SUPPLEMENTARY MATERIALS

Cost-effectiveness of a 12-month fixed-duration venetoclax treatment in combination with obinutuzumab in first-line, unfit chronic lymphocytic leukemia in the United States

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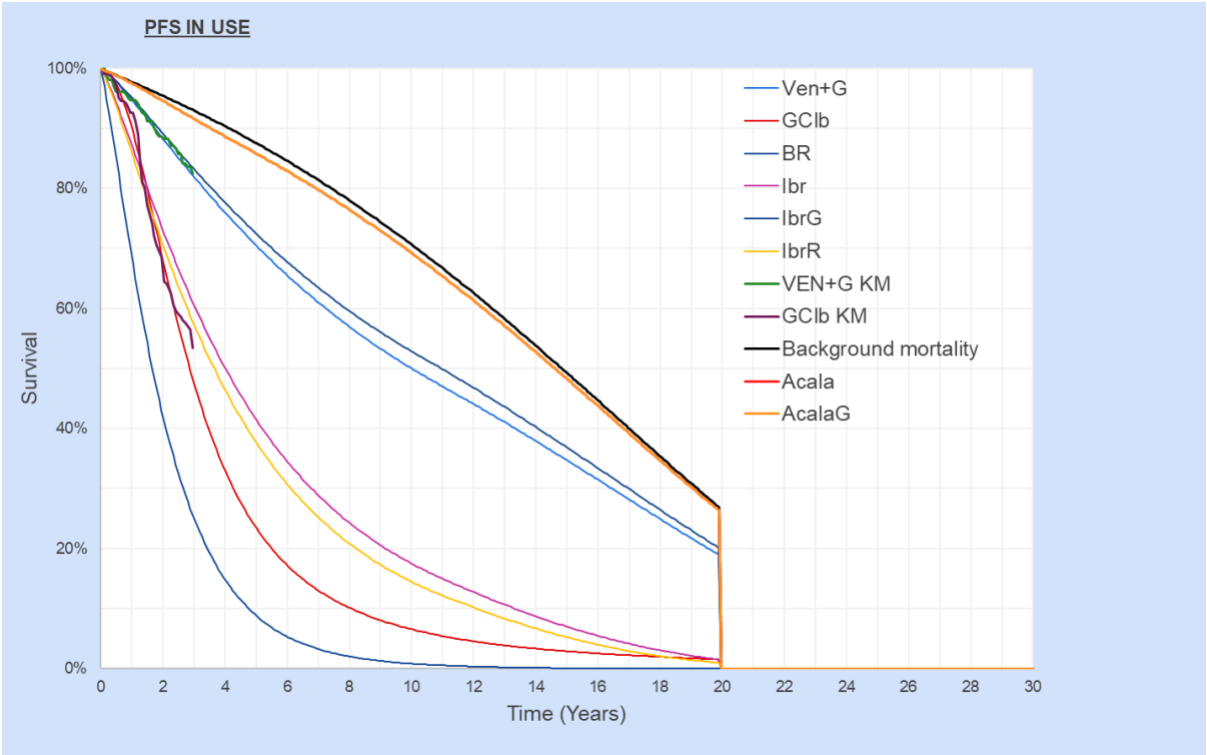
Supplementary Figure 1. Extrapolated PFS Curves Used in the Model[a]

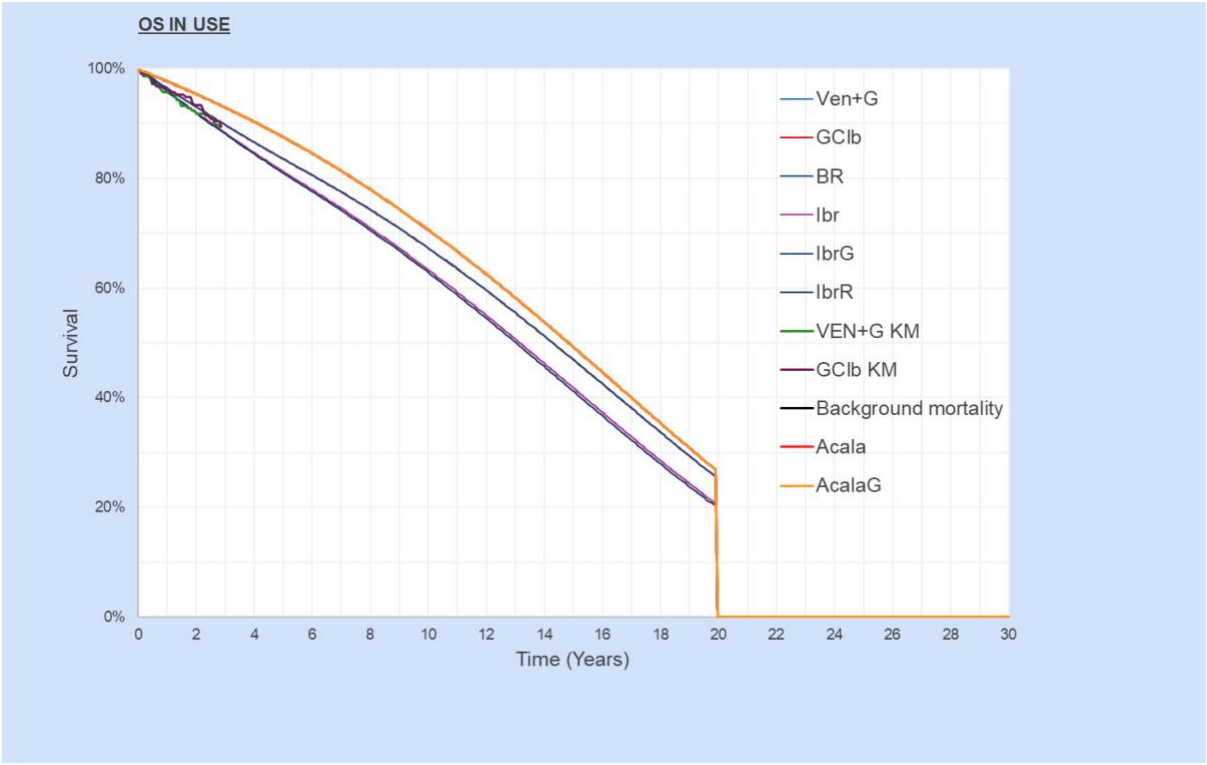


Note: VEN+G KM and GClb KM represent actual PFS data from the CLL14 trial ≥2 years after treatment cessation; other curves represent extrapolated data used in the current model.

[a]Note, Acala and AcalaG curves overlap on the graph, both are not visible.

Acala=acalabrutinib; B=bendamustine; Clb=chlorambucil; G=obinutuzumab; Ibr=ibrutinib; KM=Kaplan-Meier; Ven=venetoclax.

Supplementary Figure 2. Extrapolated OS Curves Used in the Model[a]

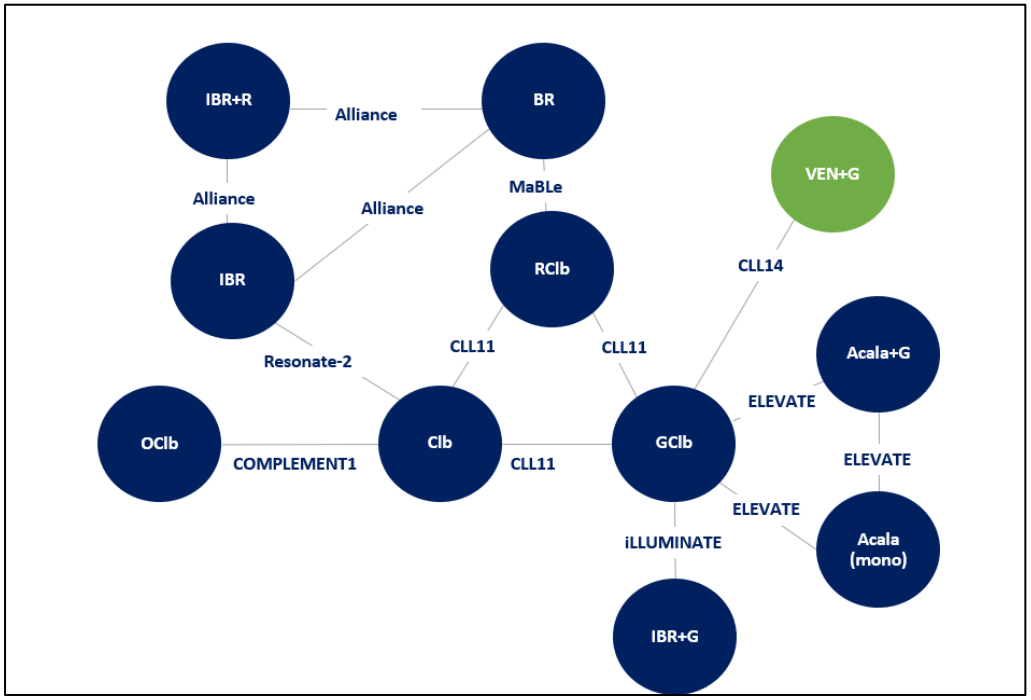


Note: VEN+G KM and GClb KM represent actual OS data from the CLL14 ≥2 years after treatment cessation; other curves represent extrapolated data used in the current model.

[a]Note, some curves overlap on the graph: VenG, GClb, and Ibr-G are not all visible; BR, Ibr, and Ibr-R are not all visible; Acala, AcalaG, and background mortality are not all visible.

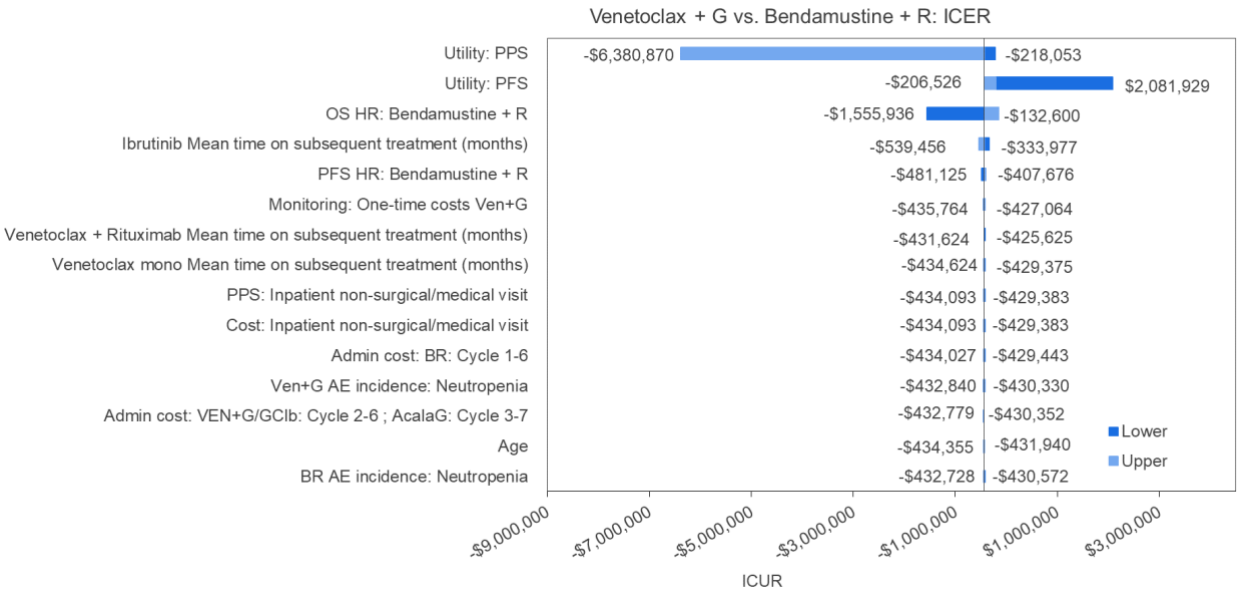
Acala=acalabrutinib; B=bendamustine; Clb=chlorambucil; G=obinutuzumab; Ibr=ibrutinib; KM=Kaplan-Meier; OS=overall survival; Ven=venetoclax.

Supplementary Figure 3. Network for Trials in Unfit CLL Used in Network Meta-Analysis



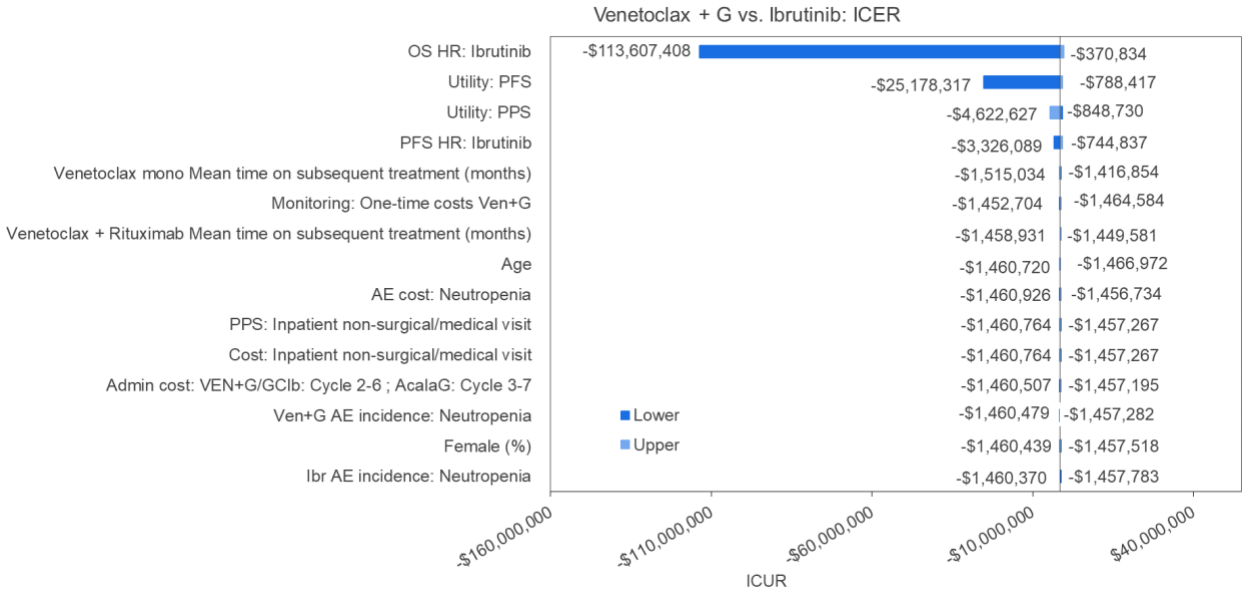
Acala=acalabrutinib; B=bendamustine; Clb=chlorambucil; CLL=chronic lymphocytic leukemia; G=obinutuzumab; I=ibrutinib; mono=monotherapy; Ven=venetoclax.

Supplementary Figure 4. Results of One-Way Deterministic Sensitivity Analysis, VenG Versus BR



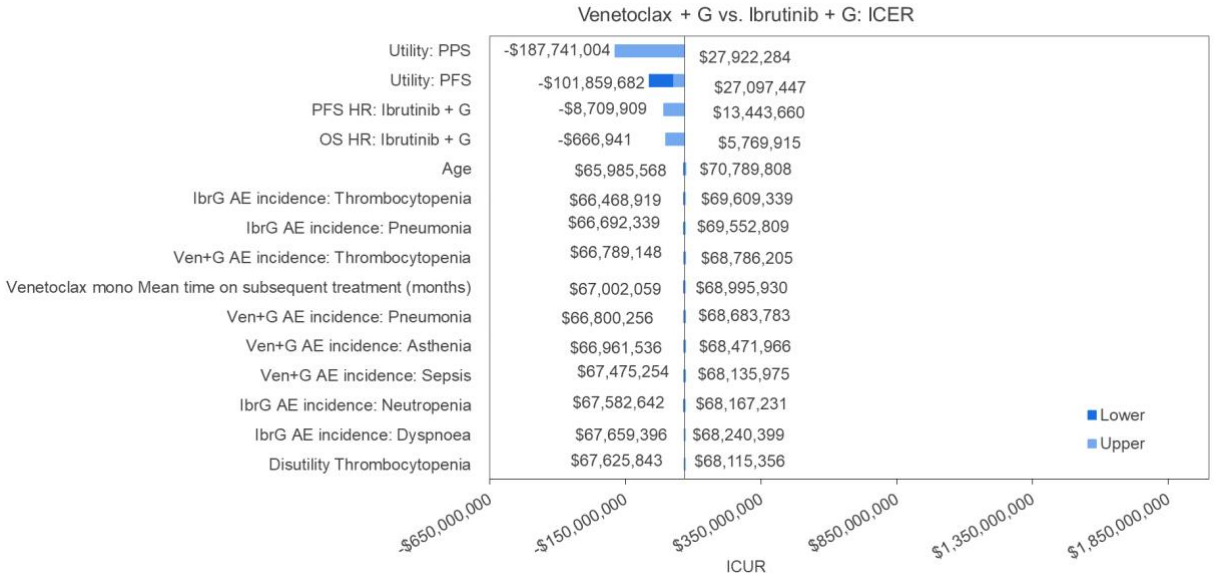
Acala=acalabrutinib; AE=adverse event; B=bendamustine; Clb=chlorambucil; G=obinutuzumab; HR=hazard ratio; ICER=incremental cost effectiveness ratio; ICUR=incremental cost utility ratio; OS=overall survival; PFS=progression-free survival; PPS=post-progression survival; R=rituximab; Ven=venetoclax.

Supplementary Figure 5. Results of One-Way Deterministic Sensitivity Analysis, VenG Versus Ibr



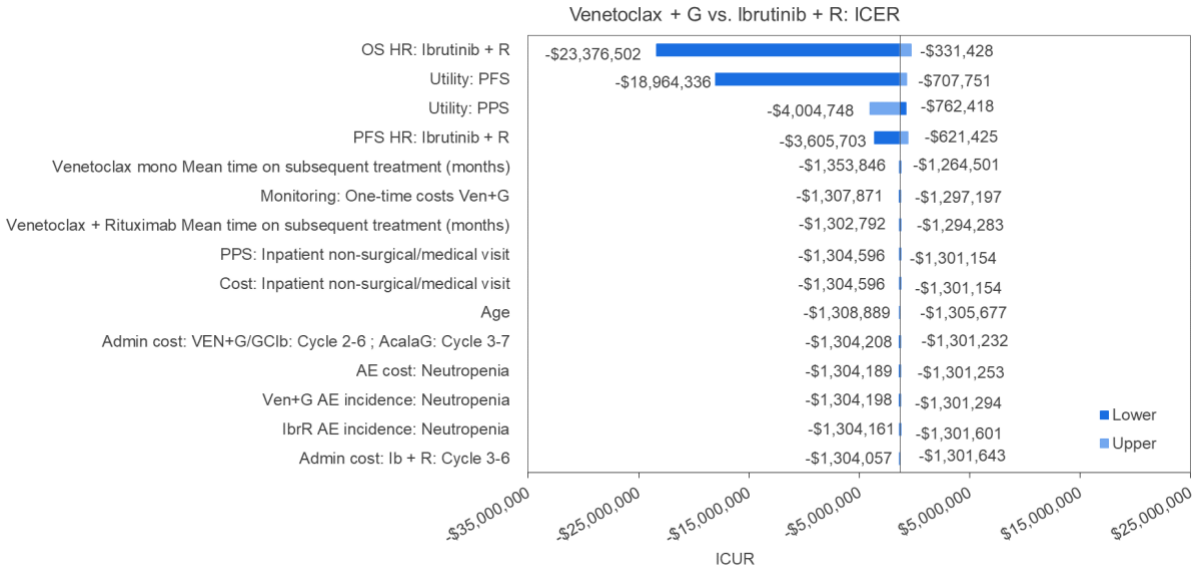
Acala=acalabrutinib; AE=adverse event; Clb=chlorambucil; G=obinutuzumab; HR=hazard ratio; Ibr=ibrutinib; ICER=incremental cost effectiveness ratio; ICUR=incremental cost utility ratio; OS=overall survival; PFS=progression-free survival; PPS=post-progression survival; Ven=venetoclax.

Supplementary Figure 6. Results of One-Way Deterministic Sensitivity Analysis, VenG Versus Ibr+G



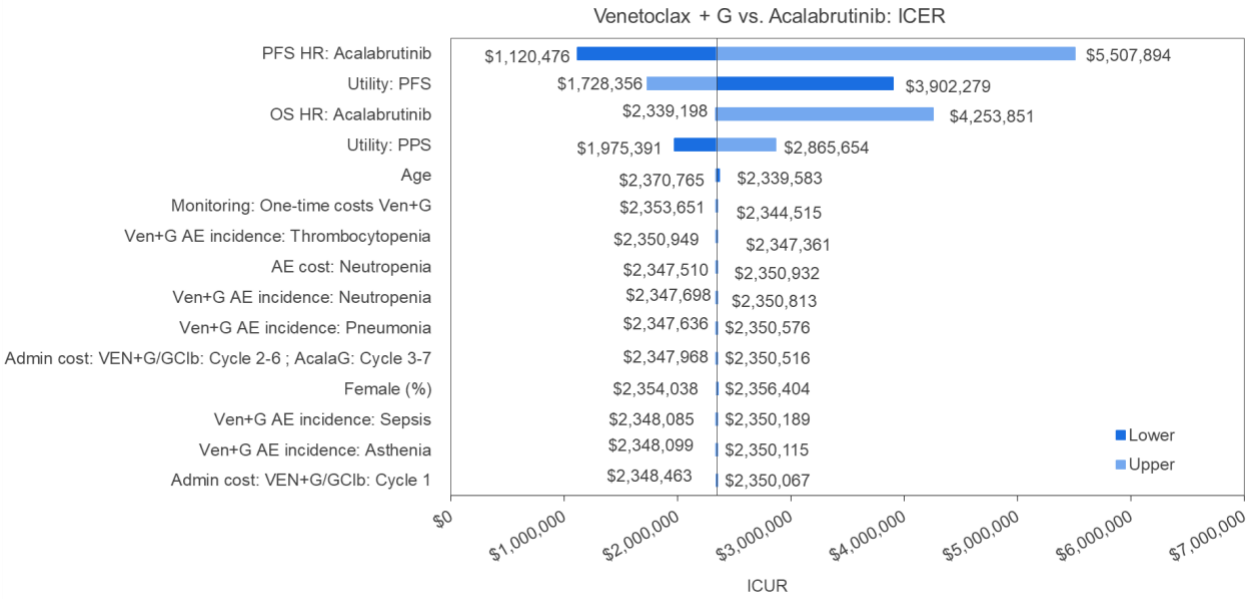
Acala=acalabrutinib; AE=adverse event; G=obinutuzumab; HR=hazard ratio; Ibr=ibrutinib; ICER=incremental cost effectiveness ratio; ICUR=incremental cost utility ratio; OS=overall survival; PFS=progression-free survival; PPS=post-progression survival; Ven=venetoclax.

Supplementary Figure 7. Results of One-Way Deterministic Sensitivity Analysis, VenG Versus Ibr+R



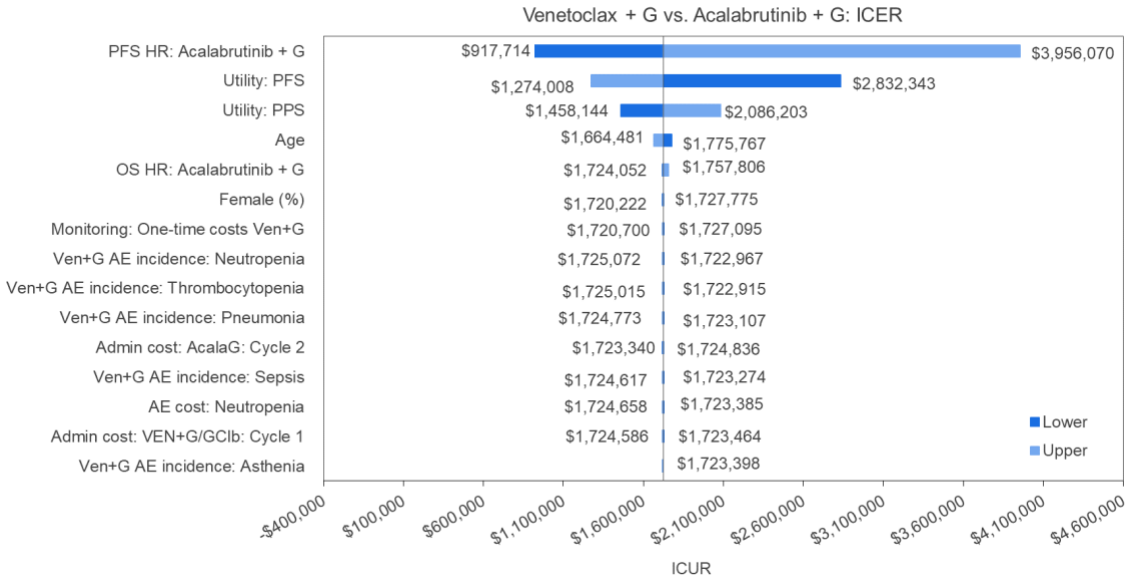
Acala=acalabrutinib; AE=adverse event; Clb=chlorambucil; G=obinutuzumab; HR=hazard ratio; Ibr=ibrutinib; ICER=incremental cost effectiveness ratio; ICUR=incremental cost utility ratio; OS=overall survival; PFS=progression-free survival; PPS=post-progression survival; R=rituximab; Ven=venetoclax.

Supplementary Figure 8. Results of One-Way Deterministic Sensitivity Analysis, VenG Versus Acala



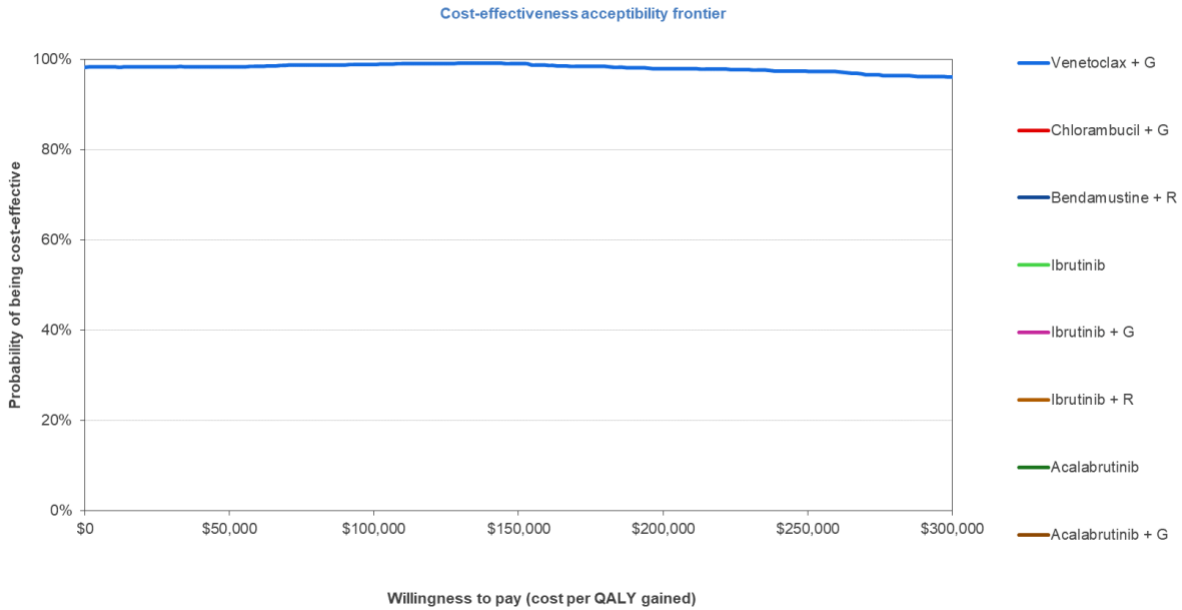
Acala=acalabrutinib; AE=adverse event; G=obinutuzumab; HR=hazard ratio; Ibr=ibrutinib; ICER=incremental cost effectiveness ratio; ICUR=incremental cost utility ratio; OS=overall survival; PFS=progression-free survival; PPS=post-progression survival; Ven=venetoclax.

Supplementary Figure 9. Results of One-Way Deterministic Sensitivity Analysis, VenG Versus Acala+G



Acala=acalabrutinib; AE=adverse event; B=bendamustine; G=obinutuzumab; HR=hazard ratio; ICER=incremental cost effectiveness ratio; ICUR=incremental cost utility ratio; OS=overall survival; PFS=progression-free survival; PPS=post-progression survival; Ven=venetoclax.

Supplementary Figure 10. Cost-Effectiveness Acceptability Frontier



G=obinutuzumab; QALY=quality-adjusted life-year; R=rituximab.

Supplementary Table 1. Dosing Regimens Used in the Model

Regimen	Drug	Administration	Dosing schedule	Trial
VenG	Venetoclax	Oral	Venetoclax: • 20 mg daily during Cycle 1, Days 22−28 • 50 mg daily during Cycle 2, Days 1−7 • 100 mg daily during Cycle 2, Days 8−14 • 200 mg daily during Cycle 2, Days 15−21 • 400 mg daily during Cycle 2, Days 22−28 and on Days 1−28 for all subsequent cycles until the end of Cycle 12	CLL14[6]
	Obinutuzumab	IV	•1000mg at Cycle 1, Day 1 •1000 mg at Cycle 1, Day 8 and Day 15 • 1000 mg at Day 1 for all subsequent cycles until the end of Cycle 6	CLL14[6]

GClb	Obinutuzumab	IV	• 1000mg at Cycle 1, Day 1 • 1000 mg at Cycle 1, Day 8 and Day 15 • 1000 mg at Day 1 for all subsequent cycles until the end of Cycle 6	CLL11[7]
	Chlorambucil	Oral	0.5 mg/kg at Day 1 and Day 15 for Cycles 1−12	CLL14[6]
BR	Bendamustine	IV (By BSA)	90 mg/m^2 on Day 1 and Day 2 of a 28-day cycle. Given for 6 cycles.	CLL10,[8] GCLLSG,[55] and MABLE[56]
	Rituximab	IV (By BSA)	375 mg/m^2 for the first cycle and 500 mg/m^2 for subsequent cycles. Given for 6 cycles	CLL10,[8] GCLLSG,[55] and MABLE[56]
Ibr	Ibrutinib	Oral	420mg daily continuously (until evidence of progressive disease or no longer being tolerated by the patient)	RESONATE-2[30]
Ibr+G	Ibrutinib	Oral	420mg (3 x 140 mg capsules) once daily until disease	ILLUMINATE[31]

			progression or unacceptable toxicity	
	Obinutuzumab	IV	1000mg over 6 cycles: Days 1 and 2 (100mg on Day 1 and 900mg on Day 2), Day 8 and Day 15 of Cycle 1 followed by Day 1 only on Cycles 2–6.	ILLUMINATE[31]
Ibr+R	Ibrutinib	Oral	420 mg/day until disease progression	ECOG[57]
	Rituximab[a]	IV (By BSA)	Cycle 2, Day 1: 50 mg/m^2 Cycle 2, Day 2: 325 mg/m^2 In subsequent cycles: Day 1: 500 mg/m^2 for 7 cycles	ECOG[57]
Acala	Acalabrutinib	Oral	100mg twice a day = 200mg/day from Cycle 1 Day 1 until disease progression or unacceptable toxicity	ELEVATE-TN[15]
Acala+G	Acalabrutinib	Oral	100mg twice a day = 200mg/day from Cycle 1 Day 1 until disease progression or unacceptable toxicity	

	Obinutuzumab	IV	• Cycle 2, Day 1 (100mg), Day 2 (900mg), 1000mg at Day 8 and Day 15 • 1000mg at Day 1 for all subsequent cycles until the end of Cycle 7	ELEVATE-TN[15]

[a]For Ibr+R, the most recently published trial (2019) was chosen (ECOG-ACRIN phase III trial E1912) to inform the dosing schedule for rituximab, since this was different to the other dosing schedules commonly adopted for rituximab. The most recent dosing schedule for Ibr+R was therefore chosen over an older publication for the ALLIANCE trial.

Acala=acalabrutinib; B=bendamustine; Clb=chlorambucil; Ibr=ibrutinib; R=rituximab; Ven=venetoclax.

Supplementary Table 3. AE Probabilities

Asthenia	2.80	0.50	0.00	0.00	0.00	0.00	0.00	0.00
Diarrhea	3.80	0.50	7.00	4.00	3.00	0.00	0.56	4.49
Dyspnea	2.40	0.50	0.00	0.00	2.00	0.00	0.00	0.00
Febrile neutropenia	5.20	3.70	0.00	1.00	5.00	1.00	1.12	1.69
IRR	9.00	10.30	0.00	0.00	2.00	0.00	0.00	2.25
Leukopenia	2.40	4.70	48.00	0.00	1.00	0.00	0.00	0.00
Neutropenia	52.80	47.70	59.00	12.00	37.00	21.00	9.50	29.78
Pneumonia	5.70	4.20	9.00	0.00	7.00	0.00	2.23	5.62
Sepsis	4.20	1.40	1.00	0.00	0.00	5.00	0.00	0.00
Thrombocytopenia	13.70	15.00	14.00	0.00	19.00	5.00	2.79	8.43
Source	CLL14[6]	CLL14[6]	CLL10[8]	RESONATE-2[30]	iLLUMINATE[31]	A041202[32]	ELEVATE TN[15]	ELEVATE TN[15]

Acala=acalabrutinib; AE=adverse events; B=bendamustine; Clb=chlorambucil; Ibr=ibrutinib; IRR=infusion-related reaction; R=rituximab; Ven=venetoclax.

Supplementary Table 2. Hazard Ratios for Comparators Versus VenG

Treatment	HR versus VenG	95% lower CI	95% upper CI
PFS			
Acala	0.6	0.3	1.0
Acala+G	0.4	0.2	0.8
BR	6.9	3.3	13.2
Ibr+G	0.9	0.5	1.6
Ibr	2.5	1.4	4.3
Ibr+R	2.8	1.2	5.4
OS			
Acala	0.6	0.3	1.2
Acala+G	0.5	0.2	1.1
BR	1.2	0.5	2.4
Ibr+G	1.0	0.4	2.1
Ibr	1.2	0.5	2.3
Ibr+R	1.2	0.4	2.6

Acala=acalabrutinib; B=bendamustine; CI=confidence interval; G=obinutuzumab; HR=hazard ratio; Ibr=ibrutinib; OS=overall survival; PFS=progression-free survival; R=rituximab; Ven=venetoclax.

Supplementary Table 3. AE Probabilities

AE incidence, %	VenG n=212	GClb n=214	BR n=279	Ibr n=136	Ibr+G n=113	Ibr+R n=181	Acala n=179	Acala+G n=178
Asthenia	2.80	0.50	0.00	0.00	0.00	0.00	0.00	0.00
Diarrhea	3.80	0.50	7.00	4.00	3.00	0.00	0.56	4.49
Dyspnea	2.40	0.50	0.00	0.00	2.00	0.00	0.00	0.00
Febrile neutropenia	5.20	3.70	0.00	1.00	5.00	1.00	1.12	1.69
IRR	9.00	10.30	0.00	0.00	2.00	0.00	0.00	2.25
Leukopenia	2.40	4.70	48.00	0.00	1.00	0.00	0.00	0.00
Neutropenia	52.80	47.70	59.00	12.00	37.00	21.00	9.50	29.78
Pneumonia	5.70	4.20	9.00	0.00	7.00	0.00	2.23	5.62
Sepsis	4.20	1.40	1.00	0.00	0.00	5.00	0.00	0.00
Thrombocytopenia	13.70	15.00	14.00	0.00	19.00	5.00	2.79	8.43
Source	CLL14[6]	CLL14[6]	CLL10[8]	RESONATE-2[30]	iLLUMINATE[31]	A041202[32]	ELEVATE TN[15]	ELEVATE TN[15]

Acala=acalabrutinib; AE=adverse events; B=bendamustine; Clb=chlorambucil; Ibr=ibrutinib; IRR=infusion-related reaction; R=rituximab; Ven=venetoclax.

Supplementary Table 4. Parameters assessed in sensitivity analysis with the base case and upper and lower bounds

Parameter	Base case	Lower	Upper
Age	71.08	70.31	71.84
Bodyweight	75.75	74.23	77.26
Female (%)	0.33	0.29	0.38
Pre-progression health state utility (all treatments)	0.67	0.53	0.79
Post-progression health state utility (all treatments)	0.60	0.48	0.71
End-of-life costs	$19,694.97	$16,024.61	$23,738.14
Monitoring costs			
One-time costs Ven+G	$15,686.00	$12,762.76	$18,906.17
Biochemistry test: liver function test	$9.08	$7.39	$10.94
Biochemistry test: renal - urea and electrolytes test (UE test)	$11.74	$9.55	$14.15
Bone marrow exam	$72.08	$58.65	$86.88
Chest X-ray	$25.23	$20.53	$30.41
CT scan	$199.30	$162.16	$240.21
Full blood count	$8.63	$7.02	$10.40
Full blood transfusion	$494.08	$402.00	$595.51
Hematologist visit	$51.90	$42.23	$62.55
Immunoglobulins blood test	$13.84	$11.26	$16.68
Inpatient non-surgical/medical visit	$690.10	$561.49	$831.77
Lactate dehydrogenase	$6.71	$5.46	$8.09
Tumor lysis syndrome prophylaxis	$15,686.00	$12,762.76	$18,906.17
Drug administration costs			
Acala+G: C2	$3,682.72	$2,996.41	$4,438.74
BR: C1–6	$1,474.34	$1,199.58	$1,777.01
CR: C1–6	$920.68	$749.10	$1,109.69

FCR: C1	$920.68	$749.10	$1,109.69
FCR: C2–6	$1,141.93	$929.12	$1,376.36
Ibr+R: C2	$1,841.36	$1,498.20	$2,219.37
Ibr+R: C3–6	$920.68	$749.10	$1,109.69
Ibr+G: C1	$3,682.72	$2,996.41	$4,438.74
Ibr+G: C1–6	$920.68	$749.10	$1,109.69
IV	$298.53	$242.89	$359.81
Rapid IV	$238.19	$193.80	$287.09
SC	$38.50	$31.33	$46.40
VenG/GClb: C1	$2,762.04	$2,247.31	$3,329.06
VenG/GClb: C2-6; Acala+G: C3–7	$920.68	$749.10	$1,109.69
Ven+R: C1–6	$920.68	$749.10	$1,109.69
AE costs			
Asthenia	$4,810.18	$3,913.76	$5,797.66
Diarrhea	$5,172.65	$4,208.67	$6,234.54
Dyspnea	$11,903.85	$9,685.45	$14,347.59
Febrile neutropenia	$13,545.98	$11,021.55	$16,326.82
IRR	$7,289.00	$5,930.62	$8,785.36
Leukopenia	$6,911.00	$5,623.07	$8,329.76
Neutropenia	$13,565.69	$11,037.59	$16,350.58
Pneumonia	$9,046.00	$7,360.19	$10,903.05
Sepsis	$17,661.00	$14,369.69	$21,286.62
Thrombocytopenia	$10,017.00	$8,150.23	$12,073.38
AE disutilities			
Asthenia	0.12	0.09	0.14
Diarrhea	0.08	0.07	0.09
Dyspnea	0.10	0.08	0.12
Febrile neutropenia	0.15	0.12	0.18

IRR	0.20	0.16	0.24
Leukopenia	0.09	0.07	0.11
Neutropenia	0.09	0.09	0.09
Pneumonia	0.20	0.19	0.20
Sepsis	0.20	0.19	0.20
Thrombocytopenia	0.11	0.09	0.13
AE duration (days)			
Asthenia	35.33	28.75	42.58
Diarrhea	3.50	2.85	4.22
Dyspnea	12.70	10.33	15.31
Febrile neutropenia	3.50	2.85	4.22
IRR	3.50	2.85	4.22
Leukopenia	14.00	11.39	16.87
Neutropenia	3.50	2.85	4.22
Pneumonia	18.21	14.82	21.95
Sepsis	7.00	5.70	8.44
Thrombocytopenia	23.20	18.87	27.96
AE incidence			
BR			
Diarrhea	0.07	0.04	0.10
Leukopenia	0.48	0.42	0.54
Neutropenia	0.59	0.53	0.65
Pneumonia	0.09	0.06	0.13
Sepsis	0.01	0.00	0.02
Thrombocytopenia	0.14	0.10	0.18
GClb			
Asthenia	0.01	0.00	0.02
Diarrhea	0.01	0.00	0.02
Dyspnea	0.01	0.00	0.02

Febrile neutropenia	0.04	0.02	0.07
IRR	0.10	0.07	0.15
Leukopenia	0.05	0.02	0.08
Neutropenia	0.48	0.41	0.55
Pneumonia	0.04	0.02	0.07
Sepsis	0.01	0.00	0.03
Thrombocytopenia	0.15	0.11	0.20
Ibr			
Diarrhea	0.04	0.01	0.08
Febrile neutropenia	0.01	0.00	0.03
Neutropenia	0.12	0.07	0.18
Ibr+G			
Diarrhea	0.03	0.01	0.07
Dyspnea	0.02	0.00	0.05
Febrile neutropenia	0.05	0.02	0.10
IRR	0.02	0.00	0.05
Leukopenia	0.01	0.00	0.03
Neutropenia	0.37	0.29	0.46
Pneumonia	0.07	0.03	0.12
Thrombocytopenia	0.19	0.12	0.27
Ibr+R			
Febrile neutropenia	0.01	0.00	0.03
Neutropenia	0.21	0.15	0.27
Sepsis	0.05	0.02	0.09
Thrombocytopenia	0.05	0.02	0.09
VenG			
Asthenia	0.03	0.01	0.05
Diarrhea	0.04	0.02	0.07
Dyspnea	0.02	0.01	0.05

Febrile neutropenia	0.05	0.03	0.09
IRR	0.09	0.06	0.13
Leukopenia	0.02	0.01	0.05
Neutropenia	0.53	0.46	0.60
Pneumonia	0.06	0.03	0.09
Sepsis	0.04	0.02	0.07
Thrombocytopenia	0.14	0.09	0.19
Mean time on subsequent treatment (months)			
Ibr	39.00	31.73	47.01
Ven+R	24.40	19.85	29.41
Ven monotherapy	16.00	13.02	19.28
OS HR			
Acala	0.63	0.29	1.19
Acala+G	0.52	0.18	1.14
BR	1.15	0.46	2.40
Ibr	1.15	0.47	2.34
Ibr+G	1.00	0.39	2.13
Ibr+R	1.17	0.43	2.57
Ibr del17p/*TP53* HR	0.84	0.30	2.35
PFS HR			
Acala	0.57	0.30	0.97
Acala+G	0.43	0.22	0.79
BR	6.94	3.25	13.19
Ibr	2.51	1.35	4.33
Ibr+G	0.92	0.48	1.61
Ibr+R	2.79	1.23	5.43
Ibr del17p/*TP53* HR	0.66	0.27	1.62
Per-cycle frequency of resource use			

Pre-progression			
Biochemistry test: liver function test	0.23	0.19	0.28
Biochemistry test: renal - urea and electrolytes test (UE test)	0.23	0.19	0.28
Full blood count	0.23	0.19	0.28
Hematologist visit	0.23	0.19	0.28
Immunoglobulins blood test	0.08	0.06	0.09
Lactate dehydrogenase	0.23	0.19	0.28
Post-progression			
CT scan	0.15	0.12	0.18
Full blood count	0.61	0.50	0.74
Hematologist visit	0.46	0.37	0.55
Immunoglobulins blood test	0.08	0.06	0.09
Inpatient non-surgical/medical visit	0.15	0.12	0.18
Lactate dehydrogenase	0.15	0.12	0.18

Acala=acalabrutinib; AE=adverse event; B=bendamustine; C=cycle; Clb=chlorambucil; CT=computed tomography; FCR=fludarabine, cyclophosphamide and rituximab; G=obinutuzumab; HR=hazard ratio; Ibr=ibrutinib; IRR, infusion-related reaction; IV=intravenous; OS=overall survival; PFS=progression-free survival; R=rituximab; SC=subcutaneous; Ven=venetoclax

Supplementary Table 5. Cost-Effectiveness of VenG Compared with Other Treatments, Scenario Adjusted for GClb Dosing

Treatment	Total costs ($)	Life-years gained	QALYs gained	Incremental costs ($)	Incremental life-years gained	Incremental QALYs gained	ICER ($/QALY)
VenG	**$291,012**	**13.01**	**6.521**	**-**	**-**	**-**	**-**
GClb	$491,040	13.01	6.188	$200,028	0	-0.333	**Dominant**
BR	$591,957	6.40	3.365	$300,945	-6.61	-3.157	**Dominant**
Ibr	$836,734	6.40	3.492	$545,722	-6.61	-3.029	**Dominant**
Ibr+G	$1,143,355	7.20	4.008	$852,343	-5.81	-2.514	**Dominant**
Ibr+R	$898,024	6.33	3.463	$607,012	-6.68	-3.058	**Dominant**
Acala	$1,391,132	9.53	5.856	$1,100,120	-3.48	-0.665	**Dominant**
Acala+G	$1,584,434	10.56	6.499	$1,293,422	-2.45	-0.022	**Dominant**

Acala=acalabrutinib; B=bendamustine; Clb=chlorambucil; G=obinutuzumab; Ibr=ibrutinib; ICER=incremental cost-effectiveness ratio; QALY=quality-adjusted life year; R=rituximab; Ven=venetoclax.

Supplementary Table 6. Cost-Effectiveness of VenG Compared with Other Treatments, Scenario Assuming Treatment Effect for OS (Dependent Model, Exponential Distribution)

Treatment	Total costs ($)	Life-years gained	QALYs gained	Incremental costs ($)	Incremental life-years gained	Incremental QALYs gained	ICER ($/QALY)
VenG	**$299, 846**	**13.05**	**6.537**	**-**	**-**	**-**	**-**
GClb	$491,040	13.01	6.188	$191,194	-0.04	-0.349	**Dominant**
BR	$595, 837	12.35	5.833	$295,992	-0.70	-0.705	**Dominant**
Ibr	$1,040,985	12.35	5.963	$745,744	-0.70	-0.516	**Dominant**
Ibr+G	$1,045,590	13.05	6.022	$1,479,685	0.01	0.022	**$67,560,740**
Ibr+R	$1,779,531	12.26	6.559	$741,139	-0.78	-0.574	**Dominant**
Acala	$1,870,806	13.56	7.196	$1,570,960	0.51	0.658	**$2,386,056**
Acala+G	$1,947,166	13.56	7.482	$1,647,320	0.51	0.945	**$1,743,895**

Acala=acalabrutinib; B=bendamustine; Clb=chlorambucil; Ibr=ibrutinib; ICER=incremental cost-effectiveness ratio; G=obinutuzumab; OS=overall survival; QALY=quality-adjusted life-year; R=rituximab; Ven=venetoclax.

Supplementary Table 7. Cost-Effectiveness of VenG Compared with Other Treatments, Scenario Assuming no Treatment Effect for OS (Dependent Model, Log-Normal Distribution)

Treatment	Total costs ($)	Life-years gained	QALYs gained	Incremental costs ($)	Incremental life-years gained	Incremental QALYs gained	ICER ($/QALY)
VenG	**$308,763**	**13.15**	6.581	**-**	**-**	**-**	**-**
GClb	$491,169	13.15	6.248	-$182,405	0.00	-0.333	**Dominant**
BR	$595,980	12.46	5.880	-$287,217	-0.69	-0.701	**Dominant**
Ibr	$1,041,129	12.46	6.011	-$736,970	-0.69	-0.512	**Dominant**
Ibr+G	$1,045,733	13.15	6.069	-$1,471,187	0.00	0.021	**$69,556,437**
Ibr+R	$1,779,950	12.37	6.602	-$732,366	-0.77	-0.570	**Dominant**
Acala	$1,870,831	13.56	7.195	-$1,562,067	0.41	0.614	**$2,542,960**
Acala+G	$1,947,166	13.56	7.482	-$1,638,403	0.41	0.901	**$1,818,051**

Acala=acalabrutinib; B=bendamustine; Clb=chlorambucil; G=obinutuzumab; Ibr=ibrutinib; ICER=incremental cost-effectiveness ratio; OS=overall survival; QALY=quality-adjusted life-year; R=rituximab; Ven=venetoclax.