SONOMA BIOTHERAPEUTICS

Protocol Clarification Letter #2

Date: July 27, 2023

Protocol: SBT777101-01, A Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Activity of Single Ascending Doses of SBT777101 in Subjects with Rheumatoid Arthritis

Dear SBT777101-01 Study Investigators,

This letter serves to correct an error identified in the SBT777101-01 protocol, Version 5.0, dated May 2, 2023. Sonoma Biotherapeutics recently identified that required plasma and peripheral blood mononuclear cells (PBMC) sampling during the Screening period was erroneously omitted from Appendix A. These additional samples will be used for cytokine analysis and flow cytometric quantification and characterization of inflammatory cell subtypes.

Current Version of Appendix A

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

Corrected Version of Appendix A

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

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Inclusion of these samples does not impact the frequency of blood collections for subjects, but will increase the volume of blood collected during the Screening period by approximately 27mL. The estimated blood volumes collected during the study will be updated in the ICF.

Please review and share with your team and IRB as appropriate. Please let me know if you have any questions or concerns. The aforementioned correction will be reflected in the next protocol amendment.

Signature: DocuSigned by: Mai H Le 34857E85ECEB4C7... Date: 7/27/2023

Mai H. Le, MD

201 Haskins Way, Suite 203 * San Francisco, CA 94080 * (415)992-6245