SONOMA BIOTHERAPEUTICS

SCHEDULE OF ASSESSMENTS: BASELINE AND SAFETY FOLLOW-UP PERIOD

SONOMA BIOTHERAPEUTICS, INC. | PROTOCOL SBT777101-01

Protocol: Version 7.0 | 30 January 2025

	Safety Follow Up																UV[a]	ET
Study Week	1				2		3	4	6	8	10	12	18	24	36	48/ES		
Study Day (visit window)	1	2	4 or 5	7 ±1	11 ±1	14 ±2	21 ±2	28 ±2	42 ±2	56 ±2	70 ±2	84 ±3	126 ±7	168 ±7	252 ±7	336 ±7		
Vital signs [b]	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Adverse events [c]	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Prior/Concomitant medications	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Full physical exam				•				•		•						•		•
Directed physical exam	•	•	•		•	•	•		•		•	•	•	•	•		•	
ICE score [d]	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•
Weight										•						•		•
12-lead triplicate ECG				•		•										•	•	•
Optional synovial biopsy for tissue [e]								•										•
Optional synovial fluid collection [e]								•				•						•
Assessment of synovitis (clinical and/or ultrasound)								•				•						•
Urine pregnancy test	•											•	•	•		•		•
Lipid tests [f]																•		
Coagulation [f]													•	•		•		
Hematology [f]		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Clinical chemistry [f]		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Urinalysis [f]										•					•	•		•
Blood sample for markers of inflammation [g]																	•	
CRP and ESR		•		•		•	•	•	•	•	•	•	•	•	•	•	•	•
Joint count assessment (28 SJC/28 TJC and 66 SJC/68 TJC)						•		•		•		•	•	•		•		•
Physician's Global Assessment of Arthritis						•		•		•		•	•	•		•		•
Patient's Global Assessment of Arthritis and Assessment of Arthritis Pain)						•		•		•		•	•	•		•		•
HAQ-DI						•		•		•		•	•	•		•		•
FACIT-F													•	•		•		•
MRI (optional) [h]			•									•		•				
Blood samples for PK (ddPCR) [i]		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

Continued on reverse

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Study Day (visit window)	1	2	4 or 5	7 ±1	11 ±1	14 ±2	21 ±2	28 ±2	42 ±2	56 ±2	70 ±2	84 ±3	126 ±7	168 ±7	252 ±7	336 ±7		
PBMC sample for cellular immunogenicity								•		•		•				•	•	•
Serum sample for ADA								•		•		•				•	•	•
Plasma sample for exploratory markers		•		•		•	•	•	•	•	•	•	•	•	•	•	•	•
Serum sample for exploratory markers		•		•		•	•	•	•	•	•	•	•	•	•	•	•	•
PBMC sample for exploratory biomarkers		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
PBMC sample for RCL												•		•		•	•	
SBT777101 administration	•																	
Overnight stay/acute safety monitoring (post-dose)	•																	
Patient self-temperature monitoring [j]		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Patient check-in (phone call, text etc) [k]		•	•	•														

ADA = anti-drug antibody; **CRP** = C-reactive protein; **ddPCR** = droplet digital polymerase chain reaction; **ECG** = electrocardiogram; **ES** = End of Study; **ESR** = erythrocyte sedimentation rate; **ET** = early termination; **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; **MRI** = magnetic resonance imaging; **RCL** = replication competent lentivirus; **SJC** = swollen joint count; **TJC** = tender joint count; **UV** = unscheduled visit; **VAS**= visual analogue score

Note: On Day 1, all assessments should be performed prior to dosing, unless otherwise specified.

a. Assessments (which may include safety labs, ECG, ICE assessment, PK, ADA, and biomarker sample collection and synovial biopsy/fluid collection) should be performed as clinically indicated.

b. Vital signs must be measured approximately 15 minutes prior to infusion, then approximately every 15 minutes during the infusion. Vitals should include cardiorespiratory monitoring (CRM, eg, telemetry) and be recorded approximately every 4 hours during the first 24 hours from initiation of infusion.

c. After informed consent has been obtained but prior to initiation of study drug, only SAEs caused by a protocol-mandated intervention should be reported. After initiation of study drug, all AEs will be reported until the end of the study. After this period, the Sponsor should be notified if the investigator becomes aware of any SAE that is believed to be related to prior study drug treatment.

d. Approximately every 4 hours while awake during the first 24 hours after initiation of infusion, with vital signs.

e. The optional synovial biopsy/fluid collection is targeted for 4 weeks post infusion, but may be performed any time after Week 2 through the end of the study.

f. Tests included in laboratory assessments are described in protocol Appendix C.

g. A sample to test for markers of inflammation, including but not limited to ferritin, IL-6, IFNγ, CRP, and ESR, should be collected as soon as possible after the onset of a suspected adverse event per institutional standards of care.

h. For 1st post infusion MRI, window extends from -1 to +2 weeks (3-6 weeks total post-infusion). For 2nd post-infusion MRI, window extends +/- 2 weeks (10-14 weeks total post-infusion). For third infusion, window extends from 24 weeks through the EOS (24-48 weeks post-infusion).

i. The PK sample collected on study Day 2 should be collected at approximately the same time of day that the infusion of study drug took place on study Day 1 (+/- 1 hour). An unscheduled PK sample should be collected as soon as possible after a suspected infusion related reaction adverse event.

j. Subjects are required to measure and record their temperatures in the patient diary at least once daily. Sites are required to review patient diaries at each visit.

k. Subjects should be contacted daily by the site (eg, by phone or text) following discharge through Day 7.