SUBJECT ELIGIBILITY FORM

PART 1: SCREENING

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

Instructions: This is part 1 of a 3-part eligibility review, for screening. Please fill out all sections in Part 1 of this form and submit it to ClinicalOperations@sonomabio.com. Please ensure to provide redacted copies of source documentation when submitting this form to Sonoma supporting the requested information below. Please do NOT send original and/or unredacted copies source document. Any missing or unclear information may require a follow-up request(s), which could result in delay of enrollment. Thank you for your attention to this important matter.

PLEASE CONFIRM (CHECK) THAT THE FOLLOWING ITEMS HAVE BEEN REVIEWED AND ELIGIBILITY HAS BEEN MET
☐ Confirm a copy of the local screening lab results is attached, with all patient-identifying health information redacted. ☐ Hematology ☐ Chemistry ☐ Pregnancy test or FSH and estradiol (for women of childbearing potential or in the absence of 12 months of amenorrhea; refer to Appendix D of the protocol) ☐ TB screening ☐ Serology ☐ Coagulation ☐ Urinalysis ☐ CRP
☐ Medical history (including prior surgeries and procedures)
☐ Concomitant medications (Prior and concomitant medications for the treatment of RA reported from first known use; all other medications reported 30 days prior to date of consent)
☐ Physical exam
☐ Homunculus (please complete separate form provided and attach)

SUBJECT INFORMATION											
Investigator name:											
Subject ID	**S**	**0**	**1**	—				—			
Subject ID format AAA-XYY-ZZZ: Protocol number AAA=S01; Country ID X= 1-9; Site number YY = 01-99; Subject number ZZZ											

Gender assigned at birth: ☐ Male ☐ Female

Year of Birth (YYYY):

Weight (kg):	Height (cm)	BMI (kg/m^2)
___ ___ ___ . ___	___ ___ ___	___ ___ . ___

MEDICAL HISTORY

PLEASE LIST ALL DIAGNOSES BELOW

Diagnosis	Ongoing?	Comments
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	

PLEASE LIST ALL PRIOR SURGICAL PROCEDURES

Procedure	Date (DD / MMM / YYYY)	Reason

PLEASE LIST ALL KNOWN ALLERGIES:	
Allergies:	**Description of Reaction:**

PLEASE LIST ALL NON-RA CONCOMITANT AND HISTORICAL MEDICATIONS FOR 30 DAYS PRIOR TO CONSENT					
Medication	**Dose, Unit**	**Frequency**	**Indication**	**Start Date**	**End Date**

PLEASE PROVIDE THE FOLLOWING INFORMATION ON THE RA DIAGNOSIS AND DISEASE STATE	
Date of RA Diagnosis (DD/MMM/YYYY): *If day is unknown, please put UK*	☐☐ / ☐☐☐ / ☐☐☐☐
DAS28CRP *Please use the DAS28 online calculator at https://www.4s-dawn.com/DAS28/ and attach a completed copy to this form* *****	SJC28:
	TJC28:
	CRP (mg/L):
*** To attach a printout, you can either take a screen capture of the page or print to save as a PDF. If you print to PDF, you will need to view the advanced print settings and select the option to include background graphics for the image to transfer properly.**	DAS28CRP score:
Is there clinical/ultrasound evidence of synovitis?	☐ Yes ☐ No

Has the subject ever had an inadequate response to or were unable to tolerate a bDMARD or tsDMARD. As a note, the subject must have been unable to tolerate or failed three different bDMARDs or tsDMARDs, with different mechanisms of action, to be eligible for this study.

Note: An inadequate response is determined by the treating physician and may be based on RA that is difficult to treat and continued disease activity as measured by ≥4/28 tender and ≥4/28 swollen joints, DAS28 ≥3.2, inability to taper corticosteroids to 7.5 mg or lower, or other appropriate measures, (Nagy et al., 2020), generally after 3 months of therapy on the recommended therapeutic dose (Frankel et al., 2021).

☐ Yes ☐ No

Please specify each drug for which the subject's RA did not adequately respond or the subject was unable to tolerate:

DRUG	START DATE	STOP DATE	DOSE

LIST OF RA MEDICATIONS (REPORTED FROM FIRST KNOWN USE)							
Treatment	**Dose**	**Route of administration**	**Frequency**	**Start Date (MM/DDD/YYYY)**	**End Date Or Ongoing (MM/DDD/YYYY)**	**Stable dose 30 days before screening (Y/N)**	**Comments**
						☐ Yes ☐ No	
						☐ Yes ☐ No	
						☐ Yes ☐ No	
						☐ Yes ☐ No	
						☐ Yes ☐ No	
						☐ Yes ☐ No	
						☐ Yes ☐ No	
						☐ Yes ☐ No	
						☐ Yes ☐ No	

PROHIBITED MEDICATION CHECKLIST FOR RA				
Subjects must remain off all agents listed below for the duration of the study, unless an RA flare requires initiation of recue therapy that includes prohibited agents.				
Medication	**Yes/No**	**Discontinuation Timing**	**Start Date (DD / MMM / YYYY)**	**Stop Date (DD / MMM / YYYY)**
Investigational Agents	☐ Yes ☐ No	30 days or 5 half-lives before screening, whichever is longer		
Intraarticular corticosteroids	☐ Yes ☐ No	90 days before screening		
Leflunomide	☐ Yes ☐ No	8 weeks before screening		
bDMARDs: abatacept	☐ Yes ☐ No	90 days before screening		

ADDITIONAL ELIGIBILITY CRITERIA REVIEW	
Have you confirmed that the subject has met all the enrollment criteria? ☐ Yes ☐ No **This is NOT an all-inclusive list and does not replace the full Inclusion/Exclusion criteria in the protocol. Please select "yes" or "no" for each criterion.**	
History of or current inflammatory joint disease other than RA or other autoimmune or inflammatory disease that may confound clinical assessments or increase subject risk in the study	☐ Yes ☐ No
Current or previous (within the past 2 years) evidence of serious uncontrolled concomitant cardiovascular, pulmonary (including obstructive pulmonary disease), renal, hepatic, endocrine (including uncontrolled diabetes mellitus) or gastrointestinal disease	☐ Yes ☐ No
Active current infection or history of recurrent bacterial, viral, fungal, mycobacterial, or other infections, including but not limited to tuberculosis and atypical mycobacterial disease, hepatitis B and C, and herpes zoster (>2 episodes within the previous 12 months)	☐ Yes ☐ No
Any major episode of infection requiring hospitalization or treatment with IV antibiotics within 4 weeks of screening or oral antibiotics/anti-infectives within 2 weeks prior to screening	☐ Yes ☐ No
History of malignancy within 5 years from the time of screening (including squamous cell carcinoma of the skin or cervix or carcinoma-in-situ), except adequately treated basal cell carcinoma	☐ Yes ☐ No
History of epilepsy or other seizure disorder, stroke, dementia, or other central nervous system disorder	☐ Yes ☐ No
Prior treatment with cell or gene therapy	☐ Yes ☐ No
Treatment with an investigational agent within 30 days or 5 half-lives, whichever is longer prior to screening	☐ Yes ☐ No
Known allergy to heparin, fresh frozen plasma (FFP) or replacement colloid/albumin	☐ Yes ☐ No
Donation of blood or clinically significant loss of blood, in the opinion of the Investigator, within 3 months prior to date of consent	☐ Yes ☐ No
Any known significantly increased risk of hypercoagulability or personal or family history of thromboembolic disease	☐ Yes ☐ No

ELECTROCARDIOGRAM (ECG) RESULTS (PLEASE ATTACHED REDATED COPY OF RESULTS)
QTcF value: ☐☐☐ msec FRIDERICIA'S FORMULA $QTc = QT / RR^{1/3}$ Overall interpretation: ☐ Normal ☐ Abnormal, not clinically significant ☐ Abnormal and clinically significant If abnormal, please provide further information below:

ENSURE ALL PROTOCOL ELIGIBILITY CRITERIA ARE SATISFIED PRIOR TO SUBMITTING THE REQUEST FORM. ☐ **I hereby confirm all Inclusion and No Exclusion criteria are met for this patient**		
Printed Name of Principal Investigator or Designee:	Signature of Principal Investigator or Designee:	Date:

Complete and email to ClinicalOperations@sonomabio.com. The Sonoma team will review and sign off, and then a signed copy will be provided for your records.

FOR SONOMA REVIEW		
All Inclusion and No Exclusion criteria are met for this patient		☐ Yes ☐ No
Printed Name of Reviewer: Role of Reviewer:	Signature of Reviewer:	Date:

Sonoma will provide a copy of the signature page with eligibility confirmation back to the site after a full review of eligibility criteria has been conducted. This step will confirm screening information and results.

SUBJECT ELIGIBILITY FORM

PART 2: PRE-APHERESIS

(to be completed prior to entering the pre-treatment study period)

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

Instructions: This is part 2 of a 3-part eligibility review, for pre-apheresis. Please fill out all sections in Part 2 of this form and submit it to ClinicalOperations@sonomabio.com**.** Please ensure to provide redacted copies of source documentation when submitting this form to Sonoma supporting the requested information below. Please do NOT send original and/or unredacted copies source document. Any missing or unclear information may require a follow-up request(s), which could result in delay of enrollment. Thank you for your attention to this important matter.

PART 1 ELIGIBILITY CONFIRMATION
Please confirm Part 1 eligibility screening review was completed, fully signed by all parties, and filed in the Investigator Site File (ISF) Binder? ☐ Yes ☐ No
☐ Mark if the subject has had a change in RA disease status since screening. If yes, please provide relevant details:
☐ Mark if the subject experienced any new or changes in medical conditions (other than RA) since screening. If yes, please provide relevant details (e.g., condition, start date, etc.)
☐ Mark if the subject has had any changes in non-RA concomitant medications since screening. If yes, please provide any changes made and to what medications.

PROHIBITED MEDICATION CHECKLIST FOR RA

Subjects should remain off all agents listed as prohibited at apheresis. However, when considered necessary by the Investigator, re-initiation of tsDMARDs following apheresis, at the pre-apheresis dose, is permitted between apheresis and IP administration following discussion with the Sponsor.

PLANNED APHERSIS DATE	**(DD / MMM / YYYY):**			
Medication	**Yes/No**	**Discontinuation Timing**	**Start Date (DD / MMM / YYYY)**	**Stop Date (DD / MMM / YYYY)**
PROHIBITED AT APHERESIS				
Intravenous or intramuscular corticosteroids	☐ Yes ☐ No	14 days before apheresis		
Azathioprine, cyclophosphamide, cyclosporine, sulfasalazine	☐ Yes ☐ No	4 weeks before apheresis		
Leflunomide (with chelation) **Cholestyramine or activated charcoal should be taken at standard doses for a minimum of 6 days but ideally for the standard 11 days**	☐ Yes ☐ No	4 weeks before apheresis		
tsDMARDs; e.g., baricitinib, filgotinib, tofacitinib, or upadacitinib	☐ Yes ☐ No	7 days before apheresis		
CHANGES IN RA TREATMENT MEDICATIONS				
Has the subject initiated or re-initiated any prohibited RA treatments since screening?	☐ Yes ☐ No	Please list all applicable agents and the date of re-initiation:		

PART 2 - PLEASE LIST ALL NEW OR CHANGES IN NON-RA CONCOMITANT MEDICATIONS SINCE SCREENING IF N/A, PLEASE INDICATE AS SUCH						
Medication	**Dose, Unit**	**Frequency**	**Indication**	**Start Date**	**End Date or Ongoing**	**Reason for Discontinuation**

ENSURE ALL PROTOCOL ELIGIBILITY CRITERIA ARE SATISFIED PRIOR TO SUBMITTING THE REQUEST FORM. ☐ **I hereby confirm all Inclusion and No Exclusion criteria are met for this patient and apheresis medication washout periods have been confirmed**		
Printed Name of Principal Investigator or Designee:	Signature of Principal Investigator or Designee:	Date:
Complete and email to ClinicalOperations@sonomabio.com. The Sonoma team will review and sign off, and then a signed copy will be provided for your records.		
FOR SONOMA REVIEW		
Printed Name of Reviewer: Role of Reviewer:	Signature of Reviewer:	Date:
Sonoma will provide a copy of the signature page with eligibility confirmation back to the site after a full review of eligibility criteria has been conducted. This step will confirm the site's ability to enroll the patient and moves the patient into the pre-treatment stage of the trial.		

SUBJECT ELIGIBILITY FORM

PART 3: PRE-INFUSION

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

Instructions: This is part 3 of a 3-part eligibility review, for pre-infusion. Please fill out all sections in Part 3 of this form and submit it to ClinicalOperations@sonomabio.com**.** Please ensure to provide redacted copies of source documentation when submitting this form to Sonoma supporting the requested information below. Please do NOT send original and/or unredacted copies source document. Any missing or unclear information may require a follow-up request(s), which could result in delay of enrollment. Thank you for your attention to this important matter.

PART 2 ELIGIBILITY CONFIRMATION
Please confirm Part 2 eligibility screening review was completed, fully signed by all parties, and filed in the Investigator Site File (ISF) Binder? ☐ Yes ☐ No
☐ Mark if the subject has had a change in RA disease status since apheresis. If yes, please provide relevant details:
☐ Mark if the subject experienced any new or changes in medical conditions (other than RA) since apheresis. If yes, please provide relevant details (e.g., condition, start date, etc.)
☐ Mark if the subject has had any changes in non-RA concomitant medications since apheresis. If yes, please provide any changes made and to what medications.

PROHIBITED MEDICATION CHECKLIST FOR RA				
Medication	**Yes/No**	**Discontinuation Timing**	**Start Date (DD / MMM / YYYY)**	**Stop Date (DD / MMM / YYYY)**
PROHIBITED AT IP ADMINISTRATION [c]				
tsDMARDs; e.g., baricitinib, filgotinib, tofacitinib, or upadacitinib	☐ Yes ☐ No	7 days before IP administration		
CHANGES IN RA TREATMENT MEDICATIONS				
Has the subject initiated or re-initiated any prohibited RA treatments since apheresis?	☐ Yes ☐ No	Please list all applicable agents and the date of re-initiation:		

PART 3 - PLEASE LIST ALL NEW OR CHANGES IN NON-RA CONCOMITANT MEDICATIONS SINCE APHERESIS IF N/A, PLEASE INDICATE AS SUCH						
Medication	**Dose, Unit**	**Frequency**	**Indication**	**Start Date**	**End Date or Ongoing**	**Reason for Discontinuation**

ENSURE ALL PROTOCOL ELIGIBILITY CRITERIA ARE SATISFIED PRIOR TO SUBMITTING THE REQUEST FORM. ☐ **I hereby confirm all Inclusion and No Exclusion criteria are met for this patient**		
Printed Name of Principal Investigator or Designee:	Signature of Principal Investigator or Designee:	Date:
Complete and email to ClinicalOperations@sonomabio.com. The Sonoma team will review and sign off, and then a signed copy will be provided for your records.		
FOR SONOMA REVIEW		
Printed Name of Reviewer: Role of Reviewer:	Signature of Reviewer:	Date:
Sonoma will provide a copy of the signature page with eligibility confirmation back to the site after a full review of eligibility criteria has been conducted. This step will confirm movement of the patient into the treatment stage of the trial.		