69)
mIGHV (n=66; Total pooled pop.)	84 (72–91)

Patients at risk

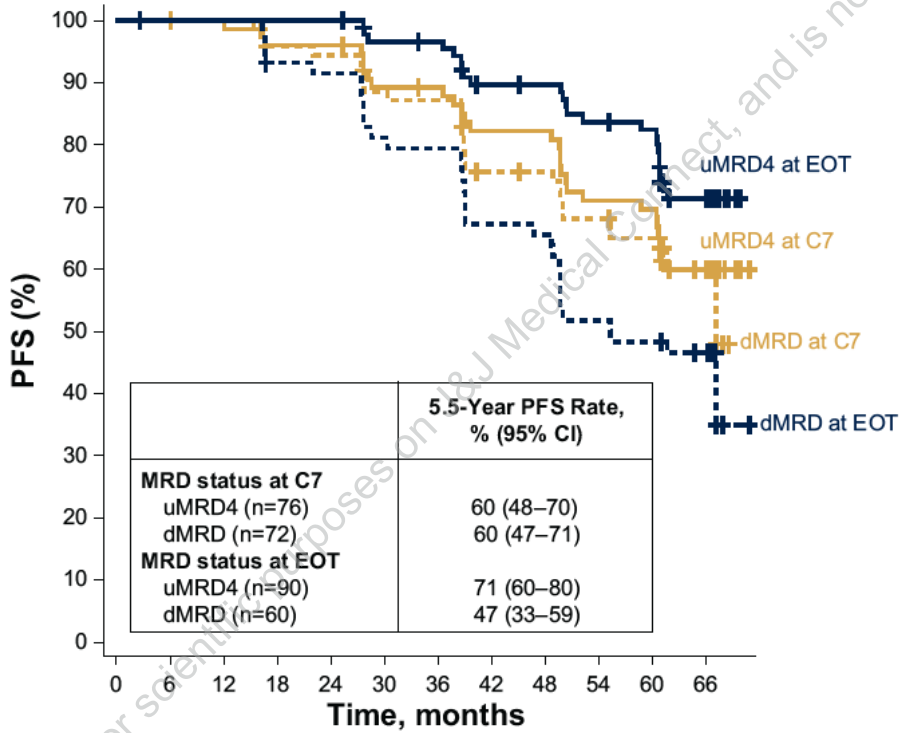
mIGHV	66	64	63	61	60	57	56	56	55	53	53	49
uIGHV	99	96	96	95	93	87	86	76	72	66	61	50

FD Cohort[a]	5.5-Year PFS Rate, % (95% CI)
uIGHV (n=71; FD cohort only)	53 (40–64)
mIGHV (n=55; FD cohort only)	80 (66–89)

[a]See Supplementary Information for details. mIGHV, mutated IGHV.

MRD Status in Peripheral Blood at EOT[a] Is More Strongly Predictive For Long-Term PFS Than MRD Status at C7[b] (FD Cohort Patients)

PFS by MRD Status in Peripheral Blood at C7 and EOT in FD Cohort Patients



	5.5-Year PFS Rate, % (95% CI)
MRD status at C7	
uMRD4 (n=76)	60 (48–70)
dMRD (n=72)	60 (47–71)
MRD status at EOT	
uMRD4 (n=90)	71 (60–80)
dMRD (n=60)	47 (33–59)

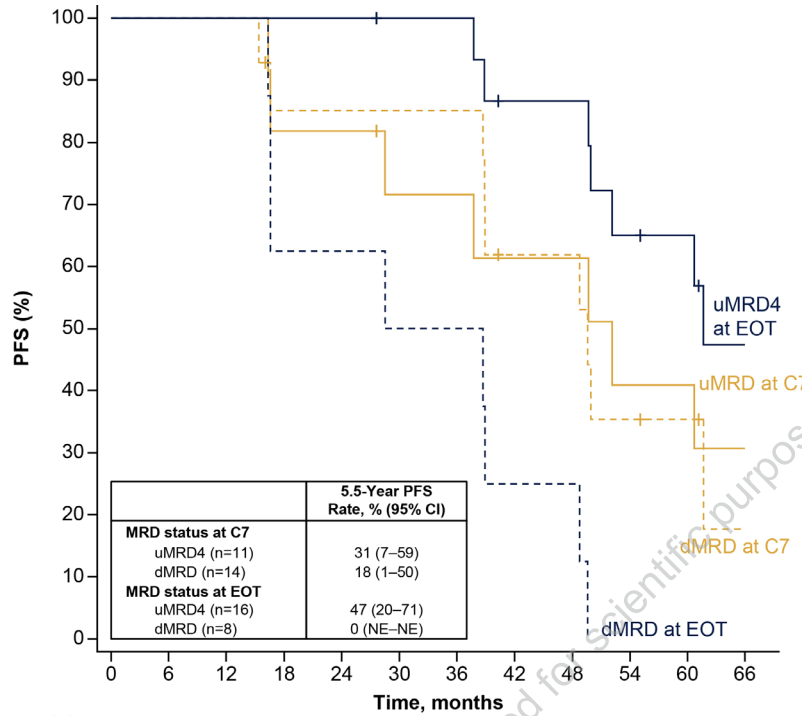
Patients at risk												
uMRD4 at C7	76	76	75	72	72	65	64	59	59	51	50	40
dMRD at C7	72	72	72	67	66	62	61	51	50	45	42	35
uMRD4 at EOT	90	90	90	90	90	85	84	76	75	70	68	54
dMRD at EOT	60	59	59	54	53	47	46	39	38	30	28	25

- Assessed in FD cohort patients only, uMRD4 rates in peripheral blood increased from 51% of patients at C7 to 60% at EOT: uMRD4 rate in bone marrow was 60% at EOT[c]

[a]3 cycles after the 15-cycle fixed-duration ibrutinib + venetoclax treatment, i.e, day 1 of C19 for the FD cohort. [b]After 3 cycles of ibrutinib and 3 cycles of ibrutinib + venetoclax. [c]See Supplementary Information for details. C7, cycle 7; EOT, end of treatment.

MRD Status at EOT Is Predictive of Long-Term PFS Regardless of del(17p)/*TP53* Status (FD Cohort Patients)

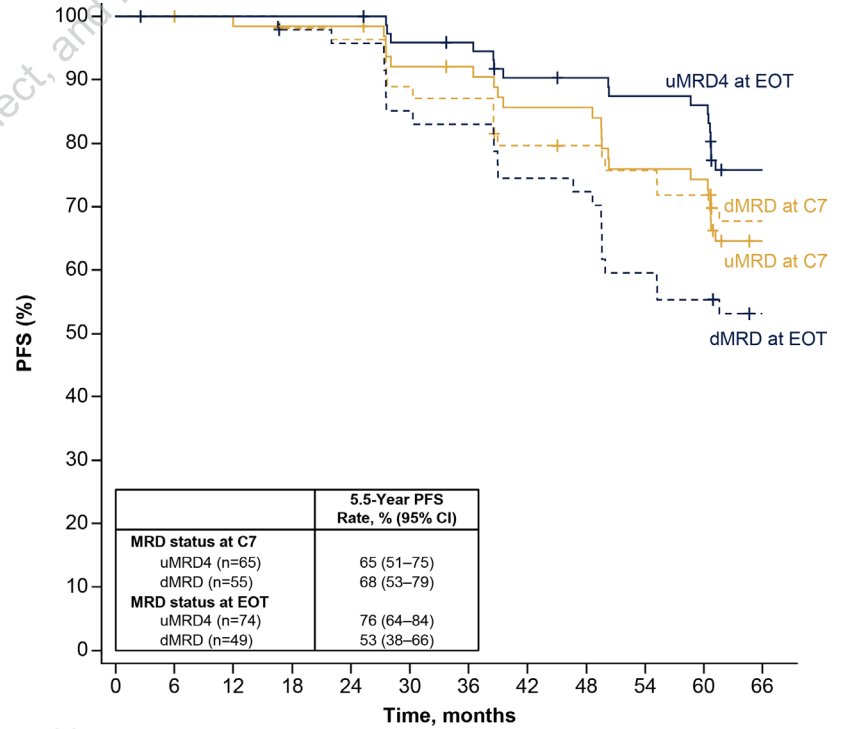
PFS by MRD Status in Patients With del(17p)/mutated *TP53* (FD Cohort only)



Patients at risk

uMRD4 at C7	11	11	11	9	9	7	7	6	6	4	4	3
dMRD at C7	14	14	14	11	11	11	11	7	7	4	3	1
uMRD4 at EOT	16	16	16	16	16	15	15	12	12	9	8	5
dMRD at EOT	8	8	8	5	5	4	4	2	2	0	0	0

PFS by MRD Status in Patients Without del(17p)/mutated *TP53* (FD Cohort only)



Patients at risk

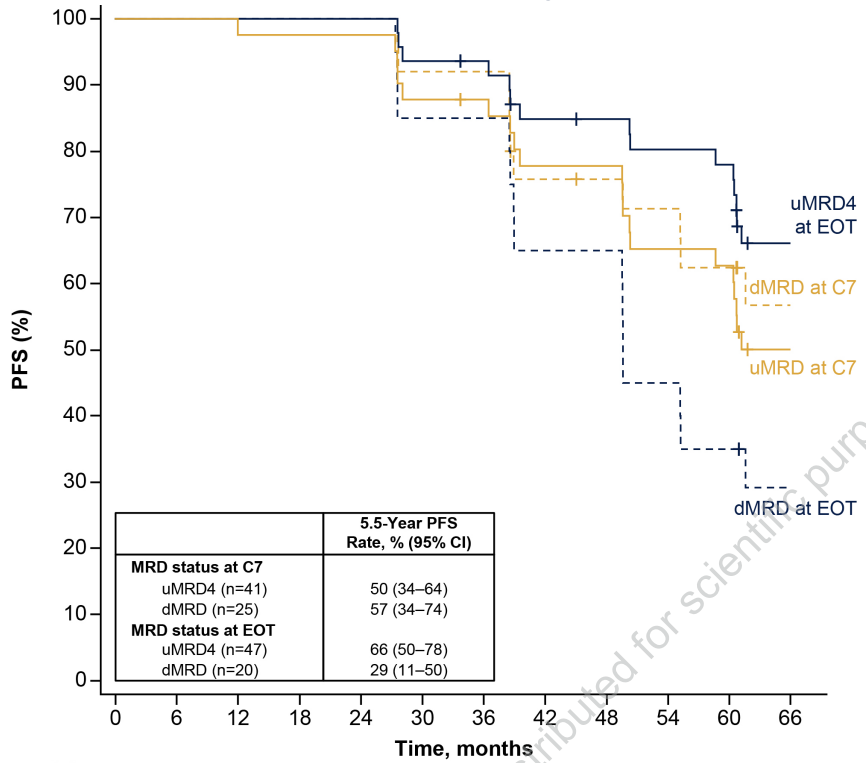
uMRD4 at C7	65	65	64	63	63	58	57	53	53	47	46	37
dMRD at C7	55	55	55	53	52	48	47	42	41	39	37	32
uMRD4 at EOT	74	74	74	74	74	70	69	64	63	61	60	49
dMRD at EOT	49	48	48	46	45	40	39	35	34	28	26	23

- Increases in peripheral blood uMRD4 rates from C7 to EOT were particularly notable in patients with del(17p)/mutated *TP53* or CK5, and in patients with uIGHV to a lesser extent[a]

[a]See Supplementary Information for details. NE, not estimable.

MRD Status at EOT Is Predictive of Long-Term PFS Regardless of IGHV Status and Also Predictive at C7 in Patients With mIGHV (FD Cohort Patients Without del(17p/*TP53*)

PFS by MRD Status in Patients Without del(17p)/*TP53* and With uIGHV (FD Cohort only)

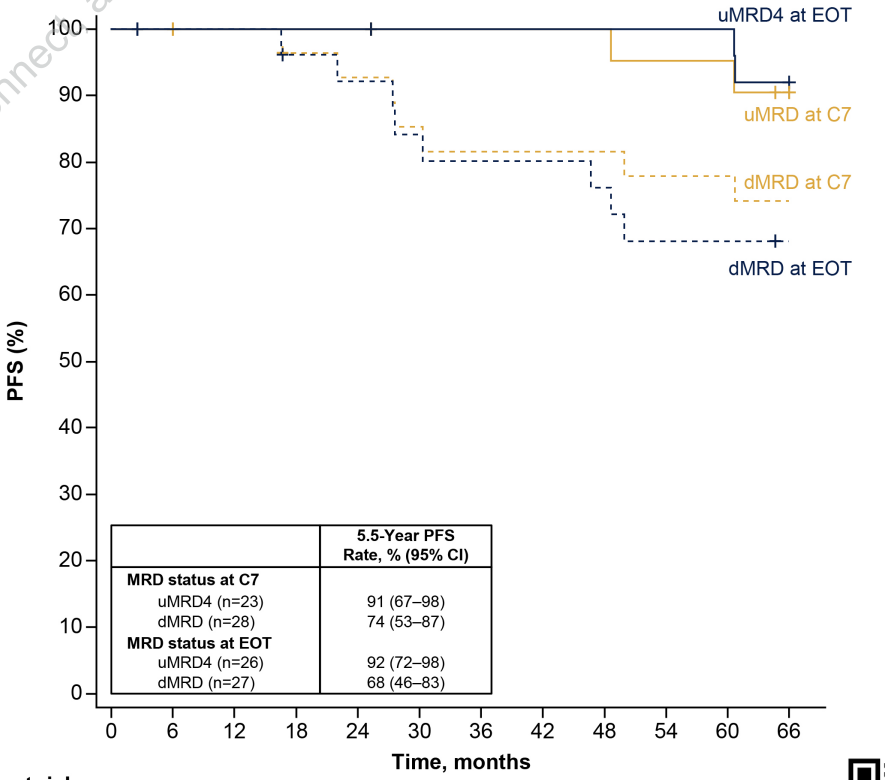


	5.5-Year PFS Rate, % (95% CI)
MRD status at C7	
uMRD4 (n=41)	50 (34–64)
dMRD (n=25)	57 (34–74)
MRD status at EOT	
uMRD4 (n=47)	66 (50–78)
dMRD (n=20)	29 (11–50)

Patients at risk

uMRD4 at C7	41	41	41	40	40	36	35	31	31	26	25	18
dMRD at C7	25	25	25	25	25	23	23	18	17	16	14	10
uMRD4 at EOT	47	47	47	47	47	44	43	38	37	35	34	25
dMRD at EOT	20	20	20	20	20	17	17	13	13	9	7	5

PFS by MRD Status in Patients Without del(17p)/*TP53* and With mIGHV (FD Cohort only)



	5.5-Year PFS Rate, % (95% CI)
MRD status at C7	
uMRD4 (n=23)	91 (67–98)
dMRD (n=28)	74 (53–87)
MRD status at EOT	
uMRD4 (n=26)	92 (72–98)
dMRD (n=27)	68 (46–83)

Patients at risk

uMRD4 at C7	23	23	22	22	22	21	21	21	21	20	20	18
dMRD at C7	28	28	28	26	25	23	22	22	22	21	21	20
uMRD4 at EOT	26	26	26	26	26	25	25	25	25	25	25	23
dMRD at EOT	27	26	26	24	23	21	20	20	19	17	17	16

No Resistance-Associated Mutations Were Identified at PD

- In the total pooled population (FD and MRD-placebo cohorts) with a median follow-up of more than 5.5 years, 64/202 patients (32%) had PD after FD ibrutinib + venetoclax treatment
- No patients had resistance-associated mutations in *BTK* or *PLCG2* at PD among 53 patients with available samples
- Two patients were found with a subclonal *BCL2 A113G* mutation of unclear significance at PD: variant allele frequencies were only 8% and 9.3%, respectively
  - Patient 1: Achieved partial response with FD ibrutinib + venetoclax retreatment (complete response was not confirmed due to missing bone marrow assessment).
    - *BCL2 A113G* mutation was not detectable at the time of eventual relapse after retreatment[a]
  - Patient 2: Did not receive retreatment in the study

[a]Patient 1 *BCL2 A113G* variant allele frequency also was noted to decline spontaneously down to 6.7% before retreatment started.

Patients Who Initiated Ibrutinib-Based Retreatment: Study Baseline Characteristics and Safety during Retreatment

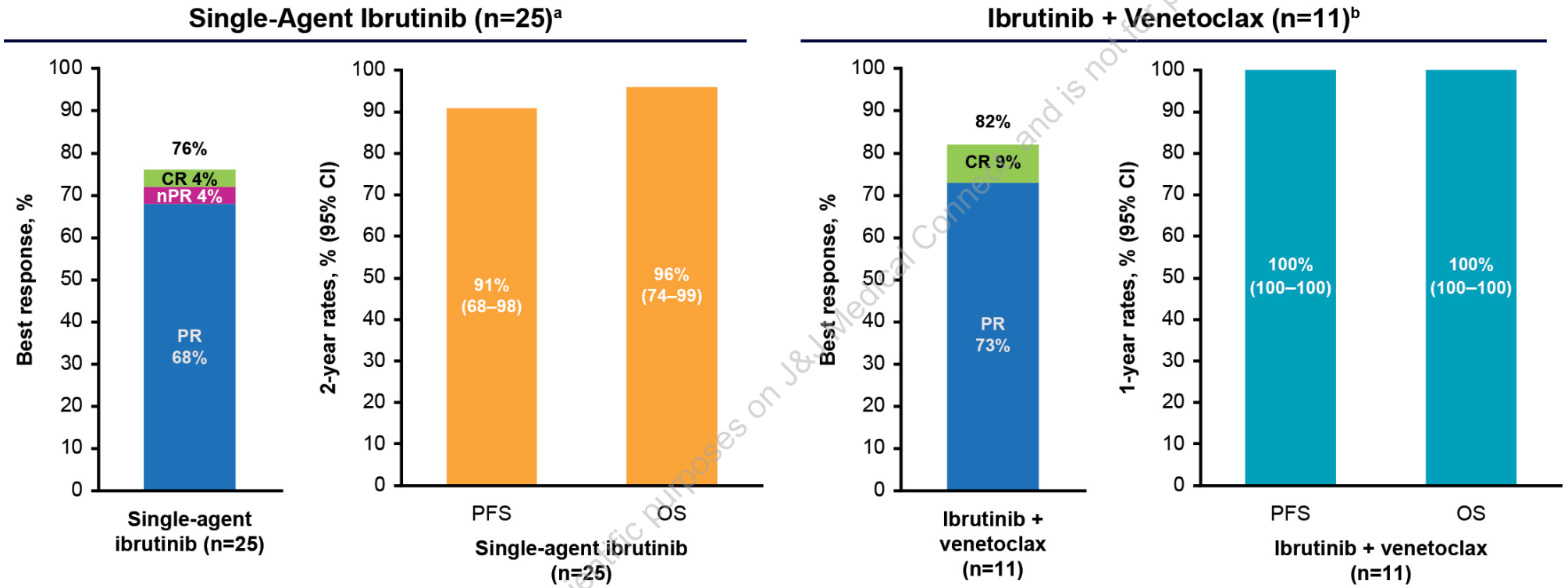
- 73% of patients remained free from next-line treatment at the 5.5-year landmark time point (95% CI, 66–79)
- In total, 36 patients (who met iwCLL criteria for treatment) initiated retreatment with either single-agent ibrutinib (n=25) or FD ibrutinib + venetoclax (n=11)
- No new safety signals were observed during retreatment, relative to the safety profile of 1L treatment with single agent ibrutinib or FD ibrutinib + venetoclax[a]
- Across the entire study period, including any retreatment received on study, secondary malignancies occurred in 24 patients: non-melanoma skin cancers occurred in 16 patients, and other cancers in 14 patients[a]

Patients Who Initiated Ibrutinib-Based Retreatment: Study Baseline Characteristics

Characteristic	Single-agent ibrutinib n=25	FD ibrutinib + venetoclax n=11	All retreated patients n=36
Median age (range), years	56.0 (39–71)	63.0 (49–69)	58.5 (39–71)
Male, n (%)	16 (64)	8 (73)	24 (67)
Rai stage III/IV, n (%)	4 (16)	2 (18)	6 (17)
High-risk genomic features, n (%)			
uIGHV	20 (80)	8 (73)	28 (78)
del(17p)/TP53	4 (16)	6 (55)	10 (28)
del(11q)[b]	7 (28)	1 (9)	8 (22)
CK (≥3 abnormalities)[c]	8 (32)	3 (27)	11 (31)
CK (≥5 abnormalities)[c]	5 (20)	2 (18)	7 (19)
Bulky LN disease, n (%)			
≥5 cm	9 (36)	2 (18)	11 (31)
≥10 cm	1 (4)	1 (9)	2 (6)

[a]See Supplementary Information for additional details. [b]Without del(17p) per Döhner hierarchy. [c]By conventional CpG-stimulated cytogenetics.

Ibrutinib-Based Retreatment Confers Promising Overall Response Rates, PFS, and OS in Patients Needing Subsequent Treatment



	Single-agent ibrutinib	FD ibrutinib + venetoclax
Median duration of follow-up, months (range)	28.4 (3.7–59.1)	15.2 (7.4–29.3)
Median duration of retreatment, months (range)	27.0 (1.1–59.1)	13.8 (6.7–18.3)

[a]Of the 6 non-responders, 4 patients achieved SD with reintroduced treatment duration ranging from 6.2–19.4 months; 1 patient was discontinued after reassessment of the putative progressive lesion as not PD, and 1 patient was diagnosed with Richter's Transformation after 1.1 month on retreatment.
[b]Of the 2 non-responders, both achieved SD with reintroduced treatment duration of 9.9 and 25.9 months, respectively.
CR, complete response; nPR, nodular partial response; PR, partial response.

Conclusions

- Ibrutinib + venetoclax is an all-oral, once-daily, chemotherapy-free FD regimen for first-line treatment of CLL/SLL
- With long-term follow-up, durable PFS and OS is observed with ibrutinib + venetoclax treatment, including in patients with high-risk genomic features
- uMRD at end of treatment is strongly associated with long-term PFS overall irrespective of high-risk genomic features
- Ibrutinib-based retreatment provides durable responses in patients needing subsequent therapy after completion of FD ibrutinib + venetoclax

Together with the GLOW study, CAPTIVATE led to the availability of the ibrutinib + venetoclax fixed-duration regimen across 78 countries; we thank the patients whose participation made this possible.

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Disclosures

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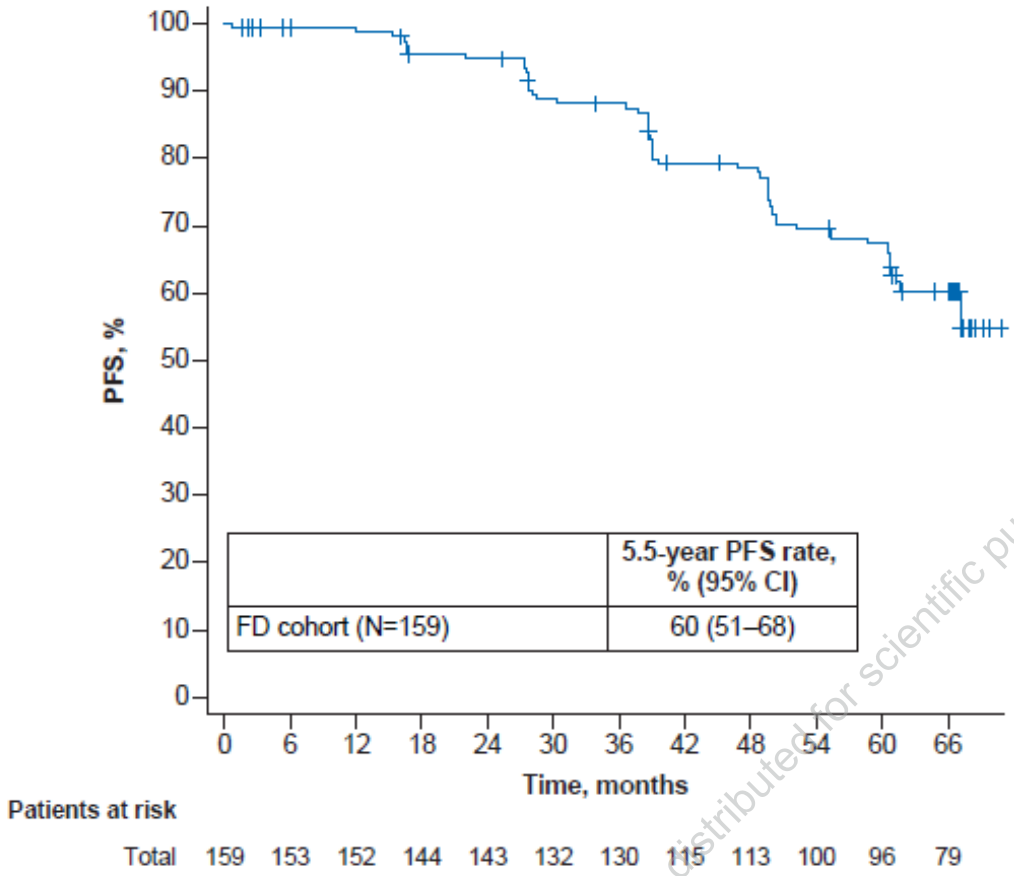
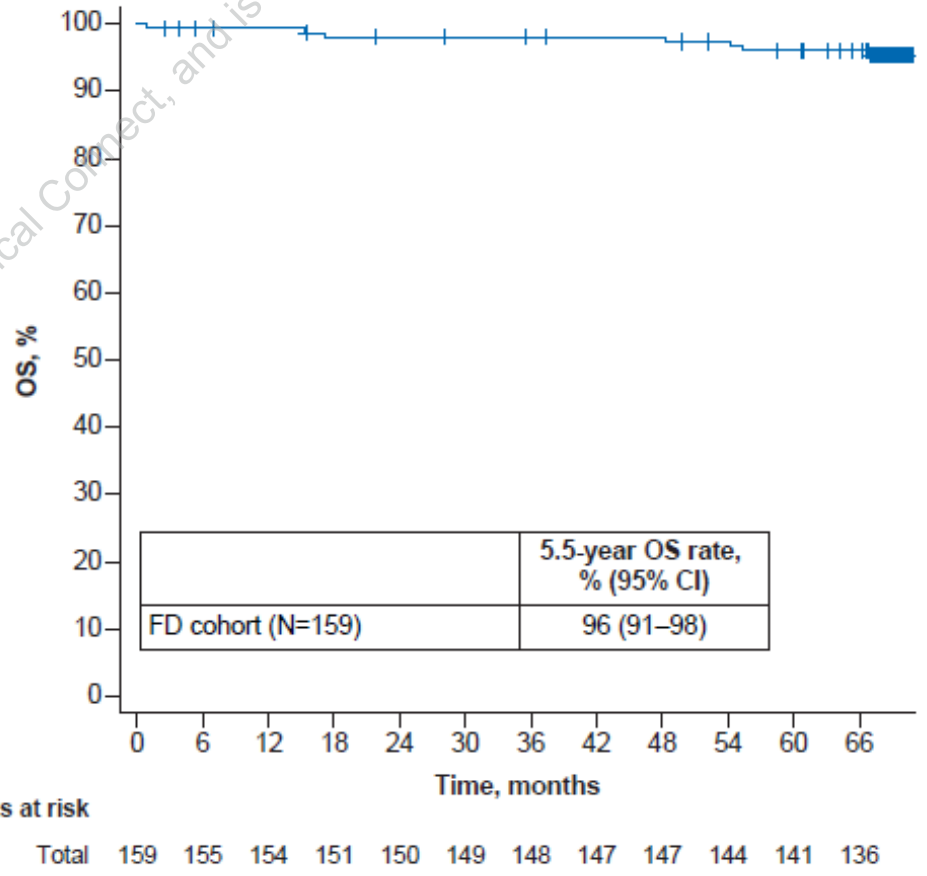
Supplementary Information

PFS and OS in the FD Cohort

PFS (FD Cohort only)



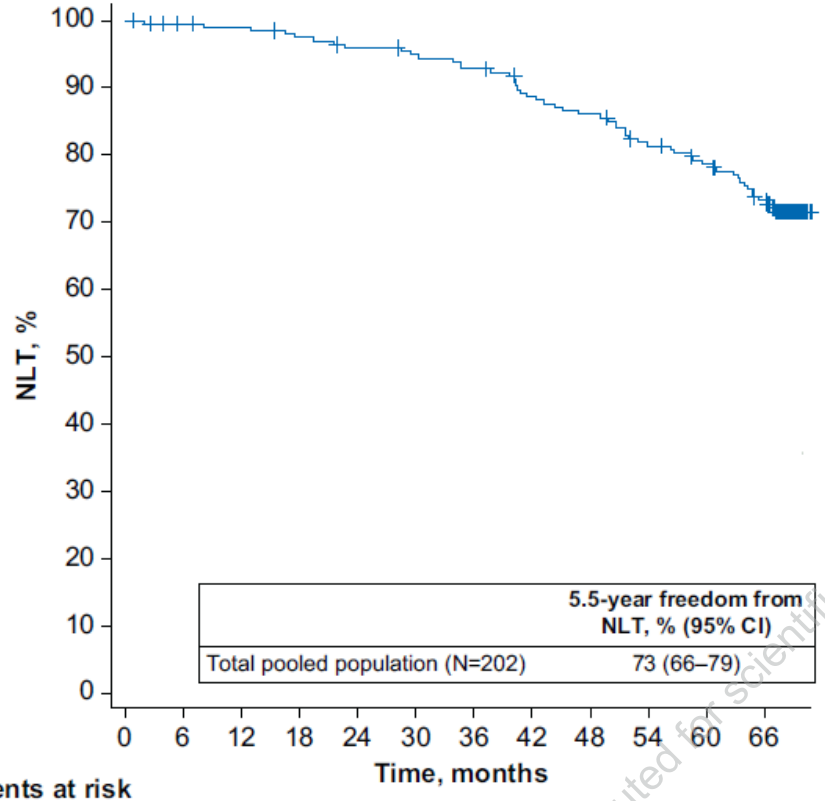
OS (FD Cohort only)



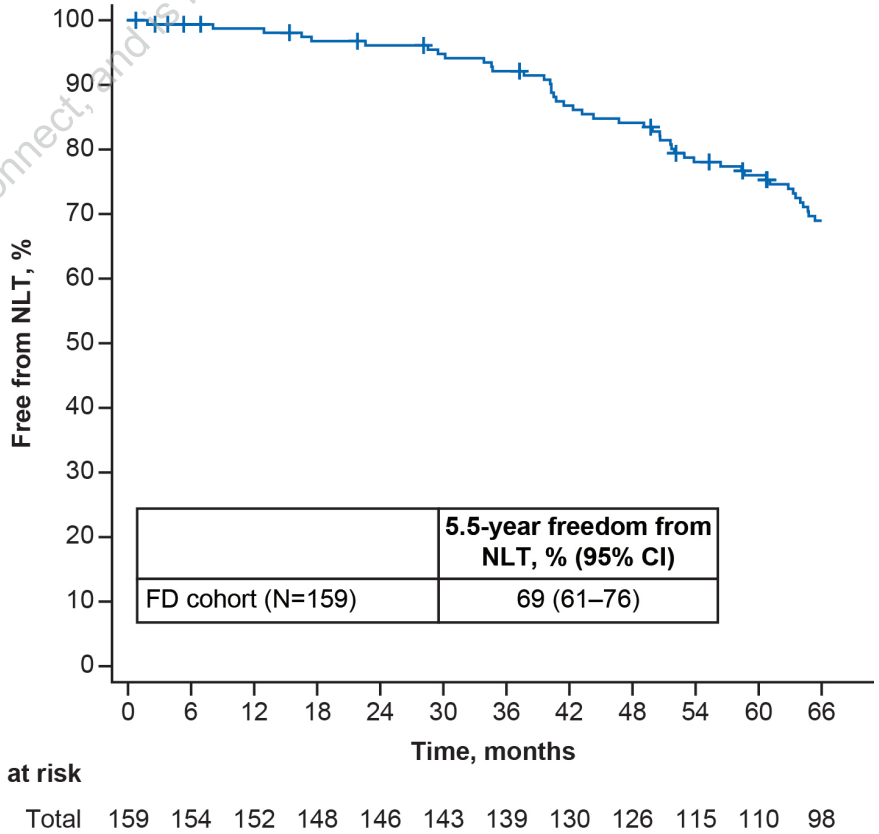
FD, fixed duration; OS, overall survival; PFS, progression-free survival.

Time to Next Treatment in the Total Pooled Population and FD Cohort Only

TTNT (Total Pooled Population)



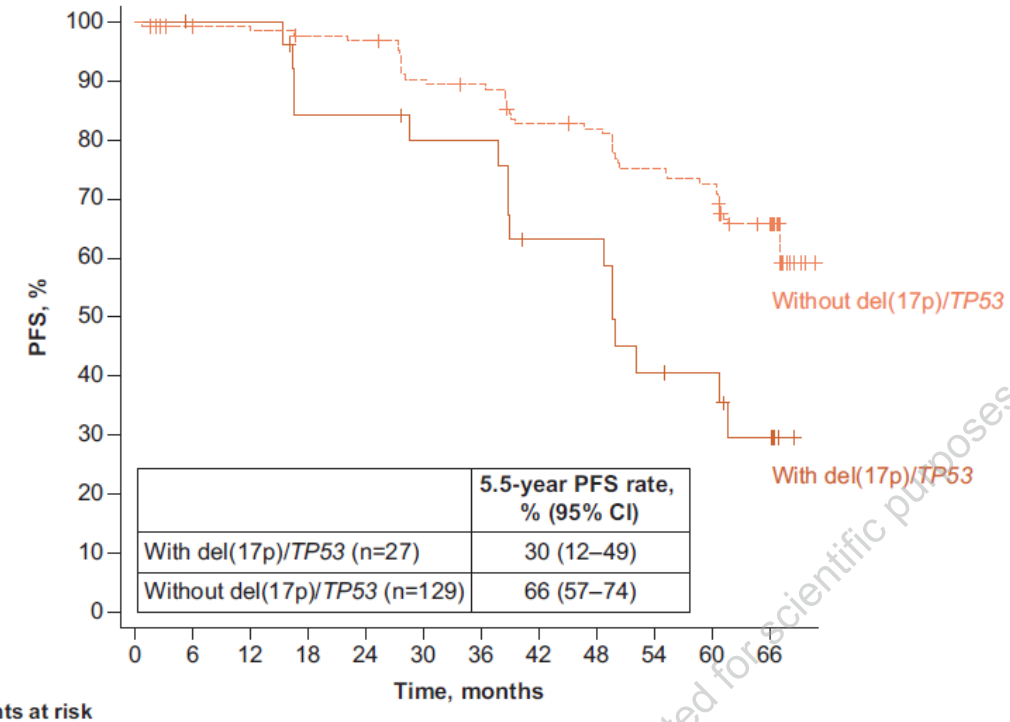
TTNT (FD Cohort only)



NLT, next-line treatment; TTNT, time to next treatment.

Impact of del(17p)/mutated *TP53* and IGHV Status On Long-Term PFS (FD Cohort)

PFS by del(17p)/*TP53* Mutation Status (FD Cohort only)

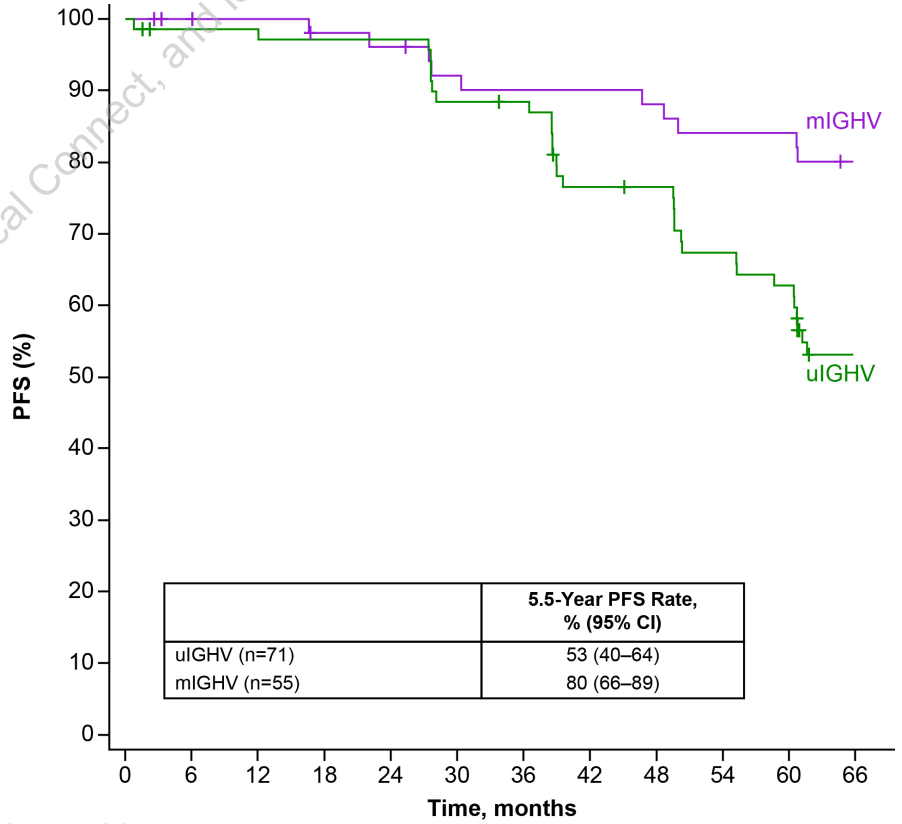


	5.5-year PFS rate, % (95% CI)
With del(17p)/*TP53* (n=27)	30 (12–49)
Without del(17p)/*TP53* (n=129)	66 (57–74)

Patients at risk

With del(17p)/*TP53*	27	26	26	21	21	19	19	14	14	9	8	5
Without del(17p)/*TP53*	129	124	123	120	119	110	108	99	97	89	86	72

PFS by IGHV Status in Patients Without del(17p)/mutated *TP53* (FD Cohort only)



	5.5-Year PFS Rate, % (95% CI)
uIGHV (n=71)	53 (40–64)
mIGHV (n=55)	80 (66–89)

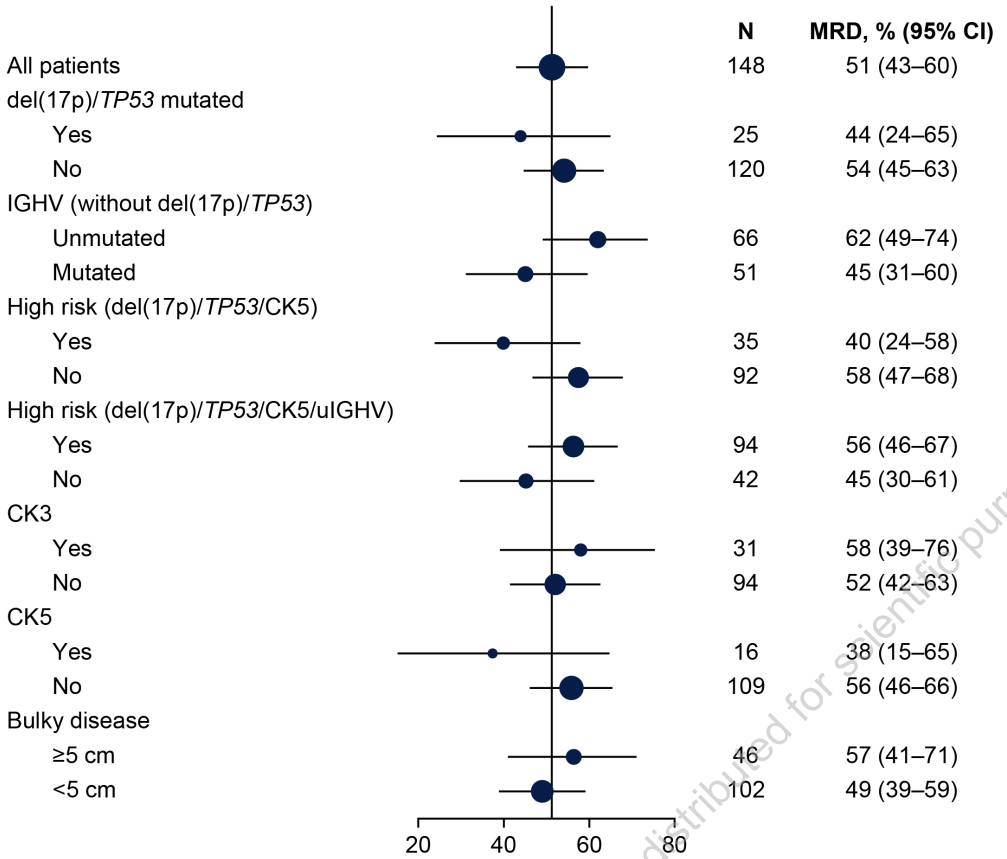
Patients at risk

mIGHV	55	53	52	50	49	46	45	45	44	42	42	39
uIGHV	71	68	68	67	67	61	60	51	50	44	41	30

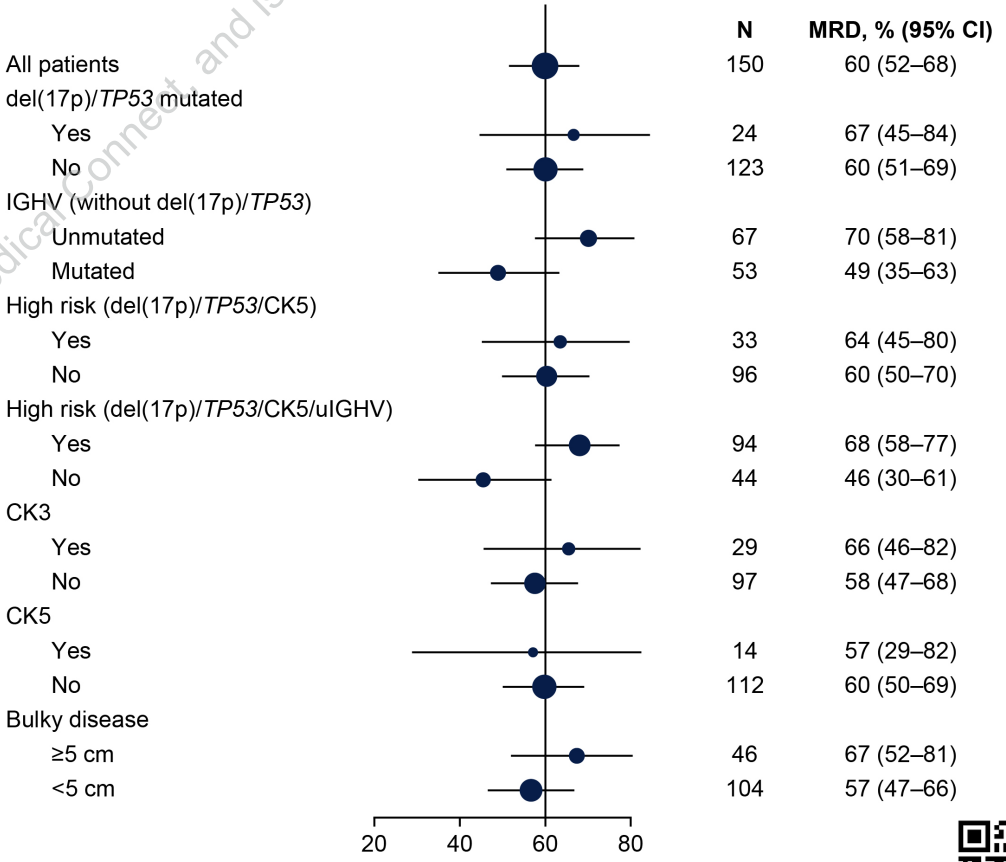
C7, cycle 7; CK, complex karyotype; FD, fixed-duration; PFS, progression-free survival; uIGHV, unmutated IGHV.

MRD Rates in FD Cohort Patients With and Without High-Risk Genomic Features

Forest Plot of uMRD4 Rates in Peripheral Blood at C7[a] According to High-Risk Genomic Features at Baseline (FD Cohort Patients)



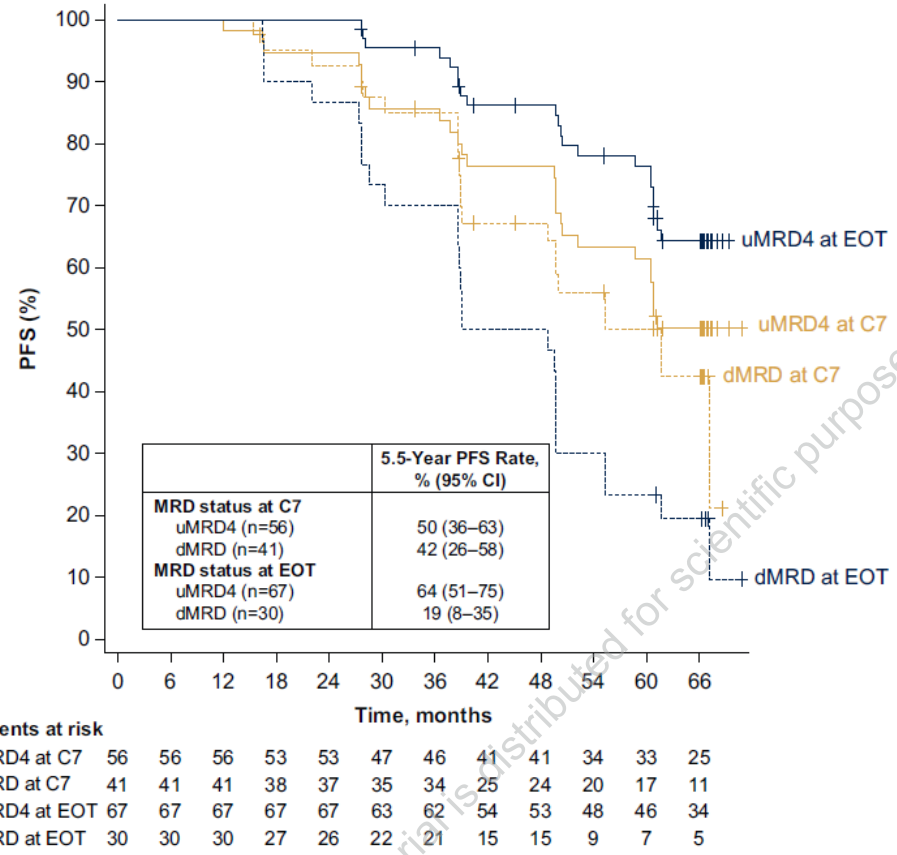
Forest Plot of uMRD4 Rates in Peripheral Blood at EOT[a] According to High-Risk Genomic Features at Baseline (FD Cohort Patients)



[a]In evaluable patients with non-missing MRD results.
C7, cycle 7; CK, complex karyotype; FD, fixed-duration; uMRD4, undetectable minimal residual disease ($<10^{-4}$).

MRD Status at EOT Is Predictive of Long-Term PFS in Patients With and Without High-Risk Genomic Features[a] and Also Predictive at C7 in Patients Without High-Risk Genomic Features (Including CK3)[a] (FD Cohort)

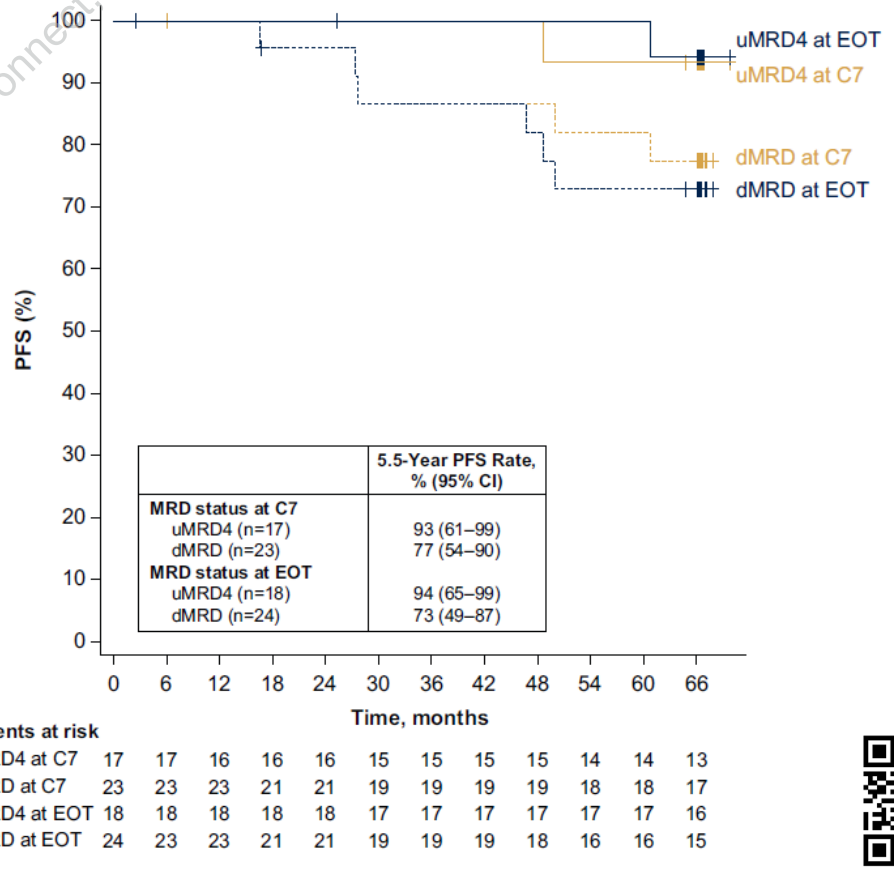
PFS by MRD Status in Patients With ≥1 High-Risk Feature (FD Cohort only)



Patients at risk

uMRD4 at C7	56	56	56	53	53	47	46	41	41	34	33	25
dMRD at C7	41	41	41	38	37	35	34	25	24	20	17	11
uMRD4 at EOT	67	67	67	67	67	63	62	54	53	48	46	34
dMRD at EOT	30	30	30	27	26	22	21	15	15	9	7	5

PFS by MRD Status in Patients Without High-Risk Features (FD Cohort only)



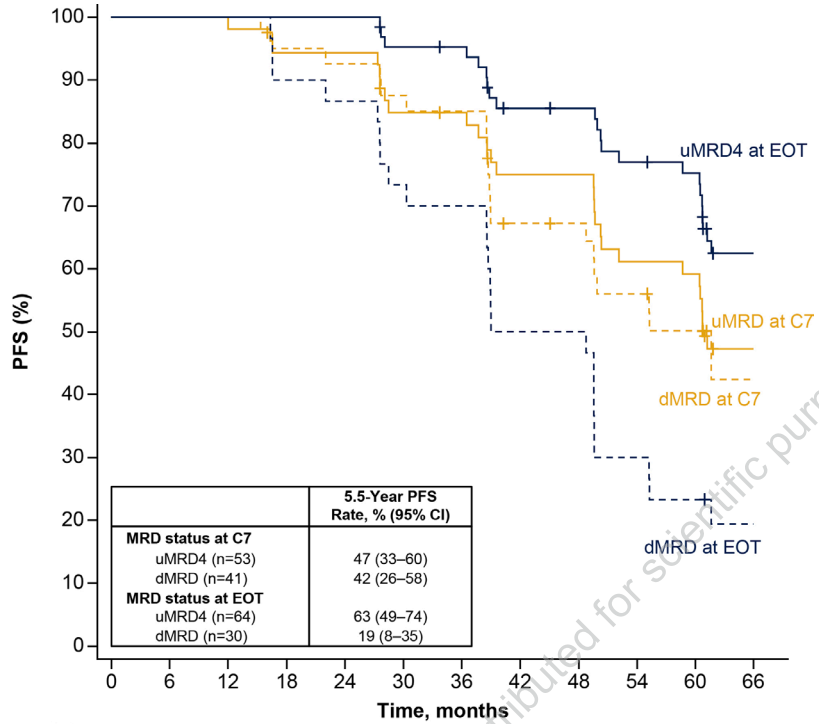
Patients at risk

uMRD4 at C7	17	17	16	16	16	15	15	15	15	14	14	13
dMRD at C7	23	23	23	21	21	19	19	19	19	18	18	17
uMRD4 at EOT	18	18	18	18	18	17	17	17	17	17	17	16
dMRD at EOT	24	23	23	21	21	19	19	19	18	16	16	15

[a]uIGHV, del(17p), mutated *TP53*, and/or CK (defined as ≥3 abnormalities).
C7, cycle 7; CK, complex karyotype; EOT, end of treatment; FD, fixed-duration; PFS, progression-free survival; uMRD4, undetectable minimal residual disease ($<10^{-4}$).

MRD Status at EOT Is Predictive of Long-Term PFS in Patients With and Without High-Risk Genomic Features[a] and Also Predictive at C7 in Patients Without High-Risk Genomic Features (Including CK5)[a] (FD Cohort)

PFS by MRD Status in Patients With ≥1 High-Risk Feature (FD Cohort only)

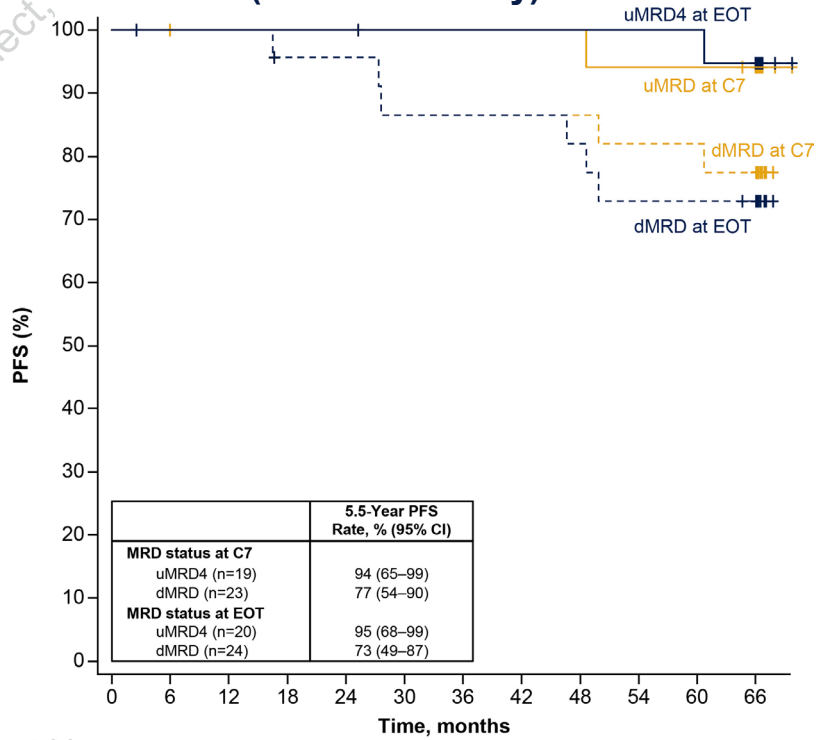


	5.5-Year PFS Rate, % (95% CI)
MRD status at C7	
uMRD4 (n=53)	47 (33–60)
dMRD (n=41)	42 (26–58)
MRD status at EOT	
uMRD4 (n=64)	63 (49–74)
dMRD (n=30)	19 (8–35)

Patients at risk

uMRD4 at C7	53	53	53	50	50	44	43	38	38	31	30	22
dMRD at C7	41	41	41	38	37	35	34	25	24	20	17	11
uMRD4 at EOT	64	64	64	64	64	60	59	51	50	45	43	31
dMRD at EOT	30	30	30	27	26	22	21	15	15	9	7	5

PFS by MRD Status in Patients Without High-Risk Features (FD Cohort only)



	5.5-Year PFS Rate, % (95% CI)
MRD status at C7	
uMRD4 (n=19)	94 (65–99)
dMRD (n=23)	77 (54–90)
MRD status at EOT	
uMRD4 (n=20)	95 (68–99)
dMRD (n=24)	73 (49–87)

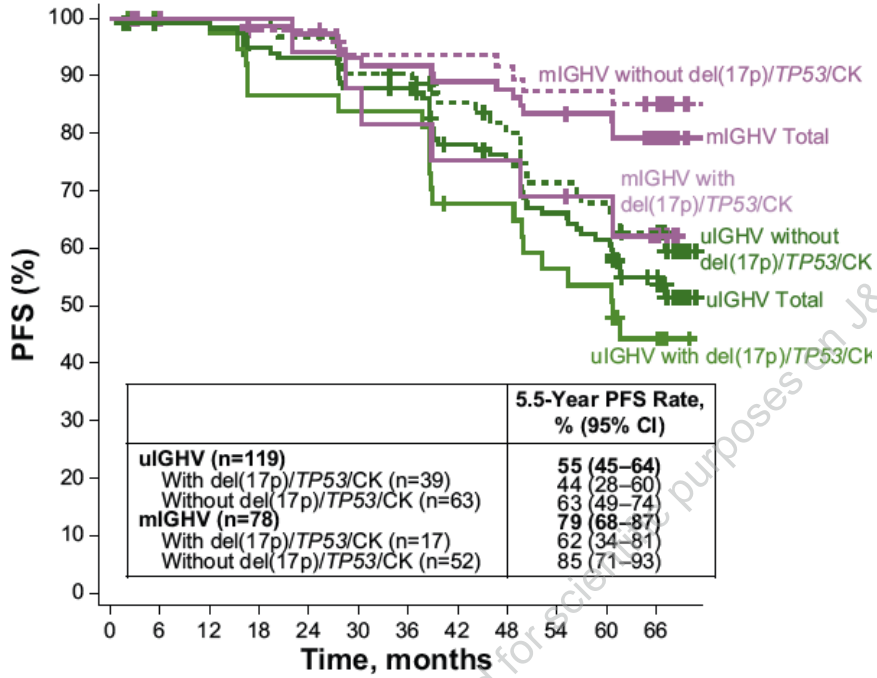
Patients at risk

uMRD4 at C7	19	19	18	18	18	17	17	17	17	16	16	15
dMRD at C7	23	23	23	21	21	19	19	19	19	18	18	17
uMRD4 at EOT	20	20	20	20	20	19	19	19	19	19	19	18
dMRD at EOT	24	23	23	21	21	19	19	19	18	16	16	15

[a]uIGHV, del(17p), mutated *TP53*, and/or CK (defined as ≥5 abnormalities).
C7, cycle 7; CK, complex karyotype; EOT, end of treatment; FD, fixed-duration; PFS, progression-free survival; uMRD4, undetectable minimal residual disease ($<10^{-4}$).

Long-Term PFS in Patients With uIGHV and mIGHV, With or Without One or More: del(17p), Mutated *TP53*, and CK3[a] (Total Pooled Population and FD Cohort)

PFS by IGHV Status With or Without Concomitant del(17p)/*TP53*/CK (Total Pooled Population)

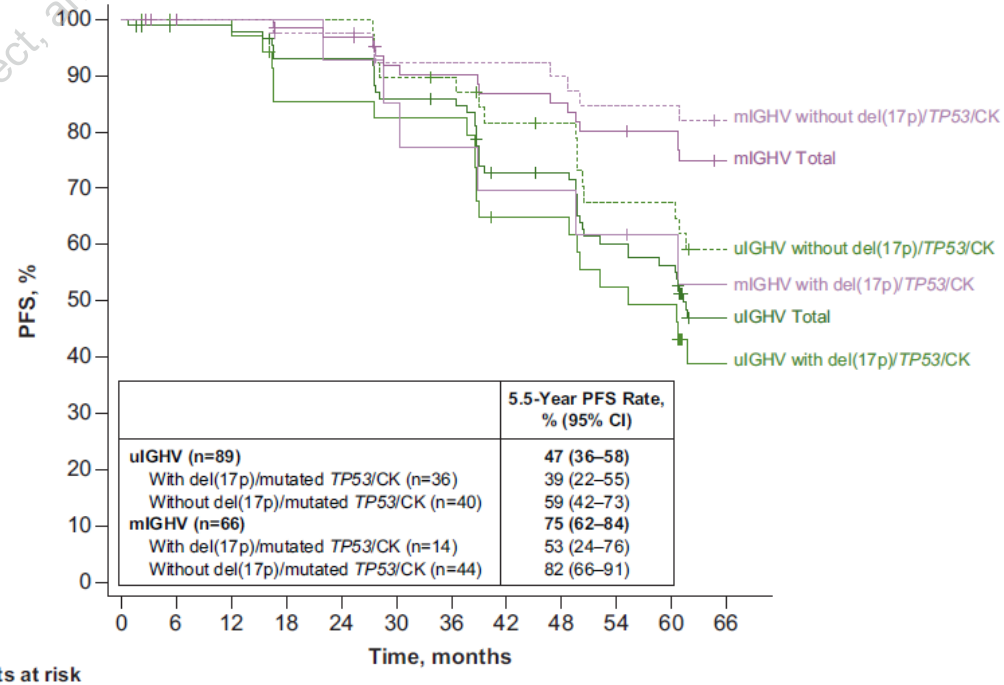


	5.5-Year PFS Rate, % (95% CI)
uIGHV (n=119)	**55 (45–64)**
With del(17p)/*TP53*/CK (n=39)	44 (28–60)
Without del(17p)/*TP53*/CK (n=63)	63 (49–74)
mIGHV (n=78)	**79 (68–87)**
With del(17p)/*TP53*/CK (n=17)	62 (34–81)
Without del(17p)/*TP53*/CK (n=52)	85 (71–93)

Patients at risk

uIGHV with del(17p)/*TP53*/CK	39	38	38	32	32	31	31	24	24	20	19	12
uIGHV without del(17p)/*TP53*/CK	63	62	62	62	60	56	55	50	46	41	39	35
uIGHV Total	119	115	115	109	107	101	100	86	82	72	67	53
mIGHV with del(17p)/*TP53*/CK	17	17	17	17	16	14	13	12	12	11	10	8
mIGHV without del(17p)/*TP53*/CK	52	50	49	47	47	44	44	44	43	41	41	39
mIGHV Total	78	76	75	73	72	67	66	64	63	60	59	54

PFS by IGHV Status With or Without Concomitant del(17p)/*TP53*/CK (FD Cohort only)



	5.5-Year PFS Rate, % (95% CI)
uIGHV (n=89)	**47 (36–58)**
With del(17p)/mutated *TP53*/CK (n=36)	39 (22–55)
Without del(17p)/mutated *TP53*/CK (n=40)	59 (42–73)
mIGHV (n=66)	**75 (62–84)**
With del(17p)/mutated *TP53*/CK (n=14)	53 (24–76)
Without del(17p)/mutated *TP53*/CK (n=44)	82 (66–91)

Patients at risk

uIGHV del(17p)/*TP53*/CK	36	35	35	29	29	28	28	21	21	17	16	9
uIGHV without del(17p)/*TP53*/CK	40	39	39	39	39	35	34	30	29	24	24	20
uIGHV Total	89	85	85	79	79	73	72	59	58	48	45	32
uIGHV del(17p)/*TP53*/CK	14	14	14	14	13	11	10	9	9	8	7	6
uIGHV without del(17p)/*TP53*/CK	44	42	41	39	39	36	36	36	35	33	33	31
uIGHV Total	66	64	63	61	60	55	54	52	51	48	47	43

[a]Defined as ≥3 abnormalities.

Safety of Ibrutinib-Based Retreatment Shows No New Safety Signals

TEAEs,[a] n (%)	Single-agent ibrutinib n=25	FD ibrutinib + venetoclax n=11
Any AE	22 (88)	11 (100)
Most frequent AEs[b]		
COVID-19	6 (24)	2 (18)
Diarrhea	5 (20)	4 (36)
Hypertension	5 (20)	5 (45)
Grade 3 or 4 AEs	9 (36)	4 (36)
AEs leading to discontinuation	1 (4)	0
AEs leading to dose reduction	0	0

Second Malignancies Across the Entire Study Period[c]

- Across the entire study period, second malignancies occurred in 24 patients:
  - During the TEAE period for FD ibrutinib + venetoclax in 12 patients (8 non-melanoma skin cancers, 6 other cancers)
  - After the initial TEAE period and before retreatment in 9 patients (4 non-melanoma skin cancers, 7 other cancers)
  - During the TEAE period for ibrutinib-based retreatment in 4 patients (4 non-melanoma skin cancers, 1 other cancer)

[a]TEAEs were collected until 30 days after the last dose of study treatment or the start of subsequent therapy, whichever occurred first. [b]Occurring in ≥20% of patients who received single-agent ibrutinib or ibrutinib + venetoclax. [c]Serious AEs considered related to study treatment and second malignancies continued to be collected after completion of the FD treatment-emergent period (up to 30 days after last dose of study treatment or start of subsequent therapy, whichever occurred first).
AE, adverse event; TEAE, treatment-emergent adverse event.