CLL or WM patients on BTK inhibitors for ≥3 months willing to get Shingrix vaccine

Screening and consent form signing +/- baseline blood draws and vaccine administration

Phone call for severe adverse events assessment Administration of second dose

Repeat lab testing

Assessment of severe adverse events and CLL/WM progression Repeat lab testing

Assessment of CLL/WM progression; zoster reactivation

Screening/Visit 1

Visit 2

Visit 3

Visit 4

Visit 5

Study Entry

4 weeks ± 1 week of dose 1

8-12 weeks of dose 1

4 weeks ± 1 week of dose 2

24 months ±3 months of dose 2

BASELINE CHARACTERISTICS

	Study cohort	CLL	WM/LPL
Sample size	32	22	10
Demographics ¹			
Age at diagnosis (years)			
Median (IQR)	59 (55,71)	56 (51, 61)	72 (70,78)
Range	36-85	36-79	60-85
Age at first vaccine (years)			
Median (IQR)	69 (59,76)	64 (58,70)	79 (74,86)
Range	50-88	50-82	68-88
Diagnosis to first vaccine (years)			
Median (IQR)	5 (2,10)	5 (3,9)	2 (1,15)
Range	1-31	1-31	1-16
Male <i>n</i> (%)	21 (65.6)	13 (59.1)	8 (80.0)
White race n (%)	31 (96.9)	21 (95.5)	10 (100)
Non-Hispanic ethnicity n (%)	32 (100)	22 (100)	10 (100)
Zoster History	, ,		
Previously vaccinated n (%)			
Yes	4 (12.5)	2 (9.1)	2 (20.0)
No	25 (78.1)	18 (81.8)	7 (70.0)
Unknown	3 (9.4)	2 (9.1)	1 (10.0)
History of VZR n (%)	, ,		· ·
Yes	5 (15.6)	4 (18.2)	1 (10.0)
No	20 (62.5)	14 (63.6)	6 (60.0)
Unknown	7 (21.9)	4 (18.2)	3 (30.0)
Treatment for CLL or WM/LPL	· · ·		· ·
Watch and wait (years)			
Median (IQR)	1.3 (0.2, 6.3)	1.5 (0.4, 6.1)	0.4 (0.05, 11.9)
Range	0.02-28.5	0.02-28.5	0.02-15.0
BTKi <i>n (%)</i>			
Ibrutinib	31 (96.9)	22 (100)	9 (90.0)
Zanubrutinib	1 (3.1)	0	1 (10.0)
BTKi therapy duration (months) ²			
Median (IQR)	32.8 (14.6, 45.2)	37.3 (27.9, 48.7)	13.5 (10.5, 23.6)
Range	4.1-70.8	4.1-70.8	9.8-47.1
CLL-specific Characteristics			
Clinical stage (Rai)			
0		2 (9.1)	
I		4 (18.2)	
II		4 (18.2)	
III		8 (36.4)	
IV		4 (18.2)	
Rituximab Treated n (%)		12 (54.6)	
Last rituximab to 1 st vaccine (years)			
Median (IQR)		3.1 (2.6, 3.9)	
Range		1.4 – 4.3	
IGHV SHM³			

	Study cohort	CLL	WM/LPL
Yes		4 (18.2)	
No		12 (54.6)	
Not done		6 (27.3)	
FISH analysis			
del17p13		1 (4.5)	
del11q22.3		2 (9.1)	
12+		7 (31.8)	
del13q14		11 (50.0)	
Negative		5 (22.7)	
Beta-2 microglobulin			
≤ 3.5 mg/L		5 (22.7)	
> 3.5 mg/L		11 (50.0)	
Not done		6 (27.3)	
WM/LPL-specific Characteristics			
MYD88 L265P mutation			10 (100)
CXCR4 mutation			
Yes			4 (40.0)
Not done			6 (60.0)
IgM Level (mg/dL)			
Median (IQR)			2870 (2215, 5033)
Range			970 - 5820

OUTCOME MEASURES

Time Point	Antibody Response (≥ 4-fold increase in serum VZgE-specific IgG over baseline)	Cellular Response (≥ 2-fold increase in the number VZgE- specific activated T cells compared to prevaccination or controls.
4 Weeks After Vaccination	75% of patients (13.2 fold increase in IgG)	81.3% of patients (4.6 fold increase in T cells)
24 Months After Vaccination	41.9% of patients (3.2 fold increase in IgG)	54.8% of patients (2.2 fold increase in T cells)

ADVERSE EVENTS

Only severe adverse events (defined as any grades 3-5 adverse events included in the CTCAE v5.0) taking place on day 1 through 4 weeks after the last dose were collected in this study, as the safety of the vaccine has previously been demonstrated. No adverse events were reported.