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Ascletis starts US Phase I trial of oral amylin agonist ASC36 for obesity

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The 86-participant study will evaluate Ascletisâ?? oral peptide candidate as the company expands its metabolic disease pipeline and proprietary oral peptide delivery platform.

Ascletis Pharma has initiated a US Phase I clinical study of ASC36 oral tablets, an investigational amylin receptor peptide agonist being developed for obesity.

The trial follows recent Investigational New Drug clearance from the US Food and Drug Administration.

The Phase I study will evaluate safety, tolerability, pharmacokinetics and pharmacodynamics following single and multiple ascending oral doses.

A total of 86 participants with obesity or overweight are expected to enrol.

Participants will have either a body mass index of at least 30 kg/m² or a BMI of at least 27 kg/m².

ASC36 is being developed using Ascletis' proprietary Peptide Oral Transport ENhancement Technology, or POTENT, which is intended to improve the oral delivery of peptide therapeutics.

In non-human primate studies, oral ASC36 achieved absolute bioavailability of between 6% and 8% at steady state.

Once-daily oral dosing for seven days produced mean body-weight reductions of up to 13.2% from baseline in the preclinical model.

Ascletis said the oral formulation could potentially use lower doses because of its oral bioavailability and potency, which may also provide manufacturing scalability advantages.

The company is developing ASC36 across both oral and injectable formulations.

Preclinical comparisons of subcutaneous ASC36 also showed greater relative body-weight reduction than comparator amylin candidates in a diet-induced obesity rat model, according to the company.

“In 2026, we initiated four Phase I studies for our peptide pipeline, including ASC36 oral tablets, our fourth and most recent one,” said Dr Jinzi Jason Wu, Founder, Chairman and Chief Executive Officer of Ascletis.

He said the programme represents an additional validation milestone for the company’s oral peptide delivery technology.

The trial adds to Ascletis’ rapidly expanding metabolic pipeline as competition intensifies around next-generation obesity therapies targeting mechanisms beyond GLP-1 alone.

The company is developing programmes spanning GLP-1, GIP and amylin pathways across oral and longer-acting injectable formulations.