

○ Therapeutics for Dermatological Diseases and Related Conditions

Title	Co-development of Targeted Therapeutics for Dermatological Diseases and Related Conditions
Definition	<ul style="list-style-type: none"> ○ Target Indications : Atopic dermatitis, psoriasis, generalized pruritus, prurigo, sensory disorders (e.g., pain, pruritus, numbness), rosacea, common warts, acne and acne scarring, chronic spontaneous urticaria, keloids, hypertrophic scars, onychomycosis, palmoplantar pustulosis, ichthyosis, melasma, vitiligo, senile lentigines, xerosis, bromhidrosis, localized hyperhidrosis, gray hair, androgenic alopecia (male/female), alopecia areata, and mucosal disorders. ○ No specific preference or separate restrictions regarding the Mechanism of Action (MoA) (Examples below are illustrative and not mandatory). <ul style="list-style-type: none"> - Normalize skin barrier function to improve dermatologic symptoms (turnover, homeostasis, keratinocyte, cell-cell adhesion, natural moisturizing factors, intercellular lipids, immune cells, correction of skin microbiome dysbiosis, etc.). - Block itch-transmission pathways in peripheral or central systems. (inhibition of excitatory neurotransmission, regulation of itch mediators, activation of inhibitory pathways, suppression of alloknosis, inhibition of signal amplification, etc.). - Enabling disease cure or long-term treatment-free remission. (epigenetic memory in skin cells, stimulus-driven memory mechanisms, pathogenic resident immune cell memory, etc.). ○ Broad modality scope (small molecules, antibodies, peptides, nucleic acids, microbiome therapeutics, etc.) and no restrictions on route of administration (topical, oral, etc.).
R&D Plan	<ul style="list-style-type: none"> ○ (Step 1) Target-based Candidate Discovery <ul style="list-style-type: none"> - Validation of disease mechanisms and target pathways - Hit identification and lead optimization aligned with target product profile - Evaluation of candidates using disease-relevant animal or cellular models - Early toxicity assessment, ADME/PK studies, and establishment of preliminary drug profiles - Development of an IND-enabling roadmap ○ (Step 2) IND-enabling Data Package Preparation <ul style="list-style-type: none"> - Establishment of GMP-compliant manufacturing processes and preparation of CMC documentation - Completion of GLP toxicology studies and additional pharmacology or PK studies, as required

	<ul style="list-style-type: none"> - IND dossier preparation, submission, and approval
Need for Support	<ul style="list-style-type: none"> ○ (Policy) Dermatological diseases such as atopic dermatitis (e.g., approximately 970,000 patients in Korea in 2024), psoriasis, and chronic pruritus impose a significant public health burden due to their chronic and recurrent nature and high prevalence. This project aligns with national strategies for K-Bio global expansion and the promotion of the advanced biopharmaceutical industry. ○ (Technical) The development of targeted therapeutics requires end-to-end R&D capabilities, from the discovery of drug candidates to the completion of IND-enabling data packages. Therefore, collaboration with global pharmaceutical companies and government support for early-stage R&D are essential. ○ (Market) Dermatological diseases present substantial unmet medical needs due to limitations in long-term systemic steroid use, frequent disease relapse, and the lack of predictive biomarkers for treatment response. The realization of precision targeted therapies could expand high-value pipelines and create opportunities for technology transfer and global commercialization. ○ (Social) Improved treatment of dermatological diseases can contribute to enhanced quality of life, better mental health, and increased work productivity, generating significant socioeconomic benefits while strengthening the global networks and professional capabilities of domestic biotech ventures.
Performance Target	<ul style="list-style-type: none"> ○ (Step 1) Identification of novel targets and candidate compounds, Demonstration of preclinical PoC (in vitro and/or in vivo), Establishment of the Target Product Profile (TPP) supported by early ADME/PK and safety data ○ (Step 2) Completion of IND-enabling studies, CMC/GMP readiness, IND submission and approval ○ (After completion) Initiation of Phase I clinical trials, Establishment of global partnerships including technology transfer agreements