

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

- | |
|---|
| <input type="checkbox"/> Confirm a <u>copy</u> of the local screening lab results is attached, <u>with all patient-identifying health information redacted</u> . <ul style="list-style-type: none"> <input type="checkbox"/> Hematology <input type="checkbox"/> Chemistry <input type="checkbox"/> 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) <input type="checkbox"/> TB screening <input type="checkbox"/> Serology <input type="checkbox"/> Coagulation <input type="checkbox"/> Urinalysis |
| <input type="checkbox"/> Medical history (including prior surgeries and procedures) |
| <input type="checkbox"/> 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) |
| <input type="checkbox"/> Physical exam |
| <input type="checkbox"/> Previous biopsy results, if available |

SUBJECT INFORMATION

Investigator Name:

Subject ID

S02 – | | | | – | | | |

*Subject ID format AAA-XY-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/m²):

| | | | . |

| | | |

| | | | . |

MEDICAL HISTORY

PLEASE LIST ALL MEDICAL DIAGNOSES BELOW

Diagnosis	Ongoing?	Comments
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> 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 <u>NON-HS</u> 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		<input type="checkbox"/> 1 – Mild (not eligible for study participation) <input type="checkbox"/> 2 – Moderate <input type="checkbox"/> 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. <input type="checkbox"/> Yes: _____ & _____ <input type="checkbox"/> No
	Date of Assessment:	Total draining tunnel (dT) count [must be less \leq 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: <div style="display: flex; justify-content: space-around; align-items: center;"> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div style="display: flex; justify-content: space-around; align-items: center;"> 1 2 3 4 5 6 7 8 9 10 </div>
	Date of Assessment:	NRS30 Score – Average Pain: <div style="display: flex; justify-content: space-around; align-items: center;"> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> </div> <div style="display: flex; justify-content: space-around; align-items: center;"> 1 2 3 4 5 6 7 8 9 10 </div>

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
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	

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
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> No	
						<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No	7 days prior to apheresis		
Oral corticosteroids >10 mg prednisone equiv. QD	<input type="checkbox"/> Yes <input type="checkbox"/> No	4 weeks prior to apheresis		
Mycophenolate mofetil (MMF)	<input type="checkbox"/> Yes <input type="checkbox"/> No	4 weeks prior to apheresis		
Cyclosporine; tacrolimus	<input type="checkbox"/> Yes <input type="checkbox"/> No	4 weeks prior to apheresis		
Investigational agents	<input type="checkbox"/> Yes <input type="checkbox"/> No	4 weeks or 5 half-lives prior to apheresis (whichever is longer)		
Biologics (other than anti-TNF and anti-IL-17 agents)	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration		
Intralesional corticosteroids	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration		
IV antibiotics	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration		
Laser treatment	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration ^a		
Incision and drainage	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration ^b		

FULL ELIGIBILITY CRITERIA REVIEW

INCLUSION CRITERIA

Please select "yes" or "no" for each criterion.

1. Age ≥ 18 and ≤ 70 years old at the time of signing the informed consent	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Body mass index (BMI) ≤ 50 kg/m ² , inclusive	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Diagnosis of clinically active moderate-to-severe HS (Hurley Stage 2 or 3), with patient-reported signs and symptoms consistent with HS for at least 6 months prior to the screening visit	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Total abscess or inflammatory nodule (AN) count of ≥ 5 , affecting at least 2 distinct anatomic regions, with at least 1 accessible AN of adequate size for biopsy (diameter > 1.5 cm)	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Total draining tunnel (dT) count of ≤ 20	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Documented history of 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	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Doses of medications for HS must be stable for at least 5 weeks prior to study drug administration (refer to Section 5 in the Protocol for further details)	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Persons of childbearing potential must agree to use 2 methods of contraception for at least 1 year post SBT777101 administration. One method must be considered a highly effective method of contraception, while the second method may be a barrier method	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Women of childbearing potential must have a negative urine pregnancy test before the administration of study drug performed on the day of study drug administration	<input type="checkbox"/> Yes <input type="checkbox"/> No
10. Individuals who are sexually active with women of childbearing potential must agree to use one method of contraception for 1 year post SBT777101 administration	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. Subjects must refrain from donating sperm for 1 year post SBT777101 administration	<input type="checkbox"/> Yes

	<input type="checkbox"/> No
12. Subjects receiving estrogen replacement therapy must agree to discontinue use at least 1 week or 5 half-lives prior to study treatment	<input type="checkbox"/> Yes <input type="checkbox"/> No
13. Ability to comply with all the requirements of the study, in the Principal Investigator's opinion	<input type="checkbox"/> Yes <input type="checkbox"/> No
14. Adequate vascular access, in the opinion of the Principal Investigator, for apheresis procedure and SBT777101 administration	<input type="checkbox"/> Yes <input type="checkbox"/> No
15. Willing to undergo repeat skin biopsies to obtain tissue during the study	<input type="checkbox"/> Yes <input type="checkbox"/> No
16. Willing to comply with study specific safety monitoring requirements	<input type="checkbox"/> Yes <input type="checkbox"/> No
17. Willing and able to provide signed informed consent	<input type="checkbox"/> Yes <input type="checkbox"/> No

EXCLUSION CRITERIA

Please select "yes" or "no" for each criterion.

1. Major surgery within 12 weeks prior to screening or planned within 12 months after dosing.	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. History of or current inflammatory or other autoimmune disease	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Complex presentations of HS, including but not limited to PAPA (pyogenic arthritis, pyoderma gangrenosum, and acne), PASH (pyoderma gangrenosum, acne, and suppurative hidradenitis), PAPASH (pyogenic arthritis, acne, pyoderma gangrenosum, and suppurative hidradenitis), and PG (pyoderma gangrenosum)	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Skin disease other than HS that may confound clinical assessments or increase subject risk in the study	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. 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	<input type="checkbox"/> Yes <input type="checkbox"/> No

6. 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)	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Uncontrolled diabetes (HbA1C > 9%)	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. 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. The timing of study drug treatment and the pretreatment biopsy may be adjusted if the patient has received one of these drugs after apheresis	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Active tuberculosis requiring treatment within 3 years prior to screening	<input type="checkbox"/> Yes <input type="checkbox"/> No
10. Latent tuberculosis diagnosed during screening that has not completed appropriate treatment	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. History of Crohn's disease	<input type="checkbox"/> Yes <input type="checkbox"/> No
12. Primary or secondary immunodeficiency (history of or currently active), including a history of HIV positivity	<input type="checkbox"/> Yes <input type="checkbox"/> No
13. Any known significantly increased risk of hypercoagulability or personal or family history of thromboembolic disease	<input type="checkbox"/> Yes <input type="checkbox"/> No
14. Females who are pregnant or breastfeeding or planning to become pregnant within 12 months from start on study	<input type="checkbox"/> Yes <input type="checkbox"/> No
15. History of malignancy within 5 years from the time of screening (including squamous cell carcinoma of the skin or cervix or carcinoma-in situ)	<input type="checkbox"/> Yes <input type="checkbox"/> No
16. History of epilepsy or other seizure disorder, stroke, dementia or other central nervous system disorder	<input type="checkbox"/> Yes <input type="checkbox"/> No
17. Known history of drug or alcohol abuse within 1 year of screening	<input type="checkbox"/> Yes <input type="checkbox"/> No
18. Any medical or psychological condition that in the judgment of the Principal Investigator would interfere with the conduct of the study or may confound the interpretation of the study results	<input type="checkbox"/> Yes <input type="checkbox"/> No

19. Any out-of-range electrocardiogram (ECG) parameter(s) or abnormal finding(s) considered clinically significant by the Principal Investigator including if the QTc calculated using Fridericia's formula (QTcF) is >480 ms	<input type="checkbox"/> Yes <input type="checkbox"/> No
20. Prior treatment with cell or gene therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No
21. Treatment within 4 weeks prior to apheresis with corticosteroids at a dose of >10 mg of prednisone equivalent QD. Of note, low dose daily inhaled corticosteroids for asthma or COPD is permitted (maximum of fluticasone propionate 250 mcg (or equivalent) . The timing of study drug treatment and the pretreatment biopsy may be adjusted if the patient has this therapy after apheresis.	<input type="checkbox"/> Yes <input type="checkbox"/> No
22. Treatment with a JAK inhibitor within 7 days prior to apheresis	<input type="checkbox"/> Yes <input type="checkbox"/> No
23. Treatment with mycophenolate mofetil (MMF) within 4 weeks prior to apheresis	<input type="checkbox"/> Yes <input type="checkbox"/> No
24. Treatment with cyclosporine or tacrolimus within 4 weeks prior to apheresis	<input type="checkbox"/> Yes <input type="checkbox"/> No
25. Treatment with an investigational agent within 4 weeks or 5 half-lives, whichever is longer, prior to date of apheresis	<input type="checkbox"/> Yes <input type="checkbox"/> No
26. Treatment with a biologic therapy (other than anti-TNF or anti-IL-17 agents) within 5 weeks prior to study drug administration. The timing of study drug treatment and the pretreatment biopsy may be adjusted if the patient has received one of these drugs after apheresis.	<input type="checkbox"/> Yes <input type="checkbox"/> No
27. Treatment with intralesional corticosteroids within 5 weeks prior to study drug administration or plans to receive intralesional corticosteroids in any lesion during the study period. The timing of study drug treatment and the pretreatment biopsy may be adjusted if the patient has this therapy after apheresis.	<input type="checkbox"/> Yes <input type="checkbox"/> No
28. Laser treatment within 5 weeks prior to study drug administration. The timing of study drug treatment and the pretreatment biopsy may be adjusted if the patient has laser treatment after apheresis.	<input type="checkbox"/> Yes <input type="checkbox"/> No
29. Incision and drainage procedure within 5 weeks prior to study drug administration. The timing of study drug treatment and the pretreatment biopsy may be adjusted if the patient has this procedure after apheresis.	<input type="checkbox"/> Yes <input type="checkbox"/> No
30. Is currently participating in another trial of an investigational or marketed drug or medical device	<input type="checkbox"/> Yes <input type="checkbox"/> No
31. Any confirmed clinically significant drug allergy and/or known hypersensitivity to protein therapeutics or formulation components or a related drug	<input type="checkbox"/> Yes

	<input type="checkbox"/> No
32. Known allergy to heparin, fresh frozen plasma (FFP) or replacement colloid/albumin	<input type="checkbox"/> Yes <input type="checkbox"/> No
33. Laboratory tests, if abnormal, may be repeated once during the screening period. Clinically significant abnormalities in laboratory test results that would exclude a subject from study participation include: <ul style="list-style-type: none"> a) AST or ALT >2 x the upper limit of normal (ULN) b) Total and direct bilirubin >1.5 x ULN c) EGFR <45 ml/min/m² (2021 CKD-EPI criteria; Delgado et al., 2022) d) Absolute neutrophil count <1.0 x 10⁹/L e) Platelet count <100 x 10⁹/L f) Hemoglobin <9 g/dL g) Positive hepatitis BsAg or hepatitis C antibody <p>Note: In the event of a potential false positive hepatitis C antibody test result, PCR testing for HCV RNA may be performed; subjects who are negative for HCV RNA by PCR are not excluded</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
34. Subjects under judicial supervision or guardianship	<input type="checkbox"/> Yes <input type="checkbox"/> No

ELECTROCARDIOGRAM (ECG) RESULTS (PLEASE ATTACHED REDATED COPY OF RESULTS)

QTcF value: |____| |____| |____| msec

Overall interpretation:

- ☐ Normal
- ☐ Abnormal, not clinically significant
- ☐ Abnormal and clinically significant
- If abnormal, please provide further information below:

FRIDERICIA'S FORMULA

$$QT_c = QT / RR^{1/3}$$

☐ 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

<p>Printed Name of Reviewer:</p> <hr/>	<p>Signature of Reviewer:</p>	<p>Date:</p>
<p>Role of Reviewer:</p> <hr/>		

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	<input type="checkbox"/> Yes <input type="checkbox"/> No	7 days prior to apheresis		
Oral corticosteroids >10 mg prednisone equiv. QD	<input type="checkbox"/> Yes <input type="checkbox"/> No	4 weeks prior to apheresis		
Mycophenolate mofetil (MMF)	<input type="checkbox"/> Yes <input type="checkbox"/> No	4 weeks prior to apheresis		
Cyclosporine; tacrolimus	<input type="checkbox"/> Yes <input type="checkbox"/> No	4 weeks prior to apheresis		
Investigational agents	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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

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

<p>Printed Name of Reviewer:</p> <hr/> <p>Role of Reviewer:</p> <hr/>	<p>Signature of Reviewer:</p>	<p>Date:</p>
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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)
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PROHIBITED AT IP ADMINISTRATION

Biologics (other than anti-TNF and anti-IL-17 agents)	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration		
Intralesional corticosteroids	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration		
IV antibiotics	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration		
Laser treatment	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration ^a		
Incision and drainage	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Please list all applicable agents and the date of re-initiation:
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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	<input type="checkbox"/> Yes <input type="checkbox"/> No	Stable dose for 5 weeks prior to study drug administration		
Anti-IL-17 agents	<input type="checkbox"/> Yes <input type="checkbox"/> No	Stable dose for 5 weeks prior to study drug administration		
Oral corticosteroids	<input type="checkbox"/> Yes <input type="checkbox"/> No	Stable dose ≤10 mg QD prednisone equivalent for 5 weeks prior to study drug administration ^c		
Oral antibiotics	<input type="checkbox"/> Yes <input type="checkbox"/> No	Stable dose for 5 weeks prior to study drug administration ^c		
Topical ointments, including topical steroids	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No	Stable dose for 5 weeks prior to study drug administration ^c		

IF N/A, PLEASE INDICATE AS SUCH

Subject Eligibility Form, V3.0 | Nov2024

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:
<hr/>		

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

<p>Printed Name of Reviewer:</p> <hr/>	<p>Signature of Reviewer:</p>	<p>Date:</p>
<p>Role of Reviewer:</p> <hr/>		

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