

Pre-screening Checklist

Please use the following checklist to review preliminary patient eligibility for the SBT777101-02 trial.

Note: This document is not considered source documentation.

KEY INCLUSION CRITERIA

If the status is yes to the following questions, the patient may be eligible for the trial. Refer to the full inclusion criteria in the protocol to ensure eligibility.

	YES	NO	NOT SURE*
A. Will the patient be ≥ 18 and ≤ 70 at the time of signing informed consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Does the patient have a body mass index (BMI) ≤ 50 kg/m ² ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. Does the patient have a diagnosis of clinically active moderate to severe Hidradenitis Suppurativa (HS)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D. Does the patient have presence of at least 1 skin lesion accessible for biopsy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E. Does the patient have documented history of inadequate response to at least a 3-month course of at least 1 conventional systemic therapy (oral antibiotic or biologic drug) for HS?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F. Is the patient willing to undergo repeat skin biopsies to obtain tissue during the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*Requires further site review

NOTES:

Continued on reverse

KEY EXCLUSION CRITERIA

If the status is yes to the following questions, the patient may NOT be eligible for the trial. Refer to the full exclusion criteria in the protocol to ensure ineligibility.

	YES	NO	NOT SURE*
A. Has the patient had major surgery within 12 weeks prior to screening or planned within 12 months after doing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B. Does the patient have a history of or current inflammatory or other autoimmune disease?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C. Does the patient have 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"/>	<input type="checkbox"/>	<input type="checkbox"/>
D. Does the patient have current or previous (within the past 2 years) evidence of serious uncontrolled concomitant cardiovascular, nervous system, pulmonary, renal, hepatic, endocrine, or gastrointestinal disease?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
E. Has the patient had prior treatment with cell or gene therapy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F. Does the patient have any confirmed clinically significant drug allergy and/or known hypersensitivity to protein therapeutics or formulation components or a related drug?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*Requires further site review

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