

FIG. 1A

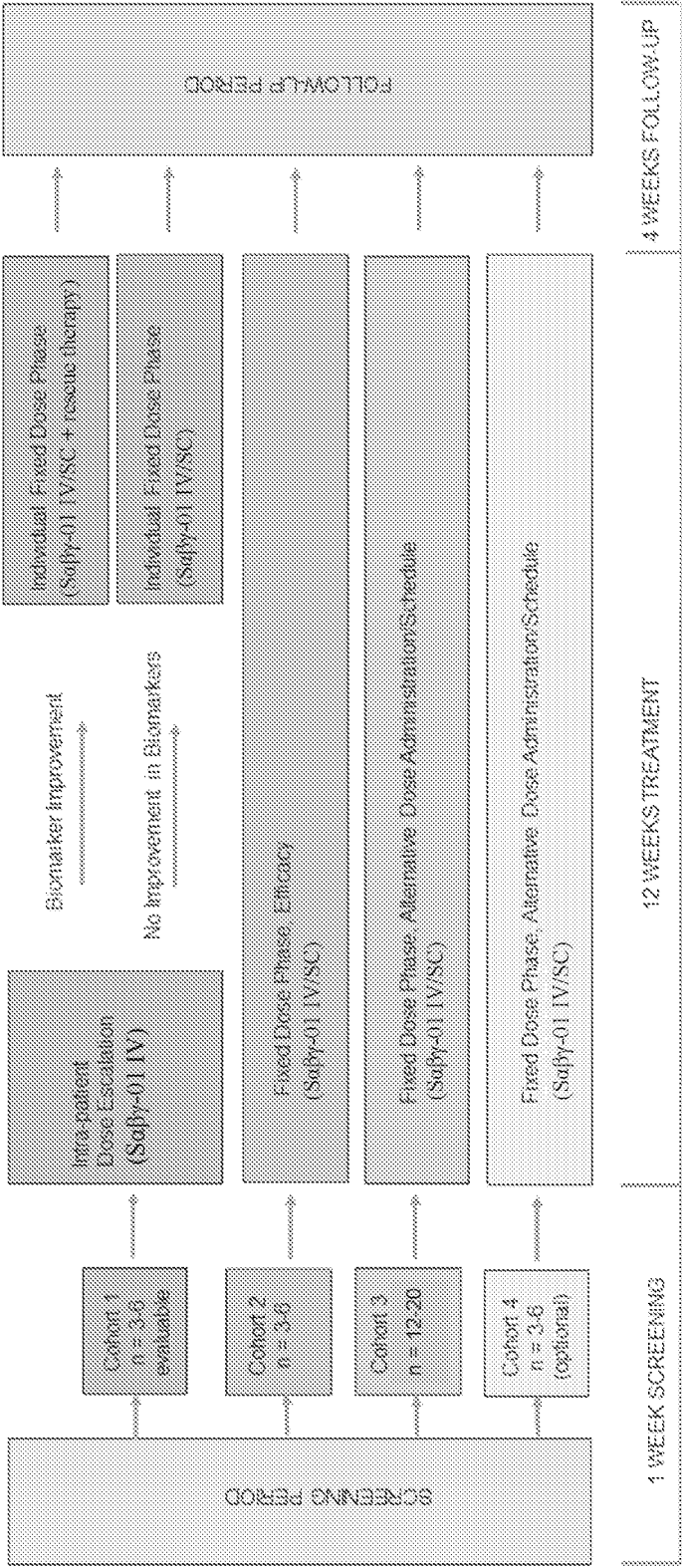


FIG. 1B

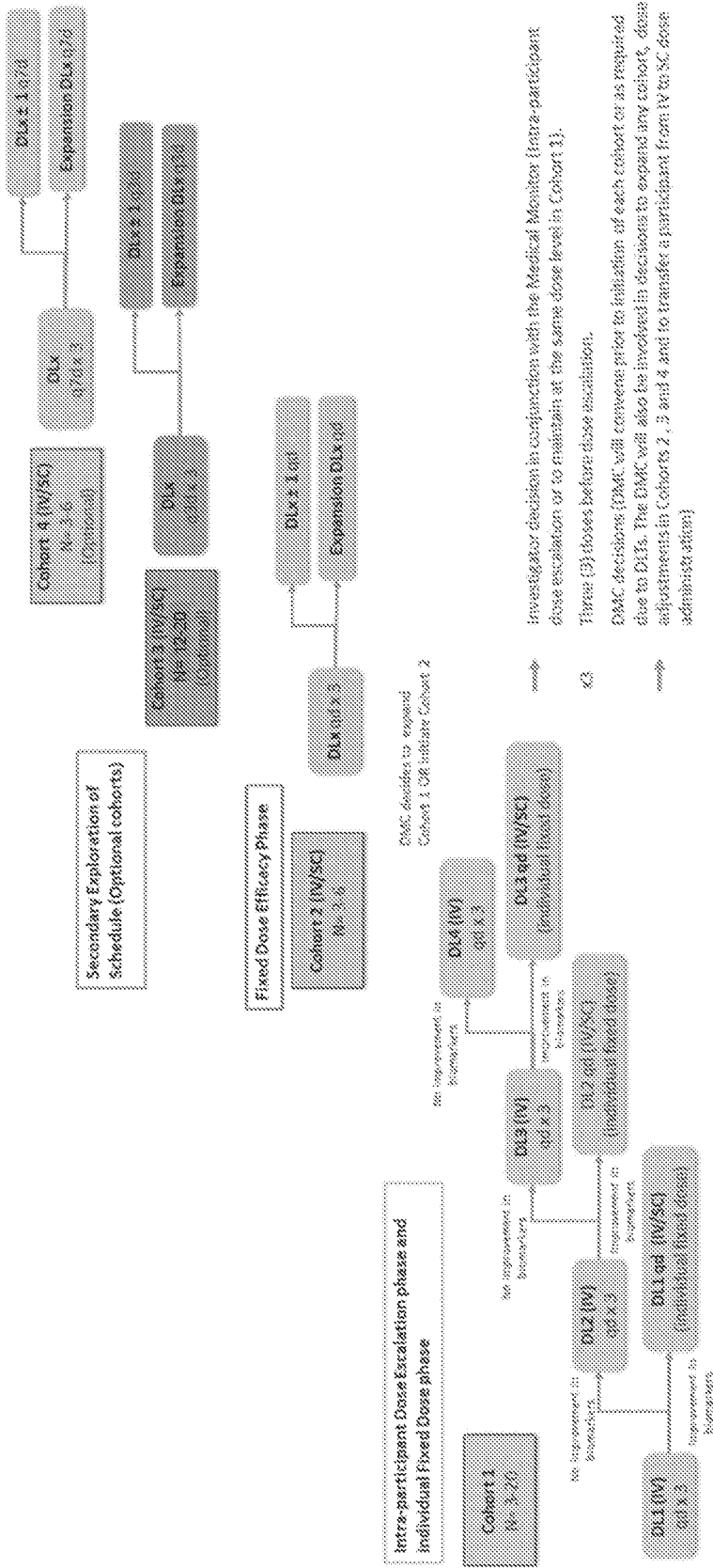


FIG. 2

Dosing strategy	All Patients		Cohort 1	Cohort 2	Cohort 3	mHLH with Frontline Safety-01 Treatment
	Both		Intrapatent dose-escalation	Fixed dose regimen	Fixed dose regimen	
Demographics						Both
N	22	6	6	8	10	
Age, median (range)	59 (20, 78)	50 (21, 67)	57 (48, 79)	47 (20, 78)	47 (21, 78)	
Female, N (%)	9 (41)	3 (50)	2 (33)	4 (40)	4 (33)	
Days from sHLH diagnosis to first ELA026 dose, median (range)	7 (0, 90)	24 (0, 90)	19 (3, 36)	6 (3, 14)	4 (0, 14)	
sHLH Status						
Treatment-Naive	13 (59)	3 (50)	2 (33)	8 (80)	11 (92)	
Early Refractory	2 (9)	NA	NA	2 (20)	1 (6)	
Relapse/Refractory	7 (32)	3 (50)	4 (66)	NA	NA	
Underlying Trigger, N (%)						
T cell lymphoma	11 (50)	2 (50)	3 (50)	5 (50)	7 (58)	
B cell lymphoma	3 (14)	0 (0)	0 (0)	3 (30)	2 (17)	
Hodgkin lymphoma	1 (5)	1 (17)	0 (0)	0 (0)	1 (6)	
Leukemia	3 (14)	2 (33)	0 (0)	1 (10)	2 (17)	
EBV	1 (5)	0 (0)	0 (0)	1 (10)	0 (0)	
Unknown/Other	3 (14)	0 (0)	3 (50)	0 (0)	0 (0)	
Malignancy Status						
N	18	6	3	9	12	
Treatment-Naive	8 (44)	3 (50)	1 (33)	4 (44)	7 (58)	
Relapse/Refractory	10 (56)	3 (50)	2 (67)	5 (56)	5 (42)	
Diagnostic and Prognostic Indicators at Baseline or Screening						
Ferritin, ng/mL, median (range)	10852 (1383, 87000)	33047 (3989, 97000)	14245 (1441, 85321)	3488 (1383, 74184)	5999 (1363, 74184)	
sCD25 ⁺ , pg/mL, median (range)	8987 (920, 142612)	59829 (1324, 114457)	13308 (2415, 69900)	8563 (920, 142612)	9239 (2356, 143612)	
CRP index (4+) ² , N (%)	8 of 22 (36)	3 of 6 (50)	2 of 6 (33)	3 of 10 (30)	5 of 12 (42)	
LDH, U/L, median (range)	730 (198, 16840)	1815 (385, 15210)	282 (249, 1880)	517 (198, 16840)	385 (198, 16840)	
Platelets, G/L, median (range)	33 (2, 182)	24 (14, 41)	45 (5, 99)	33 (2, 182)	53 (2, 105)	
CRP, mg/L, median (range)	17 (0.62, 141)	88 (0.62, 98)	18 (1, 141)	12 (3, 42)	9 (3, 67)	

FIG. 3

	Patient number TN vs. R/R sHLH, driver sHLH	Highest dose escalation level (last dose)	Added treatment		Week 12 assessment
			Anti-cancer	Anti-HLH	
Cohort 1 Intra-patient dose escalation	1 R/R, T-cell lymphoma	0.1 mg/kg (Day 6)	ICE	—	No
	2 TN, T-cell ALL	0.1 mg/kg (Day 18)	HyperCVAD	—	Yes
	3 TN, Hodgkin lymphoma	1.0 mg/kg (Day 40)	AAVD	—	Yes
	4 R/R, R/R AML	1.0 mg/kg (Day 18)	Azacitidine and venetoclax	Yes ^{1,5,6}	No
	5 TN, R/R PTCL	3.0 mg/kg (Day 57)	GemEtop	Yes ^{3,6}	Yes
	6 R/R, R/R PTCL	1.0 mg/kg (Day 16)	GemOx	Yes ¹	No
	Patient number TN vs. R/R sHLH, driver sHLH	Progressed to weekly dosing (last dose)	Added treatment		Week 12 assessment
			Anti-cancer	Anti-HLH	
Cohort 2 Fixed dose regimen	7 R/R, unknown driver	No (Day 1)	—	—	No
	8 R/R, R/R PTCL	Yes, up to 1 mg/kg (Day 56)	GemOx ⁵	Yes ⁵	No
	9 R/R, T-cell lymphoma	Yes, up to 0.5 mg/kg (Day 15)	CHOP	Yes ^{3,4}	No
	10 TN, unknown driver	No (Day 4)	—	Yes ²	No

TN = treatment naive.
R/R = relapsed or refractory

FIG. 4A

Cohort 1										Cohort 2			
Criterion #	Criterion	1 R/R	2 TN	3 TN	4 R/R	5 TN	6 R/R	7 R/R	8 R/R	9 R/R	10 TN		
1	Afebrile?												
2	Normal spleen?												
3	ANC and Plt criteria met?												
4	Ferritin criterion met?												
5	D-dimer and/or Fibrinogen criteria met?												
6	Normal neuro and CSF?												
7	No sustained worsening of sCD25?*												
	Overall response assessment	NE	PR	PR	PR	PR	PR	NE	PR	PR	NR		
Complete response (CR)													
Modified CR (mCR)													
Partial response (PR)													
HLH improvement (HI)													
No response (NR)													
Not evaluable (NE)													
*Requires no sustained worsening of sCD25 (as indicated by at least two consecutive measurements that are <2-fold higher than baseline)													

YES

>50% improvement

NO

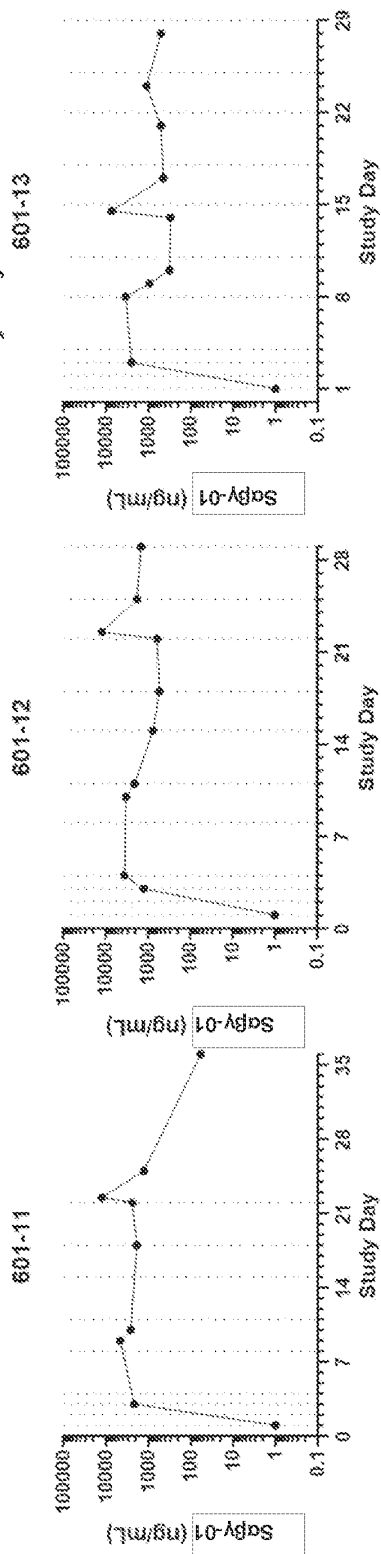
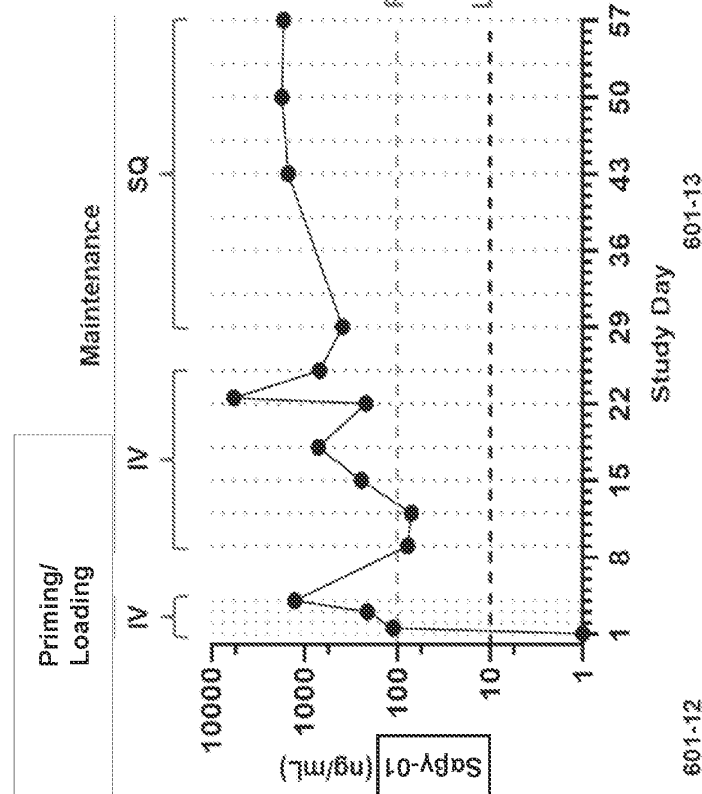
Missing data or data not interpretable

FIG. 4B

Response Assessment for mHLH Patients Treated with Saβy-01 in a Frontline Setting – Best Response by 4 Weeks

Response Criteria	Patient 2	Patient 3	Patient 5	Patient 8	Patient 13	Patient 15	Patient 16	Patient 17	Patient 19	Patient 20	Patient 21	Patient 22
1. Afebrile?	+	+	+	+	+	+	+	+	+	+	-	+
2. Normal spleen?	-			-	-	+	+	-	+	-	+	-
3. ANC and Platelet criteria met?	+	-	-	-	-	-	-	-	-	-	+	-
4. Ferritin criterion met?	0	0	-	-	+	-	+	-		+	+	-
5. D-dimer and/or Fibrinogen criteria met?	+	+	+	+	+	+	+	+	+	+	+	+
6. Normal neuro exam and CSF?	+	+	+	+	+	+	+	+	+	+	+	+
7. No sustained worsening of sCD25?	+	+	+	+	-	+	+	+	+	+	+	+
Overall response	PR	PR	PR	PR	PR	PR	mCR	PR	PR	mCR	PR	PR
+ Criterion met - Criterion not met 0 at least 50% improvement [blank] missing data or not interpretable												

Modified HLH-2004 response criteria adapted from (Locatelli 2020): Complete response (CR): Criteria 1-7 met; Modified CR (mCR): Criteria 1, 4, 5, 6, 7 met; Partial response (PR): Any 3 criteria met; HLH improvement (HI): ≥50% change or improvement from baseline in ≥3 criteria; Overall response is HI or better, without progression of any other clinical or laboratory data. No response (NR): Not meeting CR, mCR, PR or HI; ANC: absolute neutrophil count; CSF: cerebral spinal fluid; sCD25: soluble CD25.

Priming/
Loading

IV: intravenous; SQ: subcutaneous; PD: pharmacodynamic; LLOQ: lower limit of quantitation; PD threshold defined in non-human primate study. Data up in upper right presented from 602-01. Dashed lines on Day 1-4: Priming and loading series (0.1 mg/kg on Day 1, 0.3 mg/kg on Day 2 - 4, IV); twice weekly dashed line: 0.5 mg/kg IV or SQ

FIG. 5B

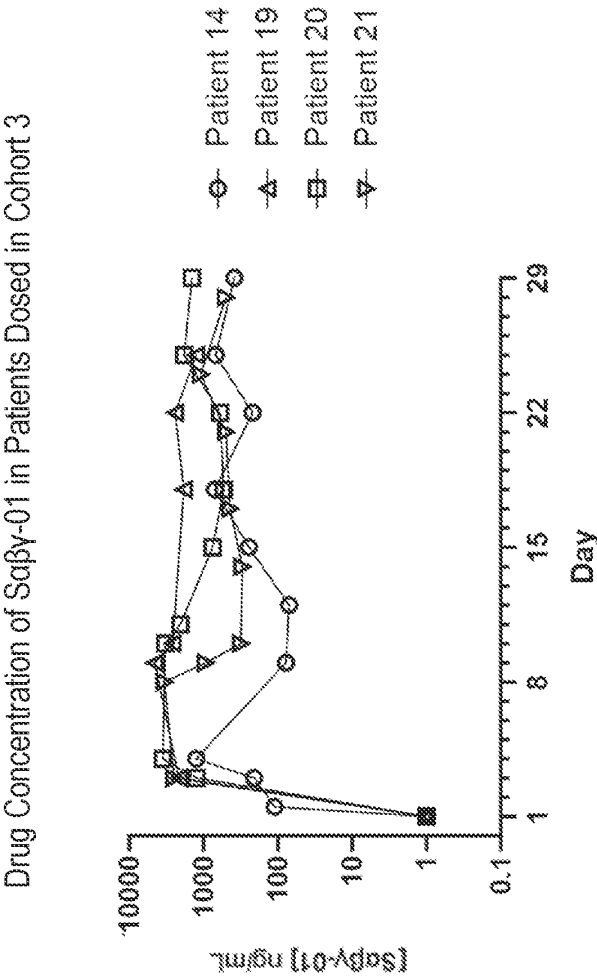
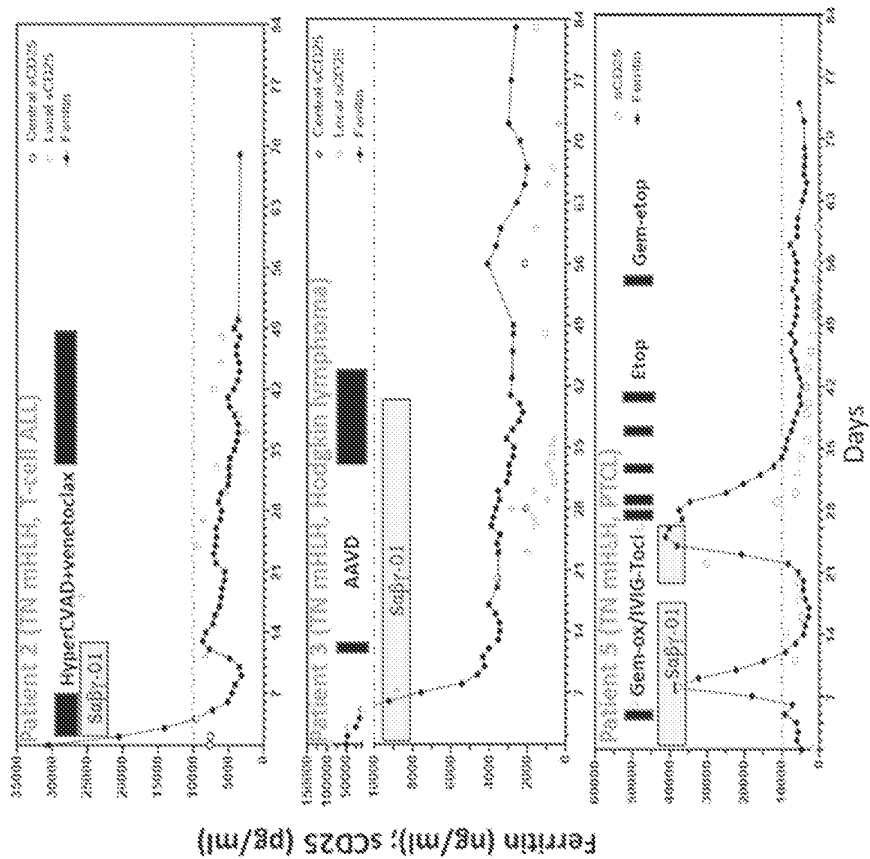


FIG. 6



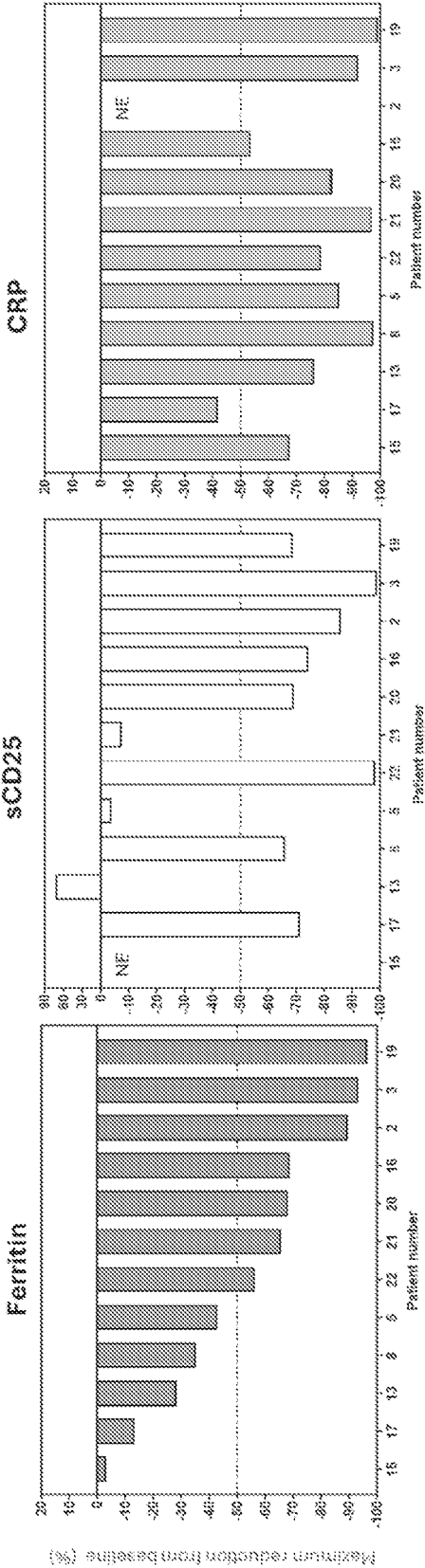
WO 2025/085854

OHL, baseline	sCD25/ ferritin, baseline	Peak sCD25 (pg/ml)	Peak ferritin (ng/ml)	Max reduction sCD25 (nadir, pg/ml)	Max reduction ferritin (nadir, ng/ml)
+	1.9	59529	30583	-96% (2518)	-90% (3171)
+	1.8	91251	50427	-100% (350)	-96% (2002)
-	2.3	55337	41132	-99% (447)	-92% (3418)

PCT/US2024/052123

FIG. 7

sCD25, Ferritin, CRP Biomarker Response in Patients Receiving Saβy-01 in a Frontline Setting



Abbreviations: sCD25: soluble CD25; CRP: C-reactive protein;
NE: not evaluable due to missed baseline value

	Ferritin	sCD25	CRP
Patients with >50% Reduction, n (%)	7 (58)	8 (67)	10 (83)
Median Reduction, % (range)	-61 (-97 to -3)	-69 (-99 to 62)	-83 (-99 to -42)

FIG. 8

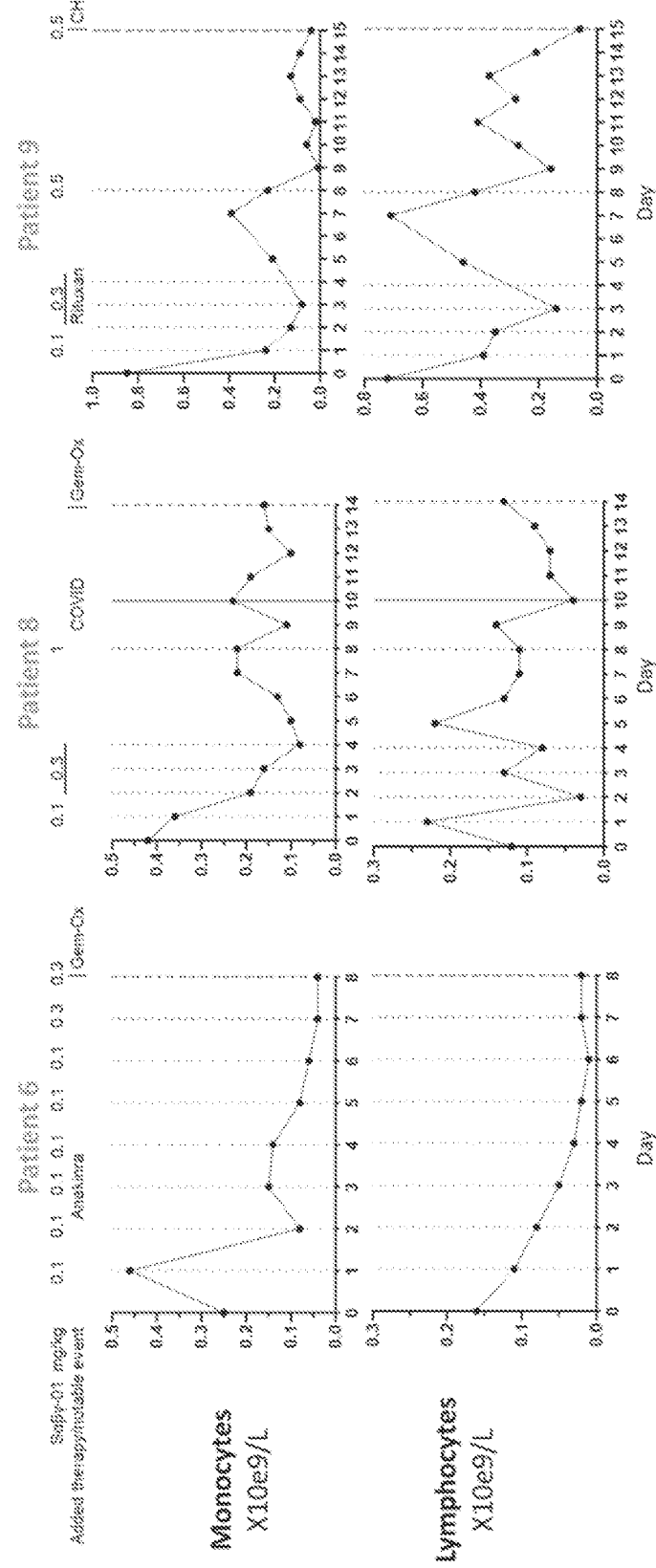


FIG. 9

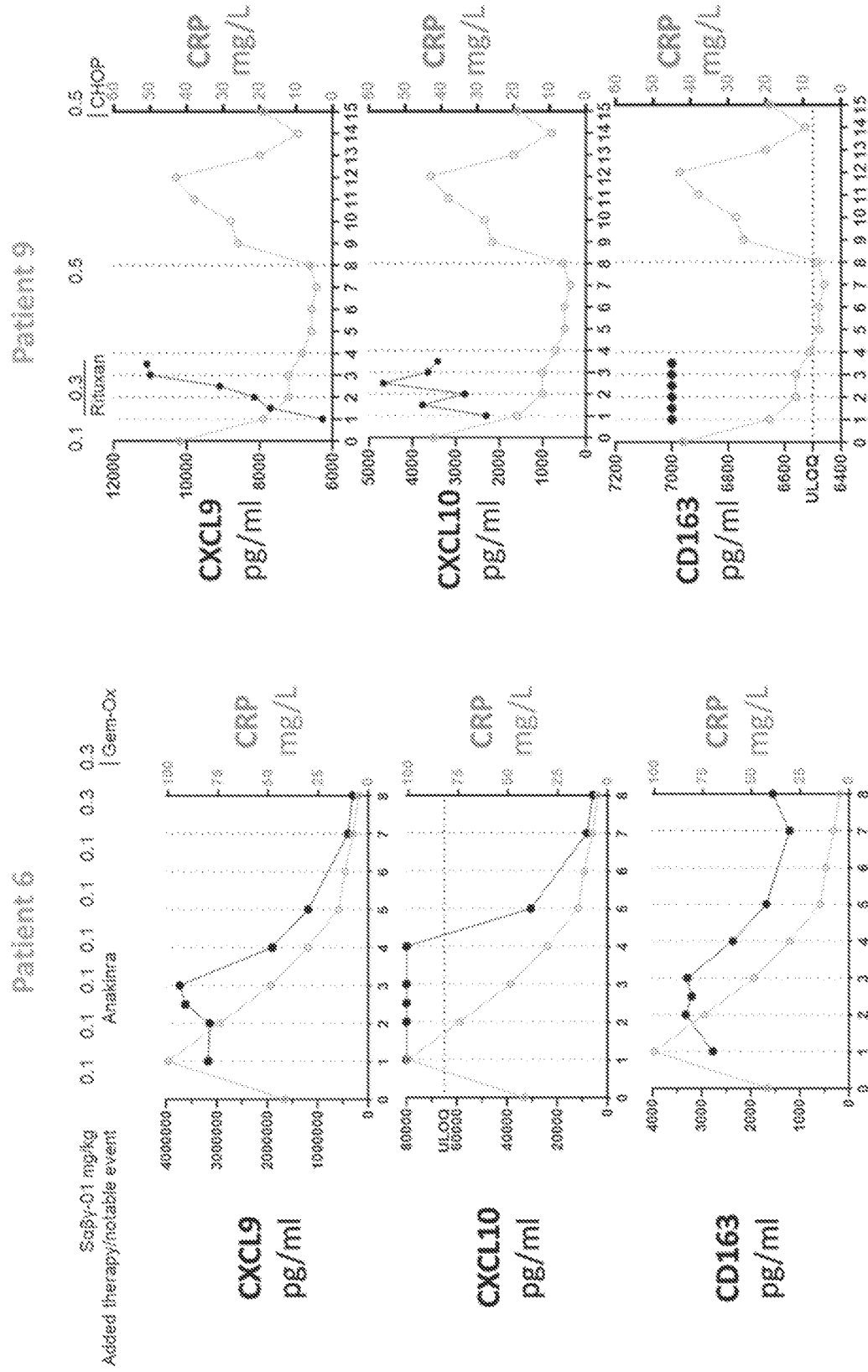


FIG. 10

Case Summary of Patient 6 with Relapsed/Refractory T-cell Lymphoma-triggered mHLH

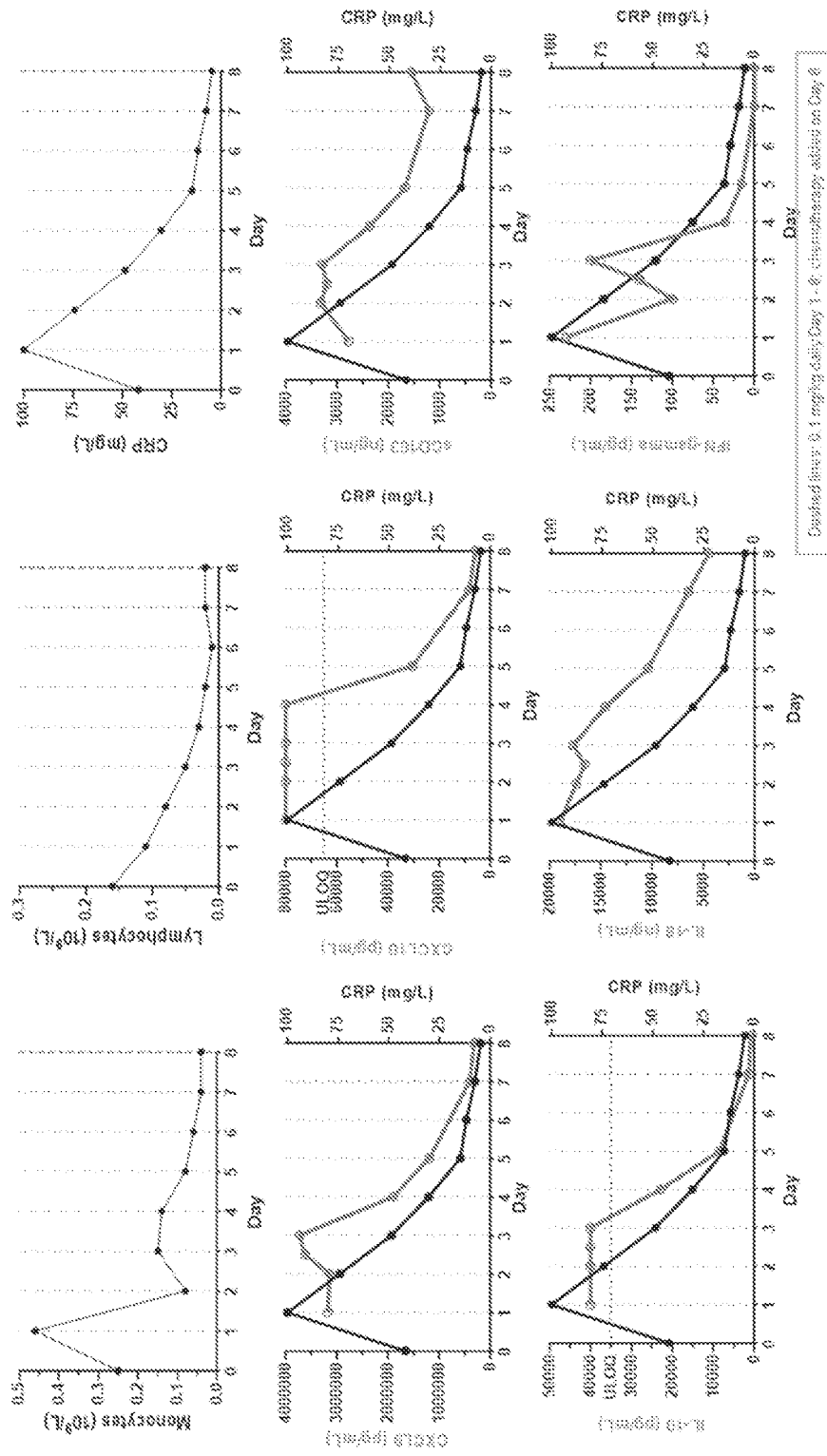


FIG. 11
Biomarker Response in mHLH Patients Treated with Saβy-01 in a Frontline Setting

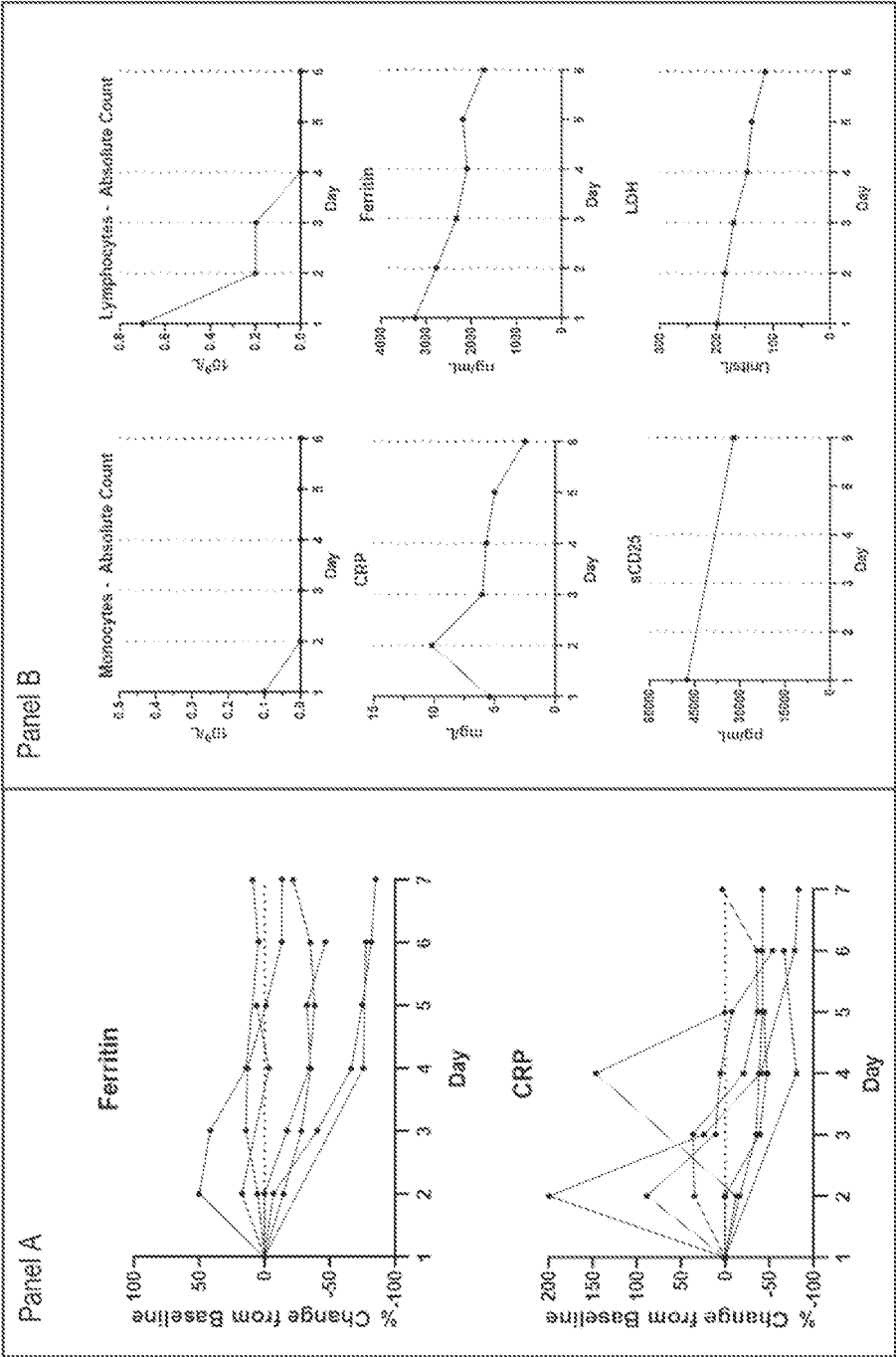


FIG. 12

Case Summary of Patient with Treatment Naïve EBV-Triggered sHLH

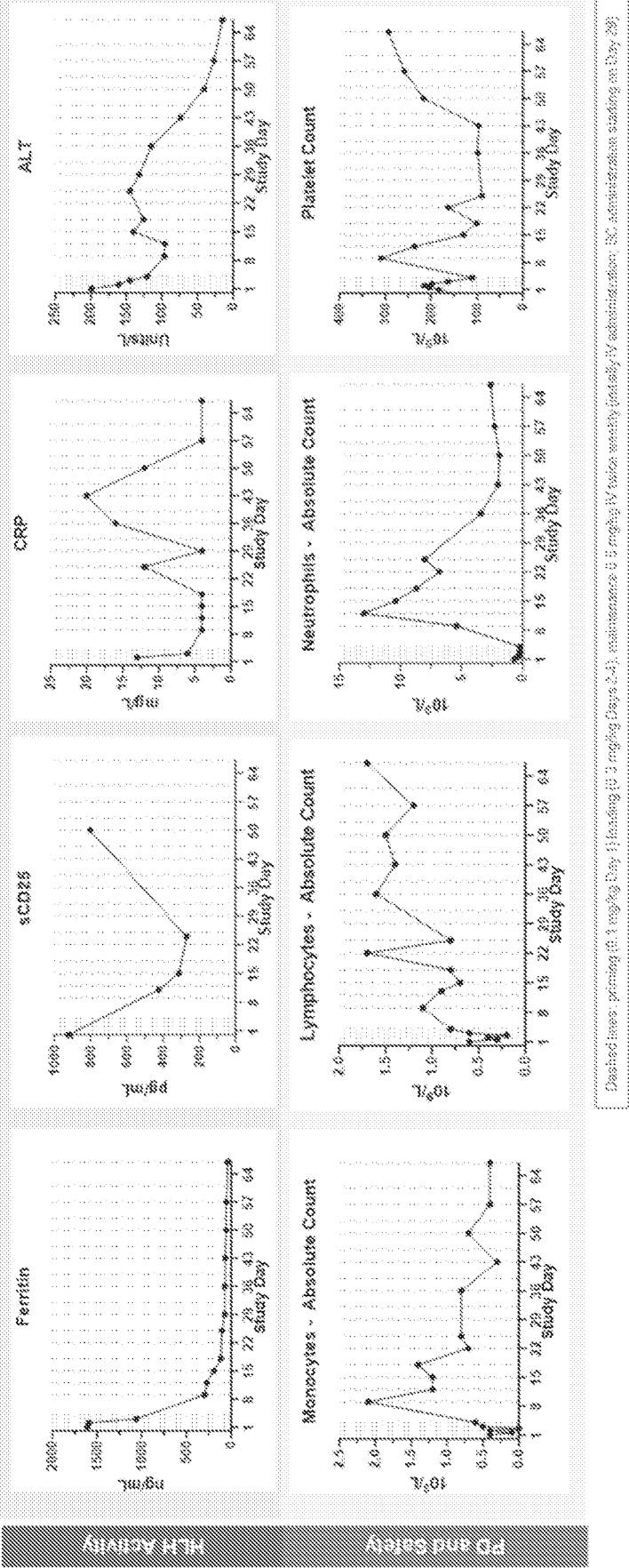


FIG. 13

Biomarker Response as Fold-Change from Baseline in 6 Patients Treated with Safy-01 in a Frontline Setting

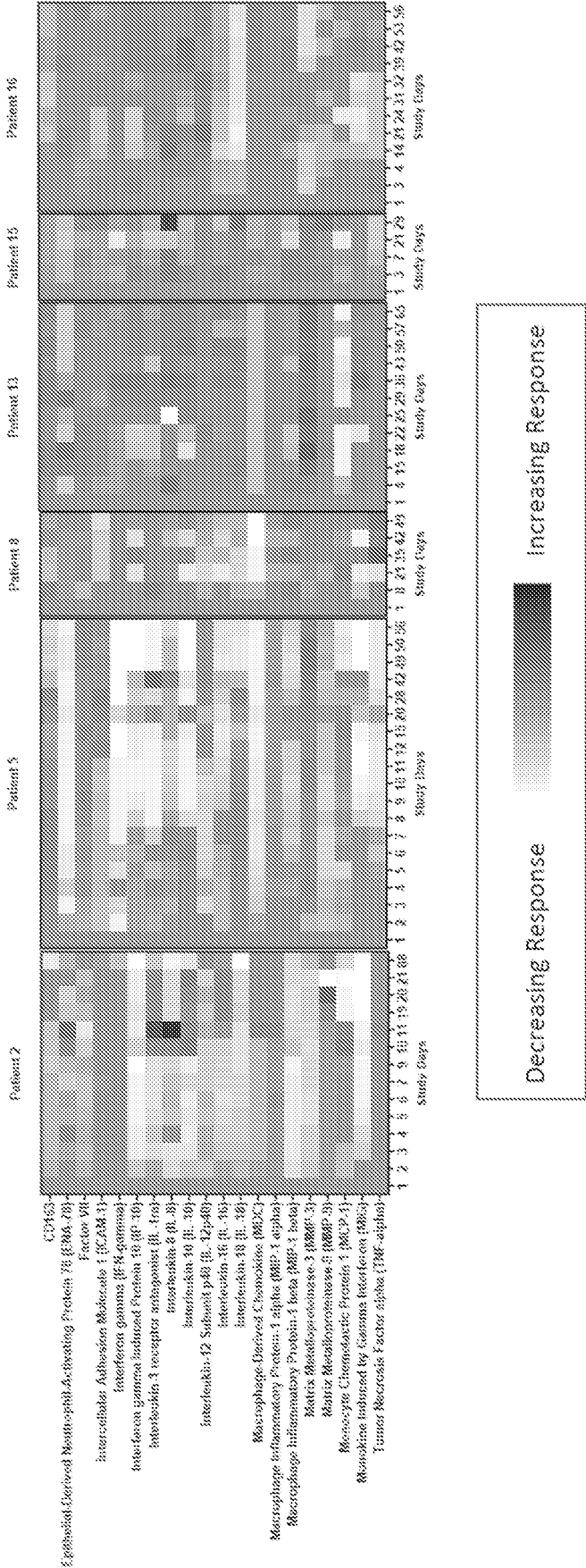
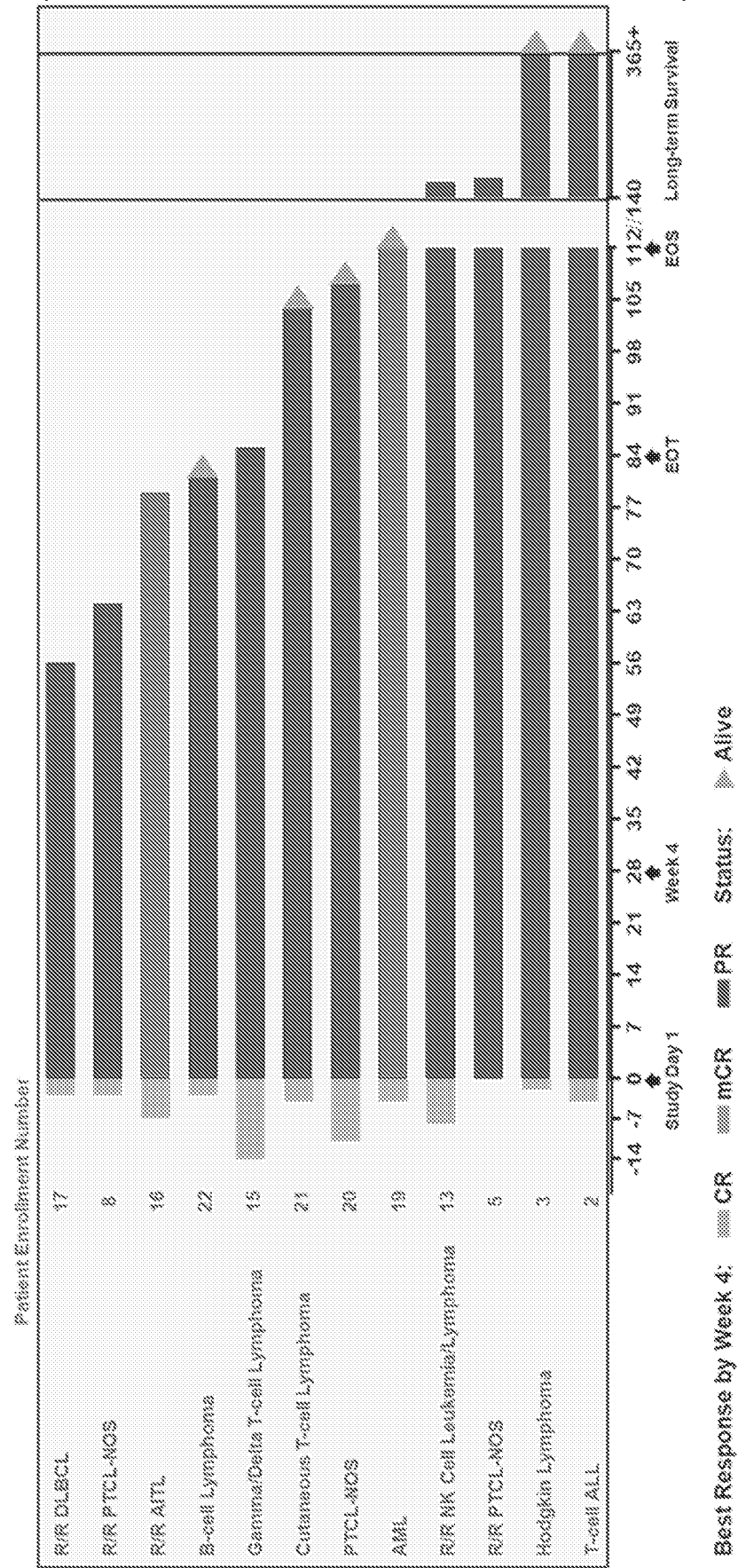


FIG. 14A



Survival and Response of All Patients Receiving Saβy-01

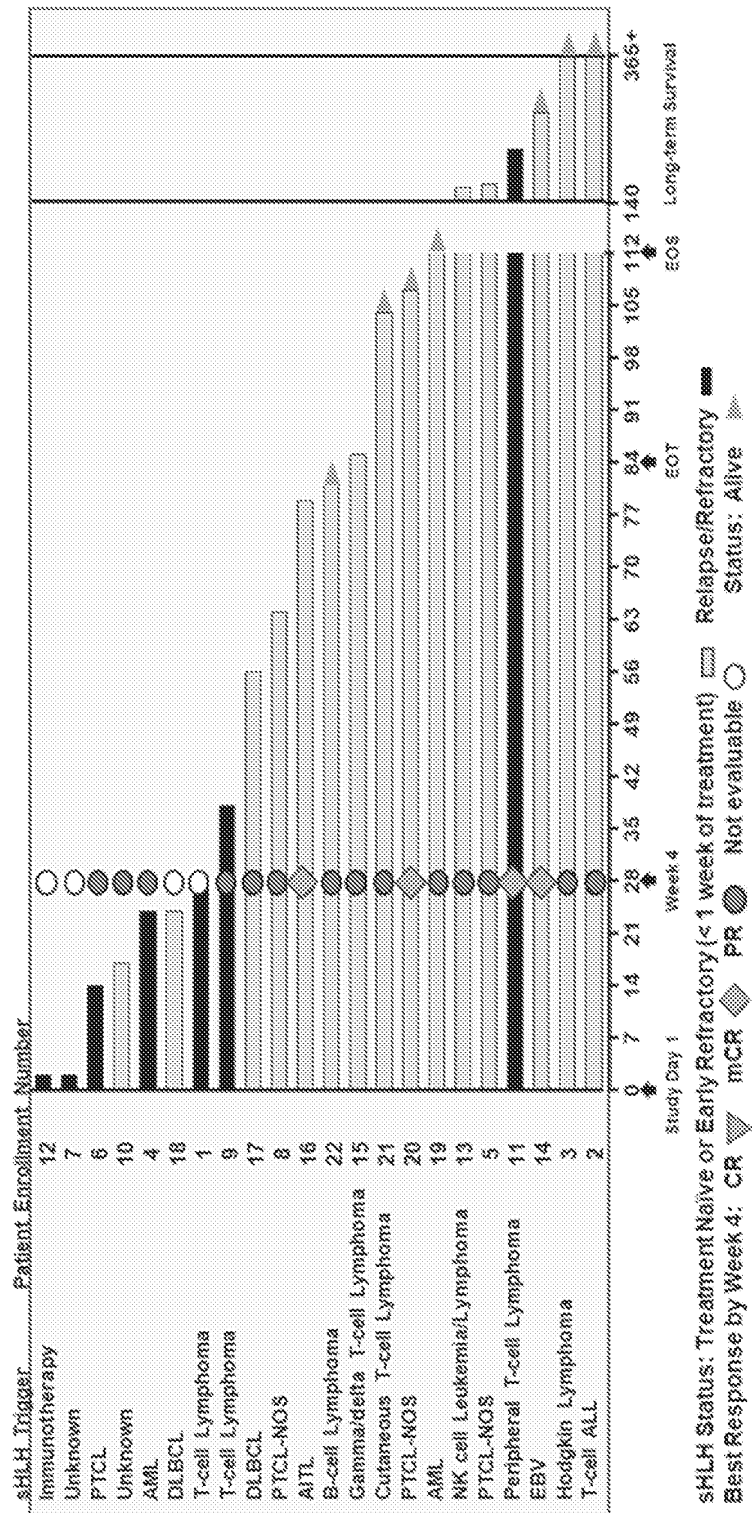


FIG. 15

Adverse event	All events					Related events				
	n (%)	1/2	3/4	5	n (%)	1/2	3/4	5	Grade	
Hypotension	8 (47)	6	2	0	2 (12)	2	0	0	0	
Sepsis*	6 (35)	0	4	2	0	0	0	0	0	
Pyrexia	6 (35)	4	2	0	2 (12)	2	0	0	0	
Dyspnoea	6 (35)	5	1	0	1 (6)	1	0	0	0	
Thrombocytopenia*	6 (35)	0	6	0	2 (12)	0	2	0	0	
Epistaxis	5 (29)	3	2	0	0	0	0	0	0	
Hyperglycaemia	5 (29)	4	1	0	0	0	0	0	0	
Multiple organ dysfunction	4 (24)	0	2	2	0	0	0	0	0	
Respiratory failure	4 (24)	0	3	1	0	0	0	0	0	
Hyponatraemia	4 (24)	3	1	0	0	0	0	0	0	
Chills	4 (24)	4	0	0	1 (6)	1	0	0	0	
Hyperkalaemia	4 (24)	4	0	0	0	0	0	0	0	
Hypomagnesaemia	4 (24)	4	0	0	0	0	0	0	0	
Neutropenia*	4 (24)	0	4	0	1 (6)	0	1	0	0	
Pneumonia	3 (18)	0	3	0	0	0	0	0	0	
Infusion related reaction	3 (18)	1	2	0	2 (12)	0	2	0	0	
Blood bilirubin increased	3 (18)	1	2	0	0	0	0	0	0	
Pain in extremity	3 (18)	1	2	0	0	0	0	0	0	
AST increased	3 (18)	2	1	0	0	0	0	0	0	
Abdominal pain	3 (18)	2	1	0	0	0	0	0	0	
Arthralgia	3 (18)	2	1	0	0	0	0	0	0	
Diarrhoea	3 (18)	2	1	0	1 (6)	1	0	0	0	
Cough	3 (18)	3	0	0	0	0	0	0	0	
Fall	3 (18)	3	0	0	0	0	0	0	0	
Hyperhidrosis	3 (18)	3	0	0	0	0	0	0	0	
Hyperphosphataemia	3 (18)	3	0	0	0	0	0	0	0	
Hypoalbuminaemia	3 (18)	3	0	0	0	0	0	0	0	
Hypophosphataemia	3 (18)	3	0	0	0	0	0	0	0	
Rash	3 (18)	3	0	0	0	0	0	0	0	
Oedema peripheral	3 (18)	3	0	0	0	0	0	0	0	

Adverse events occurring in ≥3 of N=17 dosed patients

- ~20% related infusion reactions (or symptoms), generally mild-moderate
- ~30% related neutropenia and/or thrombocytopenia, in setting of baseline cytopenia
- Manageable with routine supportive care and dose modification

Multiple organ dysfunction: multiple organ dysfunction syndrome; AST: aspartate aminotransferase; Grade according to CTCAE V5.0.

*Combined sepsis and septic shock. Combined platelet count decreased and thrombocytopenia. Combined neutrophils decreased and neutropenia.