

○ Therapeutics for Fibrotic Diseases

Title	Development of Therapeutic Agents for Fibrotic Diseases
Definition	<ul style="list-style-type: none"> <li>○ Therapeutics for fibrotic diseases are designed to prevent and reverse organ dysfunction by suppressing chronic inflammation and pathological tissue fibrosis in major organs including the liver, kidney, lung, and heart</li> <li>○ Therapeutic modalities include monoclonal antibodies, small molecules, peptides, and fusion proteins that target fundamental pathogenic mechanisms of fibrosis, such as pro-fibrotic signaling pathways, immune cell activation, and ECM remodeling</li> </ul>
R&D Plan	<ul style="list-style-type: none"> <li>○ (Step 1) Drug Candidate Identification and IND-enabling Preparation <ul style="list-style-type: none"> <li>- Discovery and characterization of novel therapeutic candidates (antibodies, small molecules, or peptides) based on key anti-fibrotic mechanisms</li> <li>- Non-clinical efficacy evaluation and pharmacological mechanism validation using in-vitro cell-based assays and disease-relevant animal models, including PK/PD and preliminary toxicity evaluation</li> <li>- IND-enabling study design and preparation (study strategy, protocol development and CRO selection, etc.)</li> <li>- Establishment of CMC processes and GMP manufacturing system (process, analytical methods, and specifications) to support subsequent IND submission</li> </ul> </li> <li>○ (Step 2) IND-enabling Package Completion and IND Approval <ul style="list-style-type: none"> <li>- GLP-compliant toxicology studies to generate an IND-enabling nonclinical data package for IND submission</li> <li>- Achieve CMC/GMP readiness and finalize CMC documentation for IND submission</li> <li>- Submit the IND and obtain IND approval</li> </ul> </li> </ul>
Need for Support	<ul style="list-style-type: none"> <li>○ (Policy) Fibrosis represents a common terminal pathology across multiple chronic diseases, aligning closely with national strategies for chronic disease management and advanced biopharmaceutical innovation.</li> </ul>

	<ul style="list-style-type: none"> <li>○ (Technical) Drug development requires end-to-end R&amp;D capabilities encompassing preclinical research, CMC development, and clinical trials. Collaboration with global pharmaceutical partners and access to specialized infrastructure are critical for successful therapeutic development.</li> <li>○ (Market) With limited approved anti-fibrotic therapies for most organ-specific fibrotic diseases, the market offers significant opportunities for first-in-class or best-in-class innovation and early market entry by Korean biopharmaceutical companies.</li> <li>○ (Social) Chronic fibrosis is a leading cause of organ failure and transplantation demand, imposing substantial economic and healthcare burdens. Successful therapeutic development will reduce societal healthcare costs and enhance national biopharmaceutical competitiveness.</li> </ul>
Performance Target	<ul style="list-style-type: none"> <li>○ (Step 1) Identify therapeutic candidates for fibrotic diseases (antibodies, small molecules, or peptides), complete preclinical proof-of-concept efficacy and preliminary PK/PD and toxicity studies, and prepare for IND-enabling studies and CMC development</li> <li>○ (Step 2) Complete IND-enabling studies including GLP toxicology and achieve CMC/GMP readiness. Submit the IND and obtain IND approval</li> <li>○ (After completion) Execute global technology-transfer agreements or establish clinical development partnerships</li> </ul>