SONOMA BIOTHERAPEUTICS

SCHEDULE OF ASSESSMENTS: TREATMENT AND SAFETY FOLLOW-UP PERIOD

SONOMA BIOTHERAPEUTICS | SBT777101-02

Protocol: Version 3.0 | 01 May 2025

	Treatment and 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		
Procedure																		
Vital signs [b]	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Adverse events [c]	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Prior/Concomitant medications	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Full physical exam [d]				●				●		●						●		●
Directed physical exam [d]	●	●	●		●	●	●		●		●	●	●	●	●		●	
ICE score [e]	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●
Weight								●		●						●		●
12-lead triplicate ECG				●				●								●	●	●
Skin biopsy and corresponding lesion photograph [f]								●				●						●
Skin photography of affected lesions [g]								●		●		●	●	●	●	●		
Urine pregnancy test	●							●				●	●	●		●		●
Lipid tests [h]								●								●		
Coagulation [h]								●						●		●		
Hematology [h]		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Clinical chemistry [h]		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Urinalysis [h]										●					●	●		●
Markers of acute inflammation [i]																	●	
CRP and ESR		●		●		●	●	●	●	●	●	●	●	●	●	●	●	●
Lesion count [j]						●		●	●	●	●	●	●	●	●	●	●	●
Subject HiSQOL score								●		●		●	●	●		●		●
NRS30								●		●		●	●	●	●	●	●	●
Collect date of the first day of the last menstrual period								●		●		●	●	●	●	●	●	●
Blood samples for PK (ddPCR) [k]		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
PBMC sample for cellular immunogenicity								●		●		●				●	●	●
Serum sample for ADA								●		●		●	●			●	●	●
Plasma for exploratory markers		●		●		●	●	●	●	●	●	●	●	●	●	●	●	●

Continued on reverse

	Treatment and 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		
Procedure																		
Serum for exploratory markers		●		●		●	●	●	●	●	●	●	●	●	●	●	●	●
PBMC for exploratory biomarkers		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
PBMC samples for RCL												●		●		●	●	
SBT777101 administration [l]	●																	
Overnight stay/acute safety monitoring (post-dose)	●																	
Subject self-temperature monitoring [m]		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Subject check-in (phone call, text etc) [n]		●	●	●														

A = abscess; **ADA** = anti-drug antibody; **CRP** = C-reactive protein; **ddPCR** = droplet digital polymerase chain reaction; **dT** = draining tunnel (fistula/sinus); **ECG** = electrocardiogram; **ES** = End of Study; **ET** = early termination; **HiSCR** = hidradenitis suppurativa clinical response; **HiSQOL** = Hidradenitis Suppurativa Quality of Life; **ICE score** = Immune Effector Cell-Associated Encephalopathy Score; **PK** = pharmacokinetic; **RCL** = replication competent lentivirus; **UV** = unscheduled visit

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 skin biopsy) 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 and for one hour thereafter. 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, all SAEs plus any AE that is the result of a protocol-specified procedure or intervention will be collected. After initiation of study drug administration, all AEs will be reported until the end of the study. After this period, the Sponsor should be notified if the Principal Investigator becomes aware of any SAE that is believed to be related to prior study drug treatment.

d. Lesion counts are optional at the physical examinations at which photographs are not taken.

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

f. The skin biopsy can be performed at or up to 7 days after the scheduled assessment visit. The timing of the skin biopsy may be changed based on evaluation of data from the first dose escalation cohort. For subjects who discontinue the study prior to Week 12, a skin biopsy at ET is optional. Please include a photograph of the lesion which is to biopsied. Please refer to the Biopsy Manual for further information.

g. Photographic documentation of all affected anatomic regions should be obtained. Photographs at other timepoints should be taken at the discretion of the investigator.

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

i. 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.

j. Lesion counts at Weeks 2, 6 and 10 will be optional. Lesion counts will be used to calculate HiSCR 50, 75 and 90 as well as IHS4.

k. The PK sample collected on study Day 2 should be collected at approximately 24 hours (±1 hour) post infusion of study drug on study Day 1. An unscheduled PK sample should be collected as soon as possible after a suspected infusion related reaction adverse event.

l. Subjects must remain at the study site/medical facility under medical supervision for at least 24 hours from the start of the Day 1 study drug infusion through completion of procedures at the Day 2 visit.

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

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