

SCHEDULE OF ASSESSMENTS: SCREENING AND PRE-TREATMENT PERIODS

SONOMA BIOTHERAPEUTICS, INC. | PROTOCOL SBT777101-01

Protocol: Version 5.0 | 02 May 2023

	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)	•		•
Synovial biopsy for tissue ^d	•		
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			•

	Screening ^a	Pre-Treatment ^b	
		Apheresis ^c	Pre-infusion
Study Day (visit window)			-10 to -4
Procedure			
Plasma sample for exploratory markers	•		•
Serum sample for exploratory markers			•
PBMC sample for exploratory biomarkers	•		•
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; **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

- The Screening period is expected to last approximately 4 weeks.
- The Pre-Treatment period is expected to last approximately 6 weeks (but up to 6 months is permitted).
- Apheresis should be scheduled and performed as soon as possible once screening eligibility is confirmed and the subject enters the Pre-Treatment period.
- Synovial biopsy and/or synovial fluid collection during the Screening period can be performed before or after remainder of screening assessments, but prior to subject entering the Pre-Treatment period.
- Assessment of vascular access is indicated for apheresis and/or administration of SBT777101 should be determined by the Investigator with subject input.
- 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.
- Markers of inflammation for safety assessment include ferritin, IL-6, and IFN γ .
- After informed consent has been obtained but prior to initiation of study drug, only SAEs caused by a protocol-mandated intervention should be reported.