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 Hidradenitis Suppurativa*

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. When redacting copies of source documents, please confirm that nothing can be read underneath prior to sending your email. 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
☐ Medical history (including prior surgeries and procedures)
☐ Concomitant medications (Prior and concomitant medications for the treatment of HS reported from first known use; all other medications reported 30 days prior to date of consent)
☐ Physical exam
☐ Previous biopsy results, if available

SUBJECT INFORMATION	
Investigator Name:	
Subject ID	S02 – ☐☐☐ – ☐☐☐

Subject ID format AAA-XYY-ZZZ: Protocol number AAA=S02; 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 MEDICAL DIAGNOSES BELOW

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

PLEASE LIST ALL PRIOR SURGICAL PROCEDURES WITHIN THE LAST 5 YEARS (OR OTHERWISE RELEVANT)		
Procedure	**Date (DD / MMM / YYYY)**	**Reason**

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

PLEASE LIST ALL NON-HS CONCOMITANT AND HISTORICAL MEDICATIONS FOR 30 DAYS PRIOR TO CONSENT			
Medication	**Indication**	**Start Date**	**End Date**

PLEASE PROVIDE THE FOLLOWING INFORMATION ON THE HS DIAGNOSIS AND DISEASE STATE		
Hurley Stage		☐ 1 – Mild (not eligible for study participation) ☐ 2 – Moderate ☐ 3 – Severe
Other HS Characteristics	Date of Assessment:	Total abscess or inflammatory nodule (AN) >1cm count: Abscess: |_____| Nodules: |_____| Do these affect at least two distinct anatomical regions with at least 1 accessible AN of adequate size for biopsy (diameter > 1.5cm)? If yes, please list them below. ☐ Yes: |_____| & |_____| ☐ No
	Date of Assessment:	Total draining tunnel (dT) count [must be less ≤ 20 to be eligible for trial]: |_____|
	Date of Assessment:	HiSQoL Score [must be a number between 0 – 68]: |_____|
	Date of Assessment:	NRS30 Score – Worst Pain: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
	Date of Assessment:	NRS30 Score – Average Pain: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

HISTORY OF INADEQUATE RESPONSES

Has the subject ever had an inadequate response (e.g., based on HiSCR50 or equivalent clinical assessment) to at least a 3-month course of at least 1 conventional systemic therapy such as antibiotics and 1 biologic drug (e.g., adalimumab or secukinumab) or demonstrated intolerance or contraindication to conventional systemic or biologic treatments for their HS, or demonstrated intolerance to, or have a contraindication to, a conventional systemic therapy for treatment of their HS?

☐ Yes ☐ No

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

DRUG	START DATE	STOP DATE	DOSE

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

FULL PROHIBITED MEDICATION CHECKLIST FOR HS

a. May not biopsy lesion that received laser treatment in last 12 months
b. May not biopsy a lesion that was surgically treated within the last 2 years

Medication	Yes/No	Discontinuation Timing	Start Date (DD / MMM / YYYY)	Stop Date (DD / MMM / YYYY)
JAK inhibitors	☐ Yes ☐ No	7 days prior to apheresis		
Oral corticosteroids >10 mg prednisone equiv. QD	☐ Yes ☐ No	4 weeks prior to apheresis		
Mycophenolate mofetil (MMF)	☐ Yes ☐ No	4 weeks prior to apheresis		
Cyclosporine; tacrolimus	☐ Yes ☐ No	4 weeks prior to apheresis		
Investigational agents	☐ Yes ☐ No	4 weeks or 5 half-lives prior to apheresis (whichever is longer)		
Biologics (other than anti-TNF and anti-IL-17 agents)	☐ Yes ☐ No	5 weeks prior to study drug administration		
Intralesional corticosteroids	☐ Yes ☐ No	5 weeks prior to study drug administration		
IV antibiotics	☐ Yes ☐ No	5 weeks prior to study drug administration		
Laser treatment	☐ Yes ☐ No	5 weeks prior to study drug administration [a]		
Incision and drainage	☐ Yes ☐ No	5 weeks prior to study drug administration [b]		

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 disease other than HS, 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 (in the opinion of the investigator) concomitant cardiovascular, nervous system, pulmonary, renal, hepatic, endocrine, or gastrointestinal disease	☐ Yes ☐ No
Active current infection or history of recurrent bacterial, viral, fungal, mycobacterial, or other infections not associated with HS, 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 antimicrobials within 5 weeks prior to study drug administration, or a change in oral antimicrobials within 5 weeks prior to study drug administration	☐ Yes ☐ No
History of malignancy within 5 years from the time of screening (History of malignancy within 5 years from the time of screening (including squamous cell carcinoma of the skin or cervix or carcinoma-in situ)	☐ 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 4 weeks or 5 half-lives, whichever is longer, prior to date of apheresis	☐ 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:	Signature of Principal Investigator:	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.		

SUBJECT ELIGIBILITY FORM

PART 2: PRE-APHERESIS

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

Instructions: This is part 2 of a 3-part eligibility review, for screening. 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. When redacting copies of source documents, please confirm that nothing can be read underneath prior to sending your email. 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 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 HS disease status since screening. If yes, please provide relevant details:

☐ Mark if the subject experienced any new or changes in medical conditions (other than HS) since screening. If yes, please provide relevant details (e.g., condition, start date, etc.)

☐ Mark if the subject has had any changes in non-HS concomitant medications since screening. If yes, please provide any changes made and to what medications.

PROHIBITED MEDICATION CHECKLIST FOR HS (PRIOR TO APHERESIS)				
Medication	**Yes/No**	**Discontinuation Timing**	**Start Date (DD / MMM / YYYY)**	**Stop Date (DD / MMM / YYYY)**
PROHIBITED AT APHERESIS				
JAK inhibitors	☐ Yes ☐ No	7 days prior to apheresis		
Oral corticosteroids >10 mg prednisone equiv. QD	☐ Yes ☐ No	4 weeks prior to apheresis		
Mycophenolate mofetil (MMF)	☐ Yes ☐ No	4 weeks prior to apheresis		
Cyclosporine; tacrolimus	☐ Yes ☐ No	4 weeks prior to apheresis		
Investigational agents	☐ Yes ☐ No	4 weeks prior to apheresis or 5 half-lives prior to apheresis (whichever is longer)		
CHANGES IN HS TREATMENT MEDICATIONS				
Has the subject initiated or re-initiated any prohibited HS 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-HS 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**		
Printed Name of Principal Investigator:	Signature of Principal Investigator:	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.		

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 Hidradenitis Suppurativa*

Instructions: This is part 3 of a 3-part eligibility review, for screening. 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. When redacting copies of source documents, please confirm that nothing can be read underneath prior to sending your email. 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 3 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 HS disease status since apheresis. If yes, please provide relevant details:

☐ Mark if the subject experienced any new or changes in medical conditions (other than HS) since apheresis. If yes, please provide relevant details (e.g., condition, start date, etc.)

☐ Mark if the subject has had any changes in non-HS concomitant medications since apheresis. If yes, please provide any changes made and to what medications.

PROHIBITED MEDICATION CHECKLIST FOR HS

a. May not biopsy lesion that received laser treatment in last 12 months
b. May not biopsy a lesion that was surgically treated within the last 2 years

Medication	Yes/No	Discontinuation Timing	Start Date (DD / MMM / YYYY)	Stop Date (DD / MMM / YYYY)
PROHIBITED AT IP ADMINISTRATION				
Biologics (other than anti-TNF and anti-IL-17 agents)	☐ Yes ☐ No	5 weeks prior to study drug administration		
Intralesional corticosteroids	☐ Yes ☐ No	5 weeks prior to study drug administration		
IV antibiotics	☐ Yes ☐ No	5 weeks prior to study drug administration		
Laser treatment	☐ Yes ☐ No	5 weeks prior to study drug administration [a]		
Incision and drainage	☐ Yes ☐ No	5 weeks prior to study drug administration [b]		
CHANGES IN HS TREATMENT MEDICATIONS				
Has the subject initiated or re-initiated any prohibited HS treatments since apheresis?	☐ Yes ☐ No	Please list all applicable agents and the date of re-initiation:		

PERMITTED TREATMENTS AND RULES CHECKLIST FOR HS

c. Treatment of exacerbations with oral corticosteroids >10 mg prednisone equivalent or intralesional corticosteroids is permitted up to 5 weeks prior to study drug dosing; oral antibiotics are permitted up to 5 weeks prior to study drug dosing. Dosing may be delayed to accommodate the timing of the treatment of exacerbations.

Medication	Yes/No	Treatment Rules	Start Date (DD / MMM / YYYY)	Stop Date (DD / MMM / YYYY)
Anti-TNF agents	☐ Yes ☐ No	Stable dose for 5 weeks prior to study drug administration		
Anti-IL-17 agents	☐ Yes ☐ No	Stable dose for 5 weeks prior to study drug administration		
Oral corticosteroids	☐ Yes ☐ No	Stable dose ≤10 mg QD prednisone equivalent for 5 weeks prior to study drug administration [c]		
Oral antibiotics	☐ Yes ☐ No	Stable dose for 5 weeks prior to study drug administration [c]		
Topical ointments, including topical steroids	☐ Yes ☐ No	Stable regimen for 5 weeks prior to study drug administration [c]		
Other treatments (eg, retinoids, antipruritics, antiandrogenics, methotrexate, apremilast) and long-acting pain medications	☐ Yes ☐ No	Stable dose for 5 weeks prior to study drug administration [c]		

PART 3 - PLEASE LIST ALL NEW OR CHANGES IN NON-HS 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:	Signature of Principal Investigator:	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.		