Trial Factsheet for Health Care Providers

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
PROTOCOL NUMBER	SBT777101-02
PHASE OF DEVELOPMENT	Phase 1
TRIAL OBJECTIVE	To evaluate and characterize the safety and tolerability of SBT777101
INVESTIGATIONAL PRODUCT	This trial involves the investigational drug SBT777101, an autologous chimeric antigen receptor (CAR) Treg cell preparation which is being developed to treat people with Hidradenitis Suppurativa (HS). • CAR T cell therapy is a relatively new approach which has been shown to be safe and effective in treating certain kinds of blood cancers. • Potential to provide sustained disease remission, without the need for frequent administration required of many standard-of-care medications for chronic diseases. • Leverages the polypharmacy of Tregs, providing a unique mechanism to suppress multiple types of inflammation while restoring immune balance. • First trial of SBT777101 in humans (currently no information on possible side effects).
TRIAL OVERVIEW	This is a multicenter Phase 1, open-label, dose-ranging study to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary clinical activity of single ascending doses of SBT777101 administered intravenously (IV) in subjects with active Hidradenitis Suppurativa (HS) who had an inadequate response to conventional systemic therapy. Up to 24 eligible patients are expected to be enrolled in the trial.
KEY ELIGIBILITY CRITERIA	• Age ≥ 18 and ≤ 70 at the time of signing the informed consent • Diagnosis of HS • Moderate to severe active disease • Inadequate response to or unable to tolerate prior treatment with available therapies • Willing to undergo repeat skin biopsies

For more information about the SBT777101-02 trial, contact:

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