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Ascletis submits US IND applications for once-monthly obesity candidates

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The filings cover ASC36, a peptide amylin receptor agonist, and ASC36_35 FDC, a co-formulation targeting amylin receptor, GLP-1R and GIPR.



Ascletis Pharma has submitted two Investigational New Drug applications to the U.S. FDA for obesity treatment candidates ASC36 and ASC36_35 FDC.

ASC36 is a next-generation peptide amylin receptor agonist being developed as a once-monthly to once-quarterly subcutaneous injection. ASC36_35 FDC is a once-monthly fixed-dose co-formulation combining ASC36 with ASC35, a peptide GLP-1R/GIPR agonist.

The filings are relevant because obesity drug development is moving rapidly beyond first-generation incretin-based therapies. While GLP-1 and GLP-1/GIP therapies have reshaped the market, there is growing interest in longer-acting and multi-mechanism approaches that may improve efficacy, dosing convenience and long-term adherence.

ASC36_35 FDC is designed to target three validated pathways: amylin receptor, GLP-1R and GIPR. The company is positioning the candidate as a potentially first-in-class once-monthly co-formulation, compared with approaches that require separate weekly injections.

Ascletis said ASC36_35 FDC demonstrated approximately 51 per cent greater relative body weight reduction than co-administration of eloralintide and tirzepatide in a head-to-head diet-induced obese rat study. The company also reported that ASC36 monotherapy produced approximately 91 per cent and 32 per cent greater relative body weight reduction than petrelintide and eloralintide monotherapies, respectively, in similar DIO rat studies.

The candidates were discovered in-house using Ascletis' Artificial Intelligence-Assisted Structure-Based Drug Discovery platform. Both ASC36 and ASC35 also use Ascletis' Ultra-Long-Acting Platform and Self-Assembling Lipid Depot formulation technology, intended to support longer dosing intervals.

In non-human primate studies, ASC36 SALD formulation demonstrated an observed half-life around six times longer than eloralintide, supporting potential once-monthly to once-quarterly administration in humans. ASC36_35 FDC also showed long observed half-lives for both ASC36 and ASC35 in non-human primates, supporting once-monthly dosing.

The development builds on Ascletis' earlier U.S. FDA IND clearance for ASC35 as a once-monthly subcutaneous treatment for obesity. Together, these programmes indicate the company is building a broader metabolic disease pipeline around long-acting peptide therapies and oral small-molecule approaches.