SONOMA BIOTHERAPEUTICS

SCHEDULE OF ASSESSMENTS: SCREENING AND PRE-TREATMENT PERIODS

SONOMA BIOTHERAPEUTICS, INC. | PROTOCOL SBT777101-01

Protocol: Version 6.0 | 19 April 2024

	Screening[a]	Pre-Treatment[b]	
		Apheresis[c]	Pre-infusion
Study Day (visit window)			**-10 to -4**
Procedure			
Informed consent	•		
Eligibility criteria	•		•
Demographics	•		
Medical history	•		•
Prior/Concomitant medications	•	•	•
Vital signs	•		•
Full physical exam	•		
Directed physical exam			•
ICE			•
Height	•		
Weight	•		•
12-lead triplicate ECG	•		•
Chest X-ray			•
Assessment of synovitis (clinical and/or ultrasound)	•		•
Optional synovial biopsy for tissue [d]		•	
Optional synovial fluid collection [d]		•	
Vein assessment [e]	•	•	
Apheresis [c]		•	
Infectious disease serology [f]	•		
TB screening [f]	•		
Serum pregnancy test	•		•
Lipid tests [f]			•
Coagulation [f]	•		•
Hematology [f]	•		•
Clinical chemistry [f]	•		•
Urinalysis [f]	•		•
Markers of inflammation [g]			•
CRP & ESR	•		•
Joint count assessment (28 SJC and 28 TJC)			•
Joint count assessment (66 SJC and 68 TJC)	•		
Physician's Global Assessment of Arthritis	•		•
Patient's Global Assessment of Arthritis and Assessment of Arthritis Pain)	•		•
HAQ-DI	•		•
FACIT-F			•
Blood samples for PK (ddPCR)			•
PBMC sample for cellular immunogenicity			•
Serum sample for ADA			•
Plasma sample for exploratory markers[i]	•	•	

Continued on reverse

	Screening[a]	Pre-Treatment[b]	
		Apheresis[c]	Pre-infusion
Study Day (visit window)			**-10 to -4**
Procedure			
Serum sample for exploratory markers[i]		•	
PBMC sample for exploratory biomarkers[i]	•	•	
PBMC sample for RCL			•
Adverse events[h]	•	•	•

ADA = anti-drug antibody; **APH** = apheresis; **CRP** = C-reactive protein; **ddPCR** = droplet digital polymerase chain reaction; **ECG** = electrocardiogram; **ESR** = erythrocyte sedimentation rate; **FACIT-F** = Functional Assessment of Chronic Illness Therapy – Fatigue; **HAQ-DI** = health assessment questionnaire disability index; **ICE score** = Immune Effector Cell-Associated Encephalopathy Score; **PK** = pharmacokinetic; **RCL** = replication competent lentivirus; **SJC** = swollen joint count; **TB** = tuberculosis; **TJC** = tender joint count; **UV** = unscheduled visit; **VAS**= visual analogue score

a. The Screening period is expected to last approximately 4 weeks (but up to 2 months is permitted).

b. The Pre-Treatment period is expected to last approximately 6 weeks (but may last up to 6 months or until study drug product expiration).

c. Apheresis should be scheduled and performed as soon as possible once screening eligibility is confirmed and the subject enters the Pre-Treatment period.

d. Synovial biopsy and/or synovial fluid collection during the Pre-Treatment period are optional and subjects must consent on the ICF for collection.

e. Assessment of vascular access is indicated for apheresis and/or administration of SBT777101 should be determined by the Investigator.

f. Tests included in laboratory assessments are described in protocol Appendix C. Fasting glucose should be collected at the pre-treatment visit and as clinically indicated.

g. Markers of inflammation for safety assessment include ferritin, IL-6, and IFNγ.

h. All SAEs plus any AE that is the result of a protocol specified procedure or intervention will be collected from the signing of the ICF until study drug administration.

i. Exploratory samples are collected during both the Screening and Pre-Treatment periods. Exploratory samples collected during the pre-treatment period should be within 5 days as the optional synovial biopsy, if it is being performed. Otherwise, collection should occur during the pre-infusion visit.