

○ Platform Technology for Dermatology

Title	Development of Antibody New Drugs for Lesion-Selective Removal in Chronic Inflammatory Skin Diseases
Definition	<ul style="list-style-type: none"> <li>○ A next-generation immunotherapeutic platform that selectively removes lesional tissue by targeting pathogenic cells and the pathological microenvironment in chronic inflammatory skin diseases (e.g. atopic dermatitis, psoriasis). Modalities include cytotoxicity-inducing antibodies (e.g., ADDC/ADCC), Engager antibodies, Fc-engineered antibodies, and functional small molecules</li> <li>- The program will discover etiologic factors and companion biomarkers and validate them in disease models aligned with human pathology (3D skin equivalents, patient-derived organoids, humanized mice) to advance candidates eligible for IND listing</li> </ul>
R&D Plan	<ul style="list-style-type: none"> <li>○ (Step1) Modality Design and Optimization <ul style="list-style-type: none"> <li>- (Dual-specific/Engager antibodies) optimize binding to lesional antigens × effector mediators (e.g., CD3, NKp46)</li> <li>- (Fc engineering) tune FcγR binding to balance cytotoxicity/phagocytosis induction with half-life and immune safety</li> <li>- (Functional small molecules) explore mechanisms for lesion-selective removal/resolution by targeting keratinocyte-immune cross-talk pathways (IL-23/IL-17, OX40L, TSLP, JAK-STAT)</li> <li>- (Human-Pathology-Concordant Model Development and Validation) Establish patient-derived skin organoids / 3D reconstructed skin, ex vivo lesional-slice assays, and humanized mouse models (AD /IMQ-psoriasis) and nominate one preclinical candidate with proof-of-concept activity</li> </ul> </li> <li>○ (Step2) IND-enabling Non-clinical · CMC · Regulatory Filing <ul style="list-style-type: none"> <li>- Complete IND-enabling nonclinical package: GLP toxicology (single/repeat dosing), immunogenicity/immunotoxicity, safety pharmacology, PK/PD; finalize translational biomarker strategy</li> <li>- Develop CMC (cell line/construct, process development, formulation) and establish QC/QA systems to support GMP-grade material</li> <li>- Conduct Pre-IND consultations with MFDS/FDA and finalize the IND dossier(including bridging/equivalence and mechanistic evidence) and submit the IND to obtain approval</li> </ul> </li> </ul>

Need for Support	<ul style="list-style-type: none"> <li>○ (Policy) Aligned with national policies for K-Bio globalization and advanced biopharma promotion; international co-development enables concurrency of clinical development and regulatory pathways, meeting strategic national objectives</li> <li>○ (Technical) Requires a high-complexity bundled toolkit (organoids, spatial omics, Fc engineering) integrated with human-pathology-concordant models and biomarkers, which exceeds the capacity of SMEs alone; thus government co-funding and risk-sharing in early non-clinical/clinical stages are essential alongside partnerships with global pharmas</li> <li>○ (Market) Atopic dermatitis and psoriasis have high unmet needs (non-response, relapse, systemic AEs) and are shifting toward precision immunotherapy. Commercialization would yield high-value pipelines and technology-export spillovers for domestic SMEs</li> <li>○ (Social) Improves quality of life and work productivity for patients; strengthens SME capabilities and global networks within the skin-immunity/re</li> </ul>
Performance Target	<ul style="list-style-type: none"> <li>○ (Step1) Complete development of one disease model that recapitulates human pathology; derive one preclinical candidate</li> <li>○ (Step2) Secure IND-enabling non-clinical efficacy and toxicology packages. Compile the full CMC/regulatory dossier; submit the IND and obtain approval</li> <li>○ (After completion) Execute a global technology-transfer agreement or a clinical/commercial development agreement</li> </ul>