

○ Immunology and Inflammation Therapeutics

Title	Co-development of Next-Generation Therapeutic Candidates for Autoimmune and Allergic Diseases Based on Precision Immunomodulation
Definition	<ul style="list-style-type: none"> ○ Development of innovative mechanism/modality-based drug candidates for autoimmune inflammatory and allergic diseases that aim at long-term remission and immune tolerance, by selectively regulating pathogenic/autoreactive immune cell populations or resetting immunity through the induction of regulatory T cells (Tregs) and tolerogenic DCs (tolDCs), thereby overcoming non-response and relapse to standard-of-care biologics. <ul style="list-style-type: none"> - Autoimmune and inflammatory diseases such as lupus / lupus nephritis, systemic sclerosis, hidradenitis suppurativa, alopecia areata, vitiligo, pemphigus / pemphigoid, inflammatory bowel disease, and rheumatoid arthritis, etc. - Allergic diseases such as chronic urticaria, food allergy, and cutaneous mastocytosis, etc. - Other skin, renal, muscle, or systemic autoimmune/allergic conditions with high unmet needs ○ Targeting pathogenic cells or molecular targets identified through human inflammatory tissue analysis, but not limited to a specific modality. <ul style="list-style-type: none"> - Including treatment strategies such as multi-target modulation (e.g., bispecific/multi-specific antibodies), proximity induction (e.g., antibody-directed protein degradation, intercellular signaling modulation), and antibody engineering/improvement (e.g., nanobodies, ADCs) - Including target validation (including assay development) and drug development research; however, diagnostics, drug repurposing, and screening equipment development are excluded
R&D Plan	<ul style="list-style-type: none"> ○ (Step 1) Pathology-based candidate target validation and securing preclinical candidates <ul style="list-style-type: none"> - Validation of targets / cell populations based on human inflammatory tissues (e.g., single-cell / spatial sequencing, multi-omics, AI/ML data analysis, etc.) - Development of disease models using patient-derived tissues (e.g., organoids or immune cell-tissue cell co-culture systems)

	<p>to evaluate candidate efficacy</p> <ul style="list-style-type: none"> - Securing 1–2 preclinical candidates based on novel modalities such as multi-target modulation and antibody-directed proximity induction - Defining disease-specific biomarkers and deriving patient stratification strategies for predicting clinical treatment response and monitoring maintenance of remission <ul style="list-style-type: none"> ○ (Step 2) Completion of the IND data package and IND approval <ul style="list-style-type: none"> - Completion of the IND-enabling nonclinical package for secured candidates, including GLP toxicology, safety pharmacology, ADME/PK, and other regulatory requirements - Establishment of CMC (process / analytical methods / specifications / stability), GMP manufacturing, and QC systems - Preparation, submission, and approval of the IND dossier
Need for Support	<ul style="list-style-type: none"> ○ (Policy) The development of precision therapeutics for immune disorders is aligned with the policy direction supporting promising technologies, including expanded bio-health R&D investment, strengthened global collaboration in advanced biopharmaceuticals, and development of targeted novel therapeutics. ○ (Technical) Immune disorders show high heterogeneity at the tissue and cellular levels, high non-response and loss-of-response rates to existing agents, and insufficient response markers. High-difficulty bundled technologies are required, including high-resolution analysis of diseased tissues, novel modalities, and the development of biomarkers and disease models; therefore, there are clear limitations to independent development by SMEs/ventures. ○ (Market) Immune disorders represent a large market ranking among the top global sales projections for 2026 (with Skyrizi ranked 3rd and Dupixent ranked 5th as single-drug products). Since First-in-class innovation and modality innovation are presented as the core of new pipeline competition, there is strong potential for technology transfer and co-development depending on the candidate. ○ (Social) Immune disorders are characterized by high prevalence, low cure rates, chronicity, and high recurrence, leading to persistent deterioration in quality of life. Precision targeted treatment and long-term remission can improve quality of life and productivity, while also contributing to the expansion of clinical, CMC, and regulatory capabilities and global networks of domestic SMEs/ventures.

Performance Target	<ul style="list-style-type: none"> ○ (Step 1) Secure candidate targets validated based on human inflammatory tissues, derive 1–2 preclinical candidates, and establish mechanism/efficacy PoC and a preclinical biomarker strategy in disease models ○ (Step 2) Secure the IND-enabling package for candidates, including GLP toxicology, as well as CMC/GMP readiness, and complete IND submission and approval ○ (After completion) Conclude at least one global co-development or technology transfer agreement, and expand the secured bundled capabilities in disease biology analysis, modality technologies, and biomarkers to similar immune/inflammatory indications
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