



## Protocol Clarification Letter #4

**Date: JUN 25, 2025**

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

Dear SBT777101-02 Study Investigators,

This letter is intended to clarify the acceptable methods of contraception as outlined in Protocol SBT777101-02, Version 3.0, dated May 1, 2025,

Per Appendix D (Contraception Guidance), oral contraceptive pills—whether containing estrogen, progestin, or both—are **not** considered acceptable forms of contraception and are therefore not listed in this section. Additionally, subjects taking oral contraceptives containing estrogen should discontinue use at least one week (or five half-lives) prior to study treatment, in accordance with Inclusion Criterion #12 and Section 5.1 (General Medications).

Please review this clarification and share it with your study team and IRB as appropriate. If you have any questions or concerns, feel free to reach out. This clarification will be incorporated into the next protocol amendment.

Signature:   
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Gilad Gordon, MD

Date: 6/26/2025