

Development of a preclinical candidate of a UniStac-based long-acting tetra-specific drug for NASH

Onegene Biotechnology



METABOLIC	Candidate
Product Type	Biological-Protein Product [Multi-specific drug]
Indication	1st indication: NASH, Cirrhosis 2nd indication: Idiopathic Pulmonary Fibrosis
Target	Glucagon-like peptide-1 [GLP-1], Glucagon [GCG], Fibroblast growth factor 21[FGF21], and α Cytokine
MoA(Mechanism of Action)	<p>The diagram illustrates the mechanism of action of the UniStac-based drug. The UniStac protein, shown as a central blue and grey structure, binds to three receptors: GLP-1/GCG (1st site), FGF21 (3rd site), and αCytokine (4th site). This binding leads to the following effects:</p> <ul style="list-style-type: none"> GLP-1/GCG (1st site): Reduces Hepatic Stress and Lipotoxicity, leading to increased Appetite, Energy Expenditure, Lipolysis, and decreased Lipogenesis and Hepatic Steatosis & Inflammation. FGF21 (3rd site): Reduces Hepatic Stress and Lipotoxicity, leading to increased Energy Expenditure, decreased Blood Glucose & Triglyceride, Hepatic Steatosis & Inflammation, and Fibrosis. αCytokine (4th site): Reduces Macrophage & Stellate Cell Activation, leading to decreased αCytokine, Inflammation, and Fibrosis. <p>Overall, these effects lead to improved Hepatic Stress Targets and Direct Fibrosis Targets.</p>
Competitiveness	<p>Best-in-Class Efficacy: Improved efficacy and therapeutic window for the NASH and liver fibrosis resolution compared to the leading FGF21 asset</p> <p>Potential Accelerated Approval: High unmet need in reversing cirrhosis (F4)</p> <p>Potential Multi-Organ Anti-Fibrosis Treatment: Strong anti-fibrosis effect in IPF mouse model</p>
Development Stage	Candidate
Route of Administration	Subcutaneous Administration