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ASIA EDITION

Ascletis doses first participant in global Phase III trial of oral GLP-1 candidate ASC30

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The AURORA programme will enrol around 4,600 participants to evaluate once-daily oral ASC30 for chronic weight management in people with and without type 2 diabetes.

Ascletis Pharma has dosed the first participant in its global Phase III clinical programme evaluating ASC30, an investigational once-daily oral small molecule GLP-1 receptor agonist for chronic weight management.

The programme consists of two pivotal multicentre, randomised, double-blind and placebo-controlled studies, AURORA-1 and AURORA-2.

Approximately 4,600 participants are expected to enrol across clinical sites in the United States, Europe and Canada.

AURORA-1 will evaluate ASC30 in participants with obesity or overweight without type 2 diabetes, while AURORA-2 will enrol participants with obesity or overweight who also have type 2 diabetes.

The studies will assess three maintenance doses of 20 mg, 40 mg and 60 mg over a treatment period of 72 weeks.

ASC30 is being developed as an oral alternative within the rapidly expanding GLP-1 therapeutic market.

Most established GLP-1 therapies have historically been delivered by injection, creating growing interest in oral small molecule approaches that may provide greater convenience and simplify manufacturing and distribution.

Ascletis expects topline results from the AURORA programme in the third quarter of 2028.

The company is targeting a US New Drug Application submission by the end of 2028, followed by a European Marketing Authorisation Application in early 2029.

If successful and subsequently approved, Ascletis believes ASC30 could become one of the first oral small molecule GLP-1 receptor agonists available in major international markets.

The programme represents a major late-stage milestone for the Chinese biotechnology company as it expands its metabolic disease portfolio internationally.

Ascletis is also developing additional oral and injectable programmes targeting GLP-1, GIP and amylin pathways for obesity and related metabolic disorders.