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Lundbeck Reports Phase II Data for Asedebart in Cushingâ??s Disease

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The investigational anti-ACTH monoclonal antibody showed urinary free cortisol normalisation in most evaluable patients.

Lundbeck has presented preliminary Phase II Part A data for asedebart, an investigational anti-adrenocorticotropic hormone monoclonal antibody, in adults with Cushing's disease.

The data were presented at ENDO 2026 in Chicago and came from an ongoing multicentre, open-label Phase II dose-titration study evaluating intravenous and subcutaneous doses of asedebart in adults with ACTH-driven Cushing's disease of pituitary origin.

This is relevant because Cushing's disease remains a rare endocrine disorder with significant treatment gaps. First-line treatment usually involves surgical removal of the pituitary tumour, but not all patients are eligible, achieve sustained remission or respond adequately to available therapies.

Asedebart is designed to neutralise excess ACTH and reduce downstream cortisol production. This differentiates it from approaches that focus mainly on adrenal steroidogenesis or pituitary tumour-directed treatment, positioning it as a potential targeted biologic for ACTH-driven disease.

At the data cut-off, 12 patients had been enrolled. Among patients who completed individualised intravenous dose titration, seven out of eight achieved normalisation of urinary free cortisol, defined as 170 nmol per 24 hours or below.

Asedebart was generally well tolerated, with no unexpected adverse events and no new safety signals observed. Treatment-emergent adverse events were reported in all 12 patients, while serious adverse events occurred in three patients, including one death due to an unrelated event. Glucocorticoid deficiency events were observed in two participants and managed with short-term hydrocortisone.

The therapy remains investigational and is not approved by any regulatory authority. Part B of the ongoing Phase II study is evaluating subcutaneous administration, including effects on cortisol reduction, safety, tolerability, pharmacokinetics and patient experience.