

☐ R&D item brief (English)

○ Oncology Therapeutics

Title	Co-development of Next-Generation Modality-Based Anticancer Drug Candidates Based on Novel Targets and Innovative Mechanisms
Definition	<ul style="list-style-type: none"><li>○ Development of First-in-class drug candidates that maximize cancer cell selectivity in solid tumors or hematological malignancies and can overcome resistance/non-response to existing cancer immunotherapy or targeted therapy, aiming at innovative drug development and co-development centered on proprietary technologies.</li><li>○ Utilization of strategies to address difficult-to-drug challenges, such as novel pathways inducing cancer cell death, synthetic lethality, driver gene vulnerabilities, and induced proximity.<ul style="list-style-type: none"><li>- Including e.g., cancer cell-targeted drug delivery technologies, ADC technologies using novel payloads, and induced proximity technologies such as PROTACs / molecular glues / LYTACs</li><li>- Including target validation (including assay development) and drug development research; however, diagnostics, drug repurposing, and screening equipment development are excluded</li></ul></li><li>○ Not limited to a specific modality, and includes small molecules, antibodies, antibody mimetics, peptides, cell therapy, genome editing / RNA-based nucleic acids, and others.</li></ul>
R&D Plan	<ul style="list-style-type: none"><li>○ <b>(Step 1)</b> Candidate target validation and securing preclinical candidates<ul style="list-style-type: none"><li>- Verification of the pathological relevance of candidate targets based on clinical/public data, patient-derived tissues, multi-omics, and cancer cells (e.g., target expression, tumor microenvironment, and associations with resistance)</li><li>- Establishment of <i>in vitro</i> evaluation models required for candidate discovery (e.g., cell-based, functional, target binding/degradation, immune cell-tumor co-culture, etc.)</li><li>- Securing 1–2 preclinical candidates through hit/lead identification and optimization, obtaining efficacy proof of concept (PoC), preliminary ADME/PK, and early safety data, and establishing the IND strategy</li></ul></li><li>○ <b>(Step 2)</b> Completion of the IND data package and IND approval<ul style="list-style-type: none"><li>- Completion of the IND-enabling package for secured candidates, including GLP toxicology, safety pharmacology, and ADME/PK</li></ul></li></ul>

	<ul style="list-style-type: none"> <li>- Establishment of CMC (process / analytical methods / specifications / stability), GMP manufacturing, and QC systems</li> <li>- Preparation, submission, and approval of the IND dossier</li> </ul>
Need for Support	<ul style="list-style-type: none"> <li>○ (Policy) Cancer is the leading cause of death in Korea (88,933 deaths in 2024, accounting for 24.8% of all causes of death), and the development of novel anticancer drugs is a strategic area linked to the government's policy direction to expand bio-health R&amp;D investment and promote global collaborative research.</li> <li>○ (Technical) Immuno-oncology and targeted anticancer therapies have limited responder populations, and complex approaches to toxicity issues and resistance mechanisms (biomarker-modality-combination strategy) are required. Therefore, it is difficult for SMEs to independently bear the risks across preclinical, CMC, and regulatory stages.</li> <li>○ (Market) The global oncology modality market is rapidly growing (e.g., the ADC market value is estimated at USD 30 billion by 2028, three times the 2023 level), and global big pharma companies are actively pursuing M&amp;A and licensing, increasing opportunities for technology transfer and co-development of candidates.</li> <li>○ (Social) It has been reported that 1 in 19 Koreans was living with cancer in 2023, and the development of innovative anticancer candidates can contribute to improved survival and quality of life for cancer patients, while also strengthening global collaboration, employment, and technological self-reliance of domestic biotech ventures.</li> </ul>
Performance Target	<ul style="list-style-type: none"> <li>○ <b>(Step 1)</b> Secure 1–2 preclinical candidates based on validated candidate targets, complete preclinical efficacy and safety validation, and finalize the IND strategy</li> <li>○ <b>(Step 2)</b> Secure the IND-enabling package, including GLP toxicology, as well as CMC/GMP readiness, and complete IND submission and approval</li> <li>○ <b>(After completion)</b> Conclude at least one global co-development or technology transfer agreement</li> </ul>

Title	Co-development of Next-Generation Therapeutic Candidates for Autoimmune and Allergic Diseases Based on Precision Immunomodulation
Definition	○ Development of innovative mechanism/modality-based drug candidates

	<p>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.</p> <ul style="list-style-type: none"> <li>- 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.</li> <li>- Allergic diseases such as chronic urticaria, food allergy, and cutaneous mastocytosis, etc.</li> <li>- Other skin, renal, muscle, or systemic autoimmune/allergic conditions with high unmet needs</li> </ul> <ul style="list-style-type: none"> <li>○ 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"> <li>- 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)</li> <li>- Including target validation (including assay development) and drug development research; however, diagnostics, drug repurposing, and screening equipment development are excluded</li> </ul> </li> </ul>
R&D Plan	<ul style="list-style-type: none"> <li>○ <b>(Step 1)</b> Pathology-based candidate target validation and securing preclinical candidates <ul style="list-style-type: none"> <li>- Validation of targets / cell populations based on human inflammatory tissues (e.g., single-cell / spatial sequencing, multi-omics, AI/ML data analysis, etc.)</li> <li>- Development of disease models using patient-derived tissues (e.g., organoids or immune cell–tissue cell co-culture systems) to evaluate candidate efficacy</li> <li>- Securing 1–2 preclinical candidates based on novel modalities such as multi-target modulation and antibody-directed proximity induction</li> <li>- Defining disease-specific biomarkers and deriving patient stratification strategies for predicting clinical treatment response and monitoring maintenance of remission</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ <b>(Step 2)</b> Completion of the IND data package and IND approval <ul style="list-style-type: none"> <li>- Completion of the IND-enabling nonclinical package for secured candidates, including GLP toxicology, safety pharmacology, ADME/PK, and other regulatory requirements</li> <li>- Establishment of CMC (process / analytical methods / specifications / stability), GMP manufacturing, and QC systems</li> <li>- Preparation, submission, and approval of the IND dossier</li> </ul> </li> </ul>
Need for Support	<ul style="list-style-type: none"> <li>○ (Policy) The development of precision therapeutics for immune disorders is aligned with the policy direction supporting promising technologies, including expanded bio-health R&amp;D investment, strengthened global collaboration in advanced biopharmaceuticals, and development of targeted novel therapeutics.</li> <li>○ (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.</li> <li>○ (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.</li> <li>○ (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.</li> </ul>
Performance Target	<ul style="list-style-type: none"> <li>○ <b>(Step 1)</b> 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</li> <li>○ <b>(Step 2)</b> Secure the IND-enabling package for candidates, including GLP toxicology, as well as CMC/GMP readiness, and complete IND submission</li> </ul>

	<p>and approval</p> <ul style="list-style-type: none"><li>○ <b>(After completion)</b> 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</li></ul>
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