Phase II Clinical Trial Protocol (Excerpt)

Study Title: A Phase II, Randomized, Double-Blind Study Evaluating GXT-201 in Adults With Moderate to Severe Plaque Psoriasis.

Sponsor: GenX Therapeutics Japan K.K.

Protocol Code: GXT-201-PSO-2026

1. Synopsis

The objective of this study is to compare the efficacy and safety of GXT-201 versus placebo over a 24-week treatment period. Approximately 180 participants will be randomized 2:1 to receive GXT-201 150 mg subcutaneously every 4 weeks or matching placebo.

Key Endpoints

- **Primary Endpoint:** Proportion of participants achieving PASI 90 at Week 16.
- **Secondary Endpoint:** Change from baseline in DLQI at Week 24, proportion achieving sPGA 0/1 at Week 24, and time to first documented relapse.

Review Point 1: Confirm the primary endpoint timing is aligned with statistical analysis plan Section 3.2 (currently Week 16 here vs Week 12 referenced in SAP draft v0.9).

2. Study Population

Participants aged 18-75 years with a documented history of plaque psoriasis for at least 12 months prior to screening and a baseline PASI score >= 12 are eligible. Key exclusions include active severe infections, prior exposure to GXT-201, or use of other systemic psoriasis therapies within 4 weeks of baseline.

Recruitment Targets

Enrollment will be stratified across 15 investigative sites in Japan and 5 sites in South Korea, with balanced representation of male and female participants.

Review Point 2: Verify visit window tolerances in Section 6 align with site scheduling constraints (+/-3 days currently; R&D feedback suggested +/-5 days for Weeks 12-24).

3. Study Design

This is a multi-center, randomized, double-blind, placebo-controlled study. The study consists of a screening period (up to 28 days), a 24-week treatment period, and a 12-week safety follow-up.

Randomization and Blinding

Randomization will be stratified by baseline PASI score (<=18 vs >18) using an interactive web response system (IWRS). Study drug and placebo are identical in appearance.

Visit Schedule Overview

Visit	Week	Procedures
Screening	-4 to 0	Informed consent, physical exam, laboratory assessments
Baseline	0	Randomization, study drug administration, PASI, DLQI
Treatment	4, 8, 12, 16, 20, 24	PASI, DLQI, safety labs, injection site assessment
Follow-up	28, 36	Safety labs, adverse event review

4. Safety Assessments

Safety will be monitored through adverse event reporting, clinical laboratory evaluations, vital signs, and physical examinations. Investigators must report serious adverse events within 24 hours via the sponsor portal.

Targeted Safety Monitoring

- Injection site reactions
- Hypersensitivity events
- Opportunistic infections

5. Efficacy Assessments

PASI and sPGA assessments will be conducted by certified dermatology assessors. DLQI will be self-administered using the validated Japanese translation.

Concomitant Medications

Use of topical corticosteroids is permitted as rescue therapy for up to 14 days, excluding the two weeks prior to Week 16 assessment.

6. Schedule of Assessments (excerpt)

Assessment	Screening	Baseline	Week 4	Week 8	Week 12	Week 16	Week 24
PASI	X	X	X	X	X	X	X
DLQI		X	X	X	X	X	X
Labs	X	X	X	X		X	X

7. Investigational Product Handling

Study drug kits will be stored at 2-8 degC and protected from light. Accountability logs must be updated at each visit and reconciled at study close-out.

8. Administrative Considerations

This protocol must be reviewed and approved by the IRB/IEC at each participating site prior to initiation. All investigators will complete GCP refresher training within 30 days of site activation.