

# **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](mailto: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"><li><input type="checkbox"/> Hematology</li><li><input type="checkbox"/> Chemistry</li><li><input type="checkbox"/> Pregnancy test or FSH and estradiol<br/>(for women of childbearing potential or in the absence of 12 months of amenorrhea; refer to Appendix D of the protocol)</li><li><input type="checkbox"/> TB screening</li><li><input type="checkbox"/> Serology</li><li><input type="checkbox"/> Coagulation</li><li><input type="checkbox"/> Urinalysis</li></ul> |
| <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/m<sup>2</sup>):

| | | | . |

| | | |

| | | | . |

## 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: <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;"><input type="checkbox"/> 1</div> <div style="text-align: center;"><input type="checkbox"/> 2</div> <div style="text-align: center;"><input type="checkbox"/> 3</div> <div style="text-align: center;"><input type="checkbox"/> 4</div> <div style="text-align: center;"><input type="checkbox"/> 5</div> <div style="text-align: center;"><input type="checkbox"/> 6</div> <div style="text-align: center;"><input type="checkbox"/> 7</div> <div style="text-align: center;"><input type="checkbox"/> 8</div> <div style="text-align: center;"><input type="checkbox"/> 9</div> <div style="text-align: center;"><input type="checkbox"/> 10</div> </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	

## 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 <sup>a</sup>		
Incision and drainage	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration <sup>b</sup>		

## 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	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> 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)	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> 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)	<input type="checkbox"/> Yes <input type="checkbox"/> No
History of epilepsy or other seizure disorder, stroke, dementia, or other central nervous system disorder	<input type="checkbox"/> Yes <input type="checkbox"/> No
Prior treatment with cell or gene therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No
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
Known allergy to heparin, fresh frozen plasma (FFP) or replacement colloid/albumin	<input type="checkbox"/> Yes <input type="checkbox"/> No
Donation of blood or clinically significant loss of blood, in the opinion of the Investigator, within 3 months prior to date of consent	<input type="checkbox"/> Yes <input type="checkbox"/> No
Any known significantly increased risk of hypercoagulability or personal or family history of thromboembolic disease	<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

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

**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](mailto: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:  <hr/> Role of Reviewer:  <hr/>	Signature of Reviewer:      	Date:    
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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](mailto: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)
<b>PROHIBITED AT APHERESIS</b>				
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)		
<b>CHANGES IN HS TREATMENT MEDICATIONS</b>				
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**

[illegible]

**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](mailto: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](mailto: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 <sup>a</sup>		
Incision and drainage	<input type="checkbox"/> Yes <input type="checkbox"/> No	5 weeks prior to study drug administration <sup>b</sup>		

#### 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 <sup>c</sup>		
Oral antibiotics	<input type="checkbox"/> Yes <input type="checkbox"/> No	Stable dose for 5 weeks prior to study drug administration <sup>c</sup>		
Topical ointments, including topical steroids	<input type="checkbox"/> Yes <input type="checkbox"/> No	Stable regimen for 5 weeks prior to study drug administration <sup>c</sup>		
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 <sup>c</sup>		

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

<b>Printed Name of Principal Investigator:</b>	<b>Signature of Principal Investigator:</b>	<b>Date:</b>
<hr/>		

Complete and email to [ClinicalOperations@sonomabio.com](mailto: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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