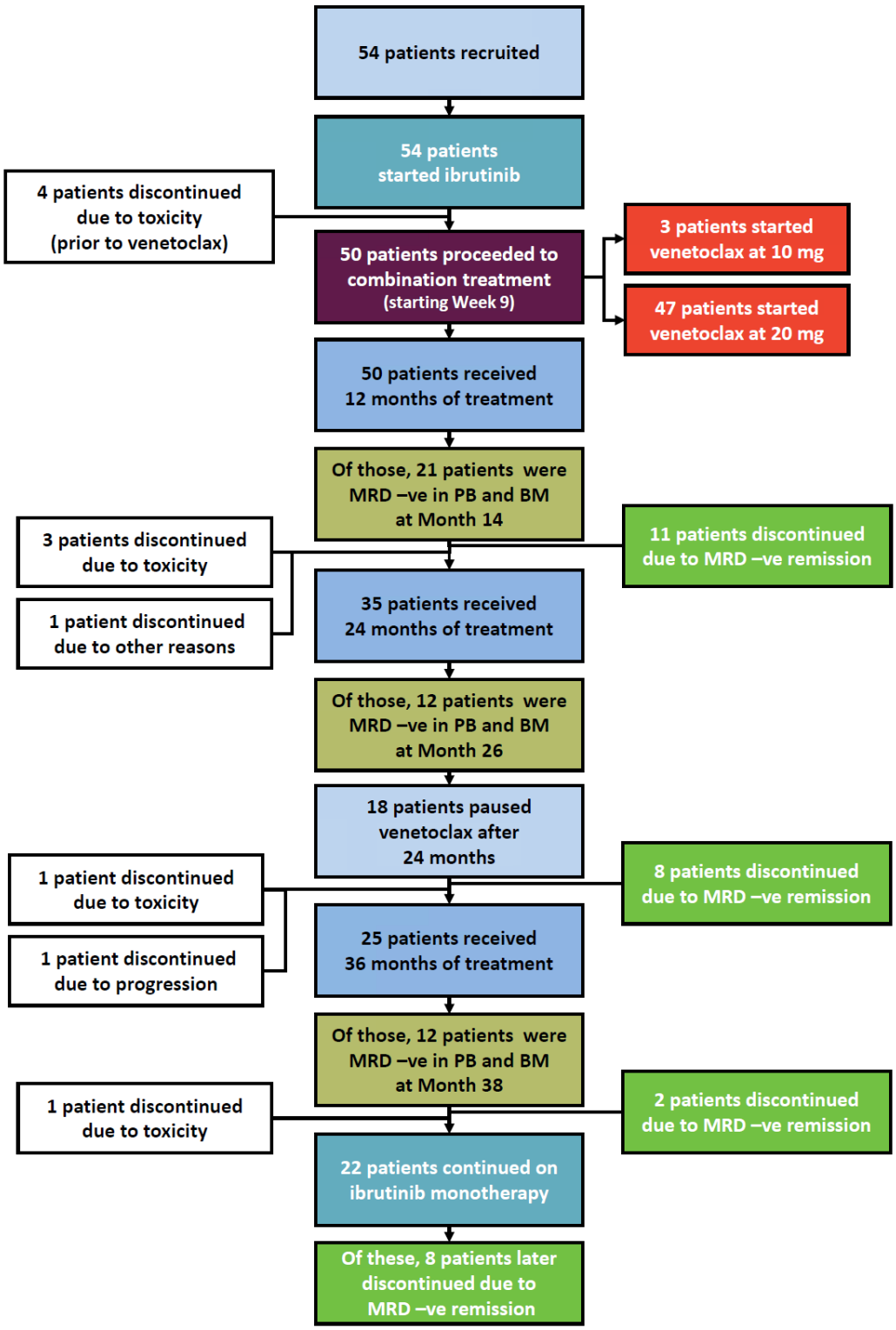
CLARITY Trial: Basic Results Summary

Contents

Participant flow

Figure 1: Participant Flow



Baseline Characteristics

Table 1: Baseline Characteristics

Current disease status	Relapsed (49)	Refractory (5)	Overall (54)
Age			
N	49	5	54
Median	63	65	64
IQR	58, 70	63, 69	58, 70
Range	31, 83	58, 75	31, 83
Gender (N (%))			
Male	34 (69)	3 (60)	37 (69)
Female	15 (31)	2 (40)	17 (31)
Total	49 (100)	5 (100)	54 (100)
Time from diagnosis to registration, years			
N	48	5	53
Median	7	7	7
IQR	5, 10	6, 11	5, 10
Range	0, 27	0, 15	0, 27
Number of previous treatments			
N	49	5	54
Median	1	2	1
IQR	1, 2	1, 3	1, 2
Range	1, 6	1, 6	1, 6
Original CLL stage (N (%))			
Progressive stage A	16 (33)	3 (60)	19 (35)
Stage B	9 (18)	1 (20)	10 (19)
Stage C	5 (10)	0 (0)	5 (9)
Not Known	19 (39)	1 (20)	20 (37)
Total	49 (100)	5 (100)	54 (100)
ECOG performance status (N (%))			
0	31 (63)	2 (40)	33 (61)
1	15 (31)	3 (60)	18 (33)
2	3 (6)	0 (0)	3 (6)
Total	49 (100)	5 (100)	54 (100)

Outcome measures

1. Primary:

1. Proportion of patients with <0.01% MRD in the blood and bone marrow at Month 14

2. Secondary:

1. Proportion of patients with <0.01% MRD in the blood and bone marrow at Months 8, 26 and 38
2. Response rate by the International Workshop on Chronic Lymphocytic Leukaemia (IWCLL) criteria at Months 8, 14, 26 and 38
3. Best response according to the IWCLL criteria at any point
4. Progression-free survival (PFS) (defined as time from date of registration to date of progression) or death from any cause
5. Overall survival (OS) (defined as time from date of registration to date of death from any cause)
6. Toxicity of combination therapy (frequency, duration and severity of adverse events (AEs) and serious adverse events (SAEs))
7. Biological Response; including:
    a. The proportion of patients with >5%, 0.5-5%, <0.5% CLL cells in cell cycle (expressing Ki67) in the peripheral blood and bone marrow at Months 8, 14, 26, and 38
    b. The proportion of patients with more than 50% reduction in BCL2 expression by CLL cells relative to baseline after 6, 12 and 24 months of ibrutinib plus venetoclax
    c. Change in the expression levels of CD10, CD103, CD11c, CD185, CD196, CD20, CD200, CD22, CD23, CD25, CD27, CD305, CD31, CD38, CD39, CD43, CD49d, CD5, CD79b, CD81, CD95, IgD, IgG, IgM or ROR1 on CLL cells relative to baseline by more than 50% and at least 500 arbitrary units in median fluorescence intensity.

Exploratory:

1. Change in phosphoprotein expression (including Akt, Syk, MAPK, ERK and Btk) in CLL cells with or without BCR-stimulation in the presence and absence of *in vitro* ibrutinib and Bcl-2 protein expression.
2. Investigation of the apoptotic pathway, including BAX expression
3. Depletion of MRD below 10-5 and 10-6 using high sensitivity flow cytometry and high-throughput sequencing
4. Mechanisms of resistance: analysis of acquired mutations in patients developing resistant disease. Additional mechanisms of resistance are likely to be reported over time and therefore this will be a retrospective analysis.
5. Epigenetic alterations: chromatin Immunoprecipitation experiments will be performed on selected cases

Results

1. Primary outcome:

1.1. Proportion of patients with <0.01% MRD in the blood and bone marrow at Month 14

2. Secondary outcomes:

2.1. Proportion of patients with <0.01% MRD in the blood and bone marrow at Months 8, 26 and 38

Table 2: MRD responses at months 8, 14, 26 and 38

Table 16: Summary of MRD negativity

Description	M8: #	M8: prop. (95% CI)	M14: #	M14: prop. (95% CI)	M26: #	M26: prop. (95% CI)	M38: #	M38: prop. (95% CI)
Negative	**13**	**26% (15%, 40%)**	**20**	**40% (26%, 55%)**	**20**	**40% (26%, 55%)**	**21**	**42% (28%, 57%)**
Negative in BM & PB	13	26% (15%, 40%)	20	40% (26%, 55%)	16	32% (20%, 47%)	12	24% (13%, 38%)
BM & PB available	*12*	*24% (13%, 38%)*	*20*	*40% (26%, 55%)*	*13*	*26% (15%, 40%)*	*6*	*12% (5%, 24%)*
BM available; imputed PB using sub.	*1*	*2% (0%, 11%)*	*0*	-	*0*	-	*0*	-
PB available; imputed BM using prev.	*0*	-	*0*	-	*3*	*6% (1%, 17%)*	*5*	*10% (3%, 22%)*
PB available; imputed BM using sub.	*0*	-	*0*	-	*0*	-	*1*	*2% (0%, 11%)*
PB <0.001%; last known BM <0.01%	0	-	0	-	4	8% (2%, 19%)	9	18% (9%, 31%)
Neither available; imputed PB using prev.	*0*	-	*0*	-	*0*	-	*1*	*2% (0%, 11%)*
PB available	*0*	-	*0*	-	*4*	*8% (2%, 19%)*	*8*	*16% (7%, 29%)*
Positive	**37**	**74% (60%, 85%)**	**30**	**60% (45%, 74%)**	**26**	**52% (37%, 66%)**	**19**	**38% (25%, 53%)**
PB <0.01%; last known BM ≥0.01%	0	-	1	2% (0%, 11%)	2	4% (0%, 14%)	2	4% (0%, 14%)
Neither available; imputed PB using sub.	*0*	-	*1*	*2% (0%, 11%)*	*0*	-	*0*	-
PB available	*0*	-	*0*	-	*2*	*4% (0%, 14%)*	*2*	*4% (0%, 14%)*
Positive in BM & / or PB	37	74% (60%, 85%)	29	58% (43%, 72%)	24	48% (34%, 63%)	16	32% (20%, 47%)
BM & PB available	*33*	*66% (51%, 79%)*	*27*	*54% (39%, 68%)*	*24*	*48% (34%, 63%)*	*7*	*14% (6%, 27%)*
BM available	*1*	*2% (0%, 11%)*	*1*	*2% (0%, 11%)*	*0*	-	*0*	-
Neither available; imputed PB using prev.	*0*	-	*0*	-	*0*	-	*1*	*2% (0%, 11%)*
Neither available; imputed PB using sub.	*0*	-	*0*	-	*0*	-	*1*	*2% (0%, 11%)*
PB available	*3*	*6% (1%, 17%)*	*1*	*2% (0%, 11%)*	*0*	-	*6*	*12% (5%, 24%)*
PB available; imputed BM using prev.	*0*	-	*0*	-	*0*	-	*1*	*2% (0%, 11%)*
Previous & next PB are ≥0.01%	0	-	0	-	0	-	1	2% (0%, 11%)
Neither available	*0*	-	*0*	-	*0*	-	*1*	*2% (0%, 11%)*
Not known	**0**	-	**0**	-	**4**	**8% (2%, 19%)**	**8**	**16% (7%, 29%)**
No measurements	0	-	0	-	0	-	2	4% (0%, 14%)
Neither available	*0*	-	*0*	-	*0*	-	*2*	*4% (0%, 14%)*
PB <0.01%; last known BM <0.01%	0	-	0	-	4	8% (2%, 19%)	6	12% (5%, 24%)
Neither available; imputed PB using prev.	*0*	-	*0*	-	*2*	*4% (0%, 14%)*	*3*	*6% (1%, 17%)*
Neither available; imputed PB using sub.	*0*	-	*0*	-	*1*	*2% (0%, 11%)*	*0*	-
PB available	*0*	-	*0*	-	*1*	*2% (0%, 11%)*	*3*	*6% (1%, 17%)*
Progression	**0**	-	**0**	-	**0**	-	**2**	**4% (0%, 14%)**
Progression confirmed prior to assessment	0	-	0	-	0	-	2	4% (0%, 14%)
Neither available	*0*	-	*0*	-	*0*	-	*2*	*4% (0%, 14%)*

= number; prop. = proportion; CI = confidence interval
prev. / sub. = nearest measurement to the time point within the previous/subsequent 6 months
Negative = <0.01% MRD; Positive = ≥0.01% MRD
NK = Not known; BM = bone marrow; PB = peripheral blood

The bold text outlines the number of patients in each category, and the italic text gives a breakdown of how that classification was reached.

2.2. Response rate by the International Workshop on Chronic Lymphocytic Leukaemia (IWCLL) criteria at Months 8, 14, 26 and 38

Table 3: Summary of responses at month 8, 14, 26 and 38

IWCLL Response (N = 50)	M8: #n	Prop. (95% CI)	M14: #n	Prop. (95% CI)	M26: #n	Prop. (95% CI)	M38: #n	Prop. (95% CI)
On treatment								
CR	20	40% (26%, 55%)	23	46% (32%, 61%)	19	38% (25%, 53%)	13	26% (15%, 40%)
CRi	4	8% (2%, 19%)	4	8% (2%, 19%)	0	0% (0%, 7%)	3	6% (1%, 17%)
PR	26	52% (37%, 66%)	19	38% (25%, 53%)	12	24% (13%, 38%)	2	4% (0%, 14%)
SD	0	0% (0%, 7%)	1	2% (0%, 11%)	1	2% (0%, 11%)	1	2% (0%, 11%)
Not known	0	0% (0%, 7%)	1	2% (0%, 11%)	1	2% (0%, 11%)	1	2% (0%, 11%)
Off treatment								
CR	0	0% (0%, 7%)	1	2% (0%, 11%)	11	22% (12%, 36%)	9	18% (9%, 31%)
CRi	0	0% (0%, 7%)	1	2% (0%, 11%)	1	2% (0%, 11%)	1	2% (0%, 11%)
PR	0	0% (0%, 7%)	0	0% (0%, 7%)	1	2% (0%, 11%)	1	2% (0%, 11%)
PD	0	0% (0%, 7%)	0	0% (0%, 7%)	1	2% (0%, 11%)	1	2% (0%, 11%)
Death	0	0% (0%, 7%)	0	0% (0%, 7%)	0	0% (0%, 7%)	1	2% (0%, 11%)
Not known (MRD -ve)	0	0% (0%, 7%)	0	0% (0%, 7%)	2	4% (0%, 14%)	13	26% (15%, 40%)
Not known	0	0% (0%, 7%)	0	0% (0%, 7%)	1	2% (0%, 11%)	4	8% (2%, 19%)

#n = number of patients in the response category;
M = Month; Prop. = proportion of patients; CI = Confidence Interval;

CR = Complete remission; CRi = CR with incomplete marrow recovery; PR = Partial remission;
SD = Stable disease; PD = Progressive disease
Not known (MRD -ve) = Response not known but discontinued due to MRD negative remission

2.3. Best response according to the IWCLL criteria at any point

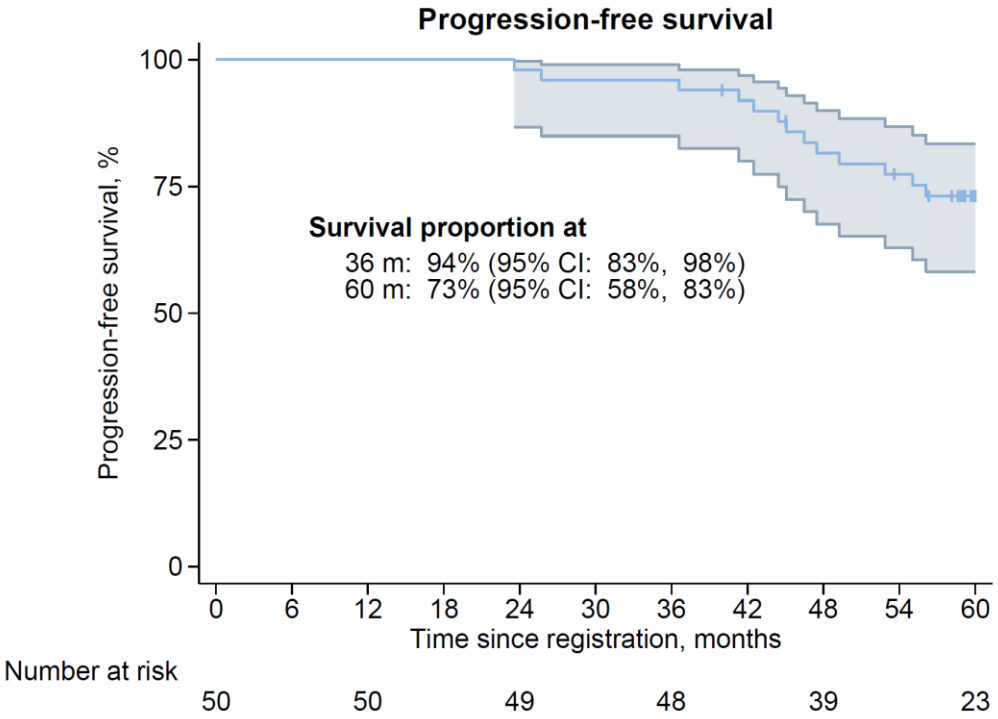
Table 4: Best response according to the IWCLL criteria at any point

Best IWCLL response (N = 50)	#n	Proportion (95% CI)
Complete Remission (CR)	43	86% (73%, 94%)
CR with incomplete marrow recovery (CRi)	1	2% (0%, 11%)
Partial Remission (PR)	6	12% (5%, 24%)

#n = number of patients in the response category
CI = Confidence Interval

2.4. Progression-free survival (PFS) (defined as time from date of registration to date of progression) or death from any cause

Figure 2: Progression Free Survival (PFS)



2.5. Overall survival (OS) (defined as time from date of registration to date of death from any cause)

Figure 3: Overall Survival (OS)

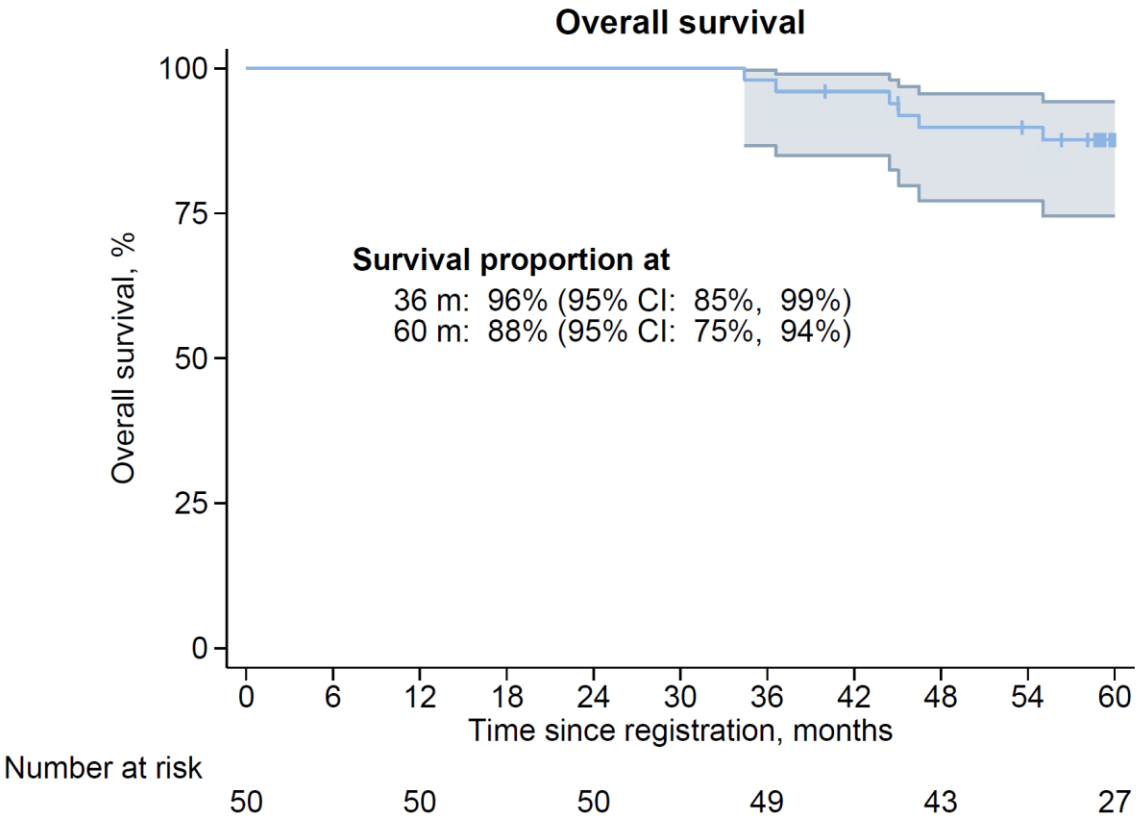


Table 5: Summary of causes of death

Cause of death (N (%))	
Chronic lymphocytic leukaemia (CLL) Related	6 (50)
Other cancer	3 (25)
Not known	3 (25)
Total	12 (100)

2.6. Toxicity of combination therapy (frequency, duration and severity of adverse events (AEs) and serious adverse events (SAEs))

A total of 1081 AEs were experienced by 53 patients

Table 6: Summary of AEs per patient

Experienced an AE of any grade? (N (%))	
No	1 (2)
Yes	53 (98)
Total	54 (100)
Number of AEs (of any grade)	
N	54
Median	19
Range	0, 85
Experienced a potentially related AE of grade 3 or above? (N (%))	
No	31 (57)
Yes	23 (43)
Total	54 (100)
Number of potentially related AEs of grade 3 or above	
N	54
Median	0
Range	0, 8
Experienced a haematological AE? (N (%))	
No	34 (63)
Yes	20 (37)
Total	54 (100)
Experienced a non-haematological AE? (N (%))	
No	1 (2)
Yes	53 (98)
Total	54 (100)

For the purposes of the table above, a haematological AE is defined as the patient experiencing at least one of: anemia, platelet count decreased, febrile neutropenia, neutrophil count decreased. Any other term is considered a non-haematological AE.

Further details on proportion of AEs and severity are shown in the figures below. A summary of AE terms can be found in the 'Adverse Events' section of this document.

Figure 4: Breakdown of toxicities occurring in at least 5% of patients: number of events reported;

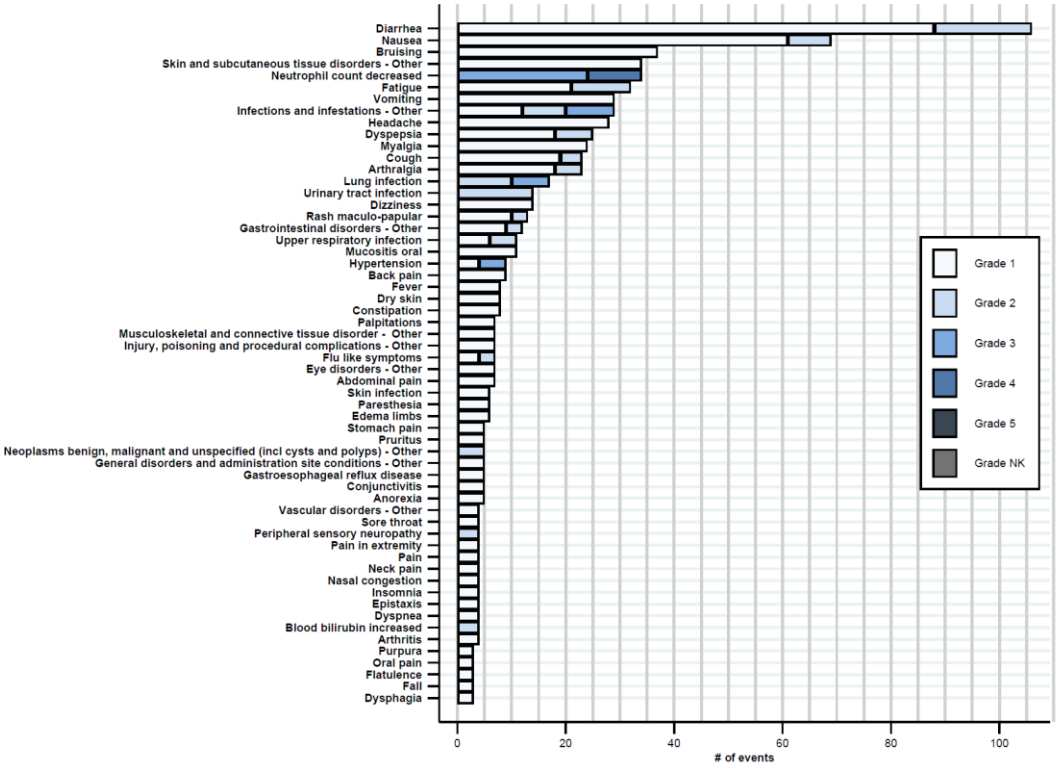


Figure 5: Breakdown of toxicities occurring in at least 5% of patients: proportion of patients, according to the maximum grade experienced

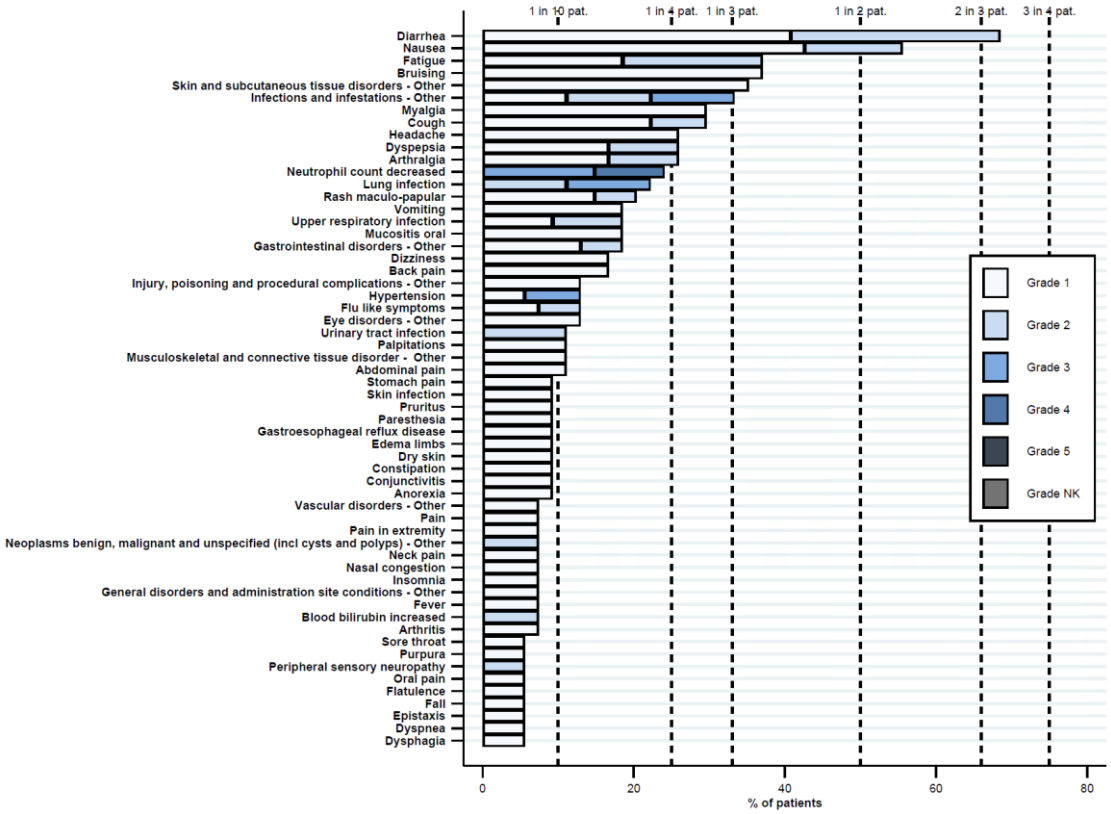


Figure 6: Breakdown of all potentially related toxicities

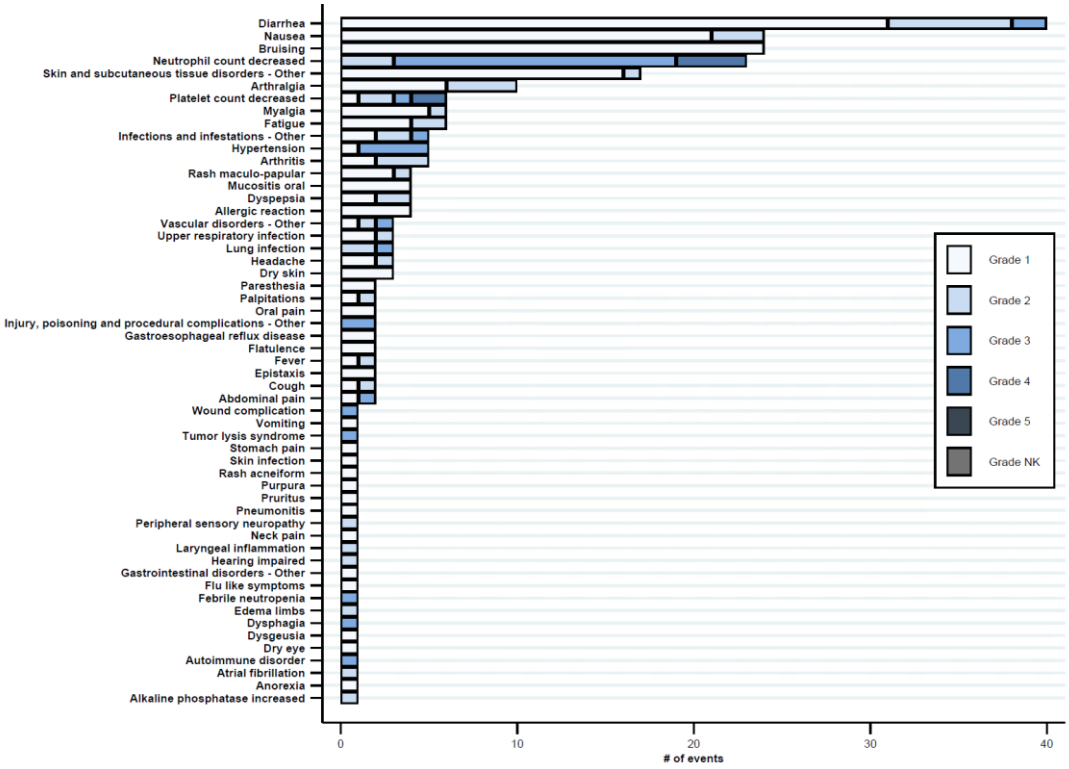
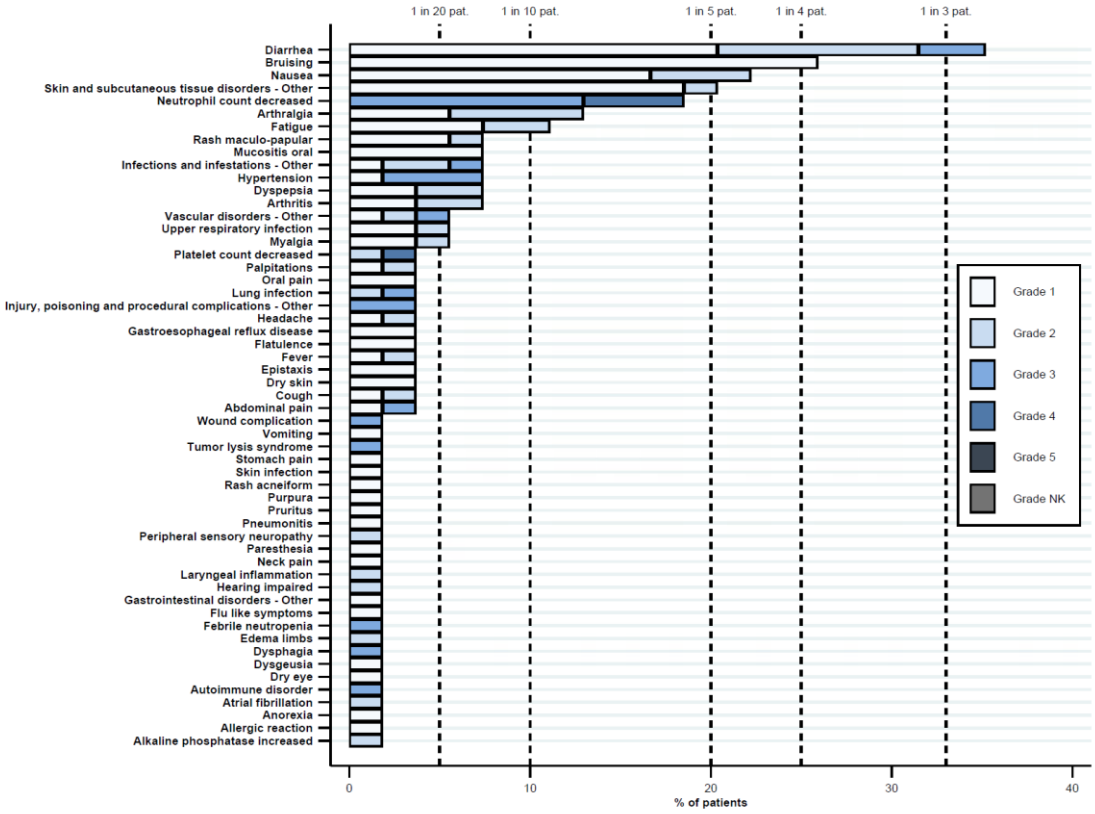


Figure 7: Breakdown potentially related toxicities: proportion of patients, according to the maximum grade experienced



A total of 48 serious adverse events (SAEs) were reported in 26 patients.

Table 7: Summary of reported Serious Adverse Events

Category of SAE (N (%))	
Unrelated SAE	18 (38)
SAR	28 (58)
Non fatal/life-threatening SUSAR	2 (4)
Total	48 (100)
Reason (N (%))	
Life-Threatening event	1 (2)
Hospitalisation	43 (90)
Life-Threatening event, Hospitalisation	1 (2)
Other reason	3 (6)
Total	48 (100)
Relatedness (N (%))	
Potentially related to ibrutinib	8 (17)
Potentially related to ibrutinib+venetoclax	20 (42)
Potentially related to venetoclax	2 (4)
Unlikely to be related to ibrutinib or venetoclax	18 (38)
Total	48 (100)
Outcome (N (%))	
Resolved - no sequelae	36 (75)
Resolved - with sequelae	12 (25)
Total	48 (100)

N = Number of events

SAR = Serious Adverse Reaction, SUSAR = Suspected Unexpected SAR

Table 8: Summary of grades in reported Serious Adverse Events

Grade of admitting event (N (%))	
1	4 (8)
2	7 (15)
3	36 (75)
4	1 (2)
Total	48 (100)
Maximum grade of an event experienced as part of the SAE* (N (%))	
1	1 (2)
2	7 (15)
3	38 (79)
4	2 (4)
Total	48 (100)

N = Number of events
May not be the admitting event

2.7. Biological Response (and Exploratory Outcomes)

In the exploratory analysis, several samples were analysed at baseline, pre-initiation of venetoclax and after venetoclax escalation. The results of these analysis were severely limited by the fact that the combination resulted in very deep clinical and minimal residual disease responses. The changes in cell surface expression, phosphorylation of intracellular kinases and apoptotic machinery pathway were analysed but no further scientific information could be inferred. This data is not further elaborated in the CSR.

Adverse Events

Table 9: Adverse Event Toxicities

Toxicity term	# occurrences	(# patients affected)
Diarrhea	121	(38)
Nausea	74	(31)
Infections and infestations (other)	43	(22)
Headache	42	(18)
Bruising	40	(21)
Fatigue	39	(24)
Neutrophil count decreased	38	(14)
Skin and subcutaneous tissue disorders (other)	38	(23)
Vomiting	35	(12)
Arthralgia	28	(15)
Myalgia	27	(16)
Cough	26	(17)
Dyspepsia	26	(15)
Platelet count decreased	24	(3)
Urinary tract infection	24	(7)
Lung infection	22	(16)
Dizziness	20	(11)
Gastrointestinal disorders (other)	18	(12)
Fever	16	(11)
Mucositis oral	16	(11)
Upper respiratory infection	15	(12)
Rash maculo-papular	14	(11)
Edema limbs	13	(9)
Hypertension	13	(10)
Musculoskeletal and connective tissue disorder (other)	13	(10)
Back pain	12	(11)
Injury, poisoning and procedural complications (other)	12	(11)
Palpitations	12	(9)
Skin infection	12	(9)
Abdominal pain	11	(10)
Dyspnea	11	(9)
Anorexia	10	(7)
Paresthesia	10	(6)
Conjunctivitis	9	(8)
Constipation	9	(6)
Dry skin	9	(5)
Gastroesophageal reflux disease	9	(7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (other)	9	(7)
Alkaline phosphatase increased	8	(4)
Blood bilirubin increased	8	(5)
Epistaxis	8	(4)
Eye disorders (other)	8	(7)
Arthritis	7	(6)
Flu like symptoms	7	(7)

Toxicity term	# occurrences	(# patients affected)
Anemia	6	(3)
Atrial fibrillation	6	(5)
Dysphagia	6	(5)
Neck pain	6	(6)
Nervous system disorders (other)	6	(4)
Pain	6	(5)
Pain in extremity	6	(6)
Pruritus	6	(6)
Vascular disorders (other)	6	(6)
Insomnia	5	(4)
Peripheral sensory neuropathy	5	(4)
Respiratory, thoracic and mediastinal disorders (other)	5	(4)
Stomach pain	5	(5)
Allergic reaction	4	(1)
Chills	4	(3)
Concentration impairment	4	(2)
Confusion	4	(2)
Depression	4	(3)
Fall	4	(4)
General disorders and administration site conditions (other)	4	(4)
Laryngeal inflammation	4	(4)
Nasal congestion	4	(4)
Otitis media	4	(2)
Rash acneiform	4	(3)
Renal and urinary disorders (other)	4	(3)
Sinusitis	4	(3)
Sore throat	4	(3)
Alopecia	3	(2)
Anxiety	3	(2)
Bloating	3	(3)
Erythema multiforme	3	(3)
Flatulence	3	(3)
Investigations (other)	3	(3)
Oral pain	3	(3)
Pericarditis	3	(1)
Purpura	3	(3)
Sinus bradycardia	3	(2)
Tremor	3	(2)
Acute kidney injury	2	(2)
Alanine aminotransferase increased	2	(1)
Anal hemorrhage	2	(1)
Aspartate aminotransferase increased	2	(1)
Blurred vision	2	(1)
Bone pain	2	(2)
Chest pain - cardiac	2	(1)
Creatinine increased	2	(2)

Toxicity term	# occurrences	(# patients affected)
Cystitis noninfective	2	(2)
Dry eye	2	(2)
Dry mouth	2	(2)
Dysgeusia	2	(2)
Ear and labyrinth disorders (other)	2	(2)
Edema face	2	(2)
Eye pain	2	(2)
Facial muscle weakness	2	(1)
Febrile neutropenia	2	(2)
Gastritis	2	(1)
Gastrointestinal pain	2	(1)
Hallucinations	2	(2)
Hearing impaired	2	(2)
Hematuria	2	(2)
Hypokalemia	2	(2)
Hypotension	2	(1)
Localized edema	2	(2)
Metabolism and nutrition disorders (other)	2	(2)
Mucosal infection	2	(2)
Myocardial infarction	2	(1)
Papulopustular rash	2	(2)
Pneumonitis	2	(2)
Productive cough	2	(2)
Psychiatric disorders (other)	2	(2)
Rhinitis infective	2	(2)
Voice alteration	2	(2)
Watering eyes	2	(2)
Abdominal distension	1	(1)
Amnesia	1	(1)
Atrial flutter	1	(1)
Autoimmune disorder	1	(1)
Bladder infection	1	(1)
Blood and lymphatic system disorders (other)	1	(1)
Breast pain	1	(1)
Cardiac disorders (other)	1	(1)
Cognitive disturbance	1	(1)
Dental caries	1	(1)
Dysarthria	1	(1)
Dysmenorrhea	1	(1)
Dysphasia	1	(1)
Enterocolitis	1	(1)
Esophageal hemorrhage	1	(1)
Esophageal obstruction	1	(1)
Eye infection	1	(1)
Eyelid function disorder	1	(1)
Flank pain	1	(1)

Toxicity term	# occurrences	(# patients affected)
Gum infection	1	(1)
Heart failure	1	(1)
Hemorrhoids	1	(1)
Hepatic failure	1	(1)
Hepatobiliary disorders (other)	1	(1)
Hiccups	1	(1)
Hot flashes	1	(1)
Hypercalcemia	1	(1)
Hyperuricemia	1	(1)
Hypocalcemia	1	(1)
Hypophosphatemia	1	(1)
Immune system disorders (other)	1	(1)
Infusion site extravasation	1	(1)
Joint effusion	1	(1)
Left ventricular systolic dysfunction	1	(1)
Lethargy	1	(1)
Lip infection	1	(1)
Lymph node pain	1	(1)
Lymphedema	1	(1)
Middle ear inflammation	1	(1)
Nail loss	1	(1)
Neuralgia	1	(1)
Non-cardiac chest pain	1	(1)
Paroxysmal atrial tachycardia	1	(1)
Penile infection	1	(1)
Penile pain	1	(1)
Peripheral motor neuropathy	1	(1)
Pharyngolaryngeal pain	1	(1)
Pleural hemorrhage	1	(1)
Pleuritic pain	1	(1)
Reproductive system and breast disorders (other)	1	(1)
Scalp pain	1	(1)
Sinus disorder	1	(1)
Sinus tachycardia	1	(1)
Skin ulceration	1	(1)
Soft tissue infection	1	(1)
Spinal fracture	1	(1)
Surgical and medical procedures (other)	1	(1)
Term not reported	1	(1)
Thromboembolic event	1	(1)
Thrombotic thrombocytopenic purpura	1	(1)
Tinnitus	1	(1)
Tooth infection	1	(1)
Toothache	1	(1)
Tumor lysis syndrome	1	(1)
Urinary frequency	1	(1)

Toxicity term	# occurrences	(# patients affected)
Urinary retention	1	(1)
Urinary tract pain	1	(1)
Uveitis	1	(1)
Vaginal infection	1	(1)
Vertigo	1	(1)
Weight gain	1	(1)
Weight loss	1	(1)
Wound complication	1	(1)

Serious Adverse Events

Table 10: Serious Adverse Event Toxicities

Toxicity term	Unrelated SAE	SAR	NF/LT SUSAR
Lung infection	3 (3)	10 (9)	0 (0)
Fever	1 (1)	3 (3)	0 (0)
Infections and infestations (other) - *COVID-19*	2 (2)	0 (0)	0 (0)
Laryngeal inflammation	1 (1)	1 (1)	0 (0)
Upper respiratory infection	1 (1)	1 (1)	0 (0)
Abdominal pain	0 (0)	0 (0)	1 (1)
Acute kidney injury	1 (1)	0 (0)	0 (0)
Anemia	0 (0)	1 (1)	0 (0)
Atrial fibrillation	0 (0)	1 (1)	0 (0)
Chest pain - cardiac	1 (1)	0 (0)	0 (0)
Confusion	1 (1)	0 (0)	0 (0)
Eye disorders (other) - *Vitreal Bleed*	0 (0)	1 (1)	0 (0)
Gastrointestinal disorders (other) - *Retroperitoneal Bleed*	0 (0)	1 (1)	0 (0)
Immune system disorders (other) - *Pemphigus*	0 (0)	0 (0)	1 (1)
Infections and infestations (other) - *Groin abcess*	1 (1)	0 (0)	0 (0)
Infections and infestations (other) - *Infection*	0 (0)	1 (1)	0 (0)
Infections and infestations (other) - *Pneumonia*	0 (0)	1 (1)	0 (0)
Infections and infestations (other) - *Viral infection*	0 (0)	1 (1)	0 (0)
Investigations (other) - *Lower Respiratory Tract Infection*	1 (1)	0 (0)	0 (0)
Myocardial infarction	0 (0)	1 (1)	0 (0)
Neck pain	0 (0)	1 (1)	0 (0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (other) - *Malt Lymphoma*	1 (1)	0 (0)	0 (0)
Pruritus	1 (1)	0 (0)	0 (0)
Rhinitis infective	1 (1)	0 (0)	0 (0)
Skin infection	0 (0)	1 (1)	0 (0)
Soft tissue infection	0 (0)	1 (1)	0 (0)
Thromboembolic event	1 (1)	0 (0)	0 (0)
Tumor lysis syndrome	0 (0)	1 (1)	0 (0)
Urinary tract infection	1 (1)	0 (0)	0 (0)
Vascular disorders (other) - *Haematoma (Retroperitoneal)*	0 (0)	1 (1)	0 (0)

Note: Data are # occurrences (# patients affected) NF= Non fatal /text life-threatening