Press release
Valby, 14 June 2026

Lundbeck presents new Phase II asedebart data in Cushing's disease at ENDO 2026

- Asedebart is an investigational monoclonal antibody designed to neutralize excess adrenocorticotropic hormone (ACTH) and reduce downstream cortisol production in Cushing's disease (CD)
- Urinary free cortisol (UFC) normalization is a clinically relevant measure in CD, where chronic cortisol excess is a key driver of morbidity, mortality and quality-of-life burden
- Preliminary Phase II Part A data showed UFC normalization in most evaluable adults with CD who completed individualized intravenous dose titration with asedebart[1]

Valby, Denmark, Sunday 14 June 2026 – H. Lundbeck A/S (Lundbeck) today announced preliminary Phase II Part A data from its ongoing study evaluating asedebart (Lu AG13909), an anti-adrenocorticotropic hormone (ACTH) monoclonal antibody, in adults with Cushing's disease (CD). CD is characterized by overproduction of ACTH by a pituitary adenoma and involves dysfunction of the hypothalamic-pituitary-adrenal (HPA) axis.[2] Urinary free cortisol (UFC) is a key measure of cortisol burden in CD, where chronic hypercortisolism is central to CD's clinical impact. Asedebart's mechanism of action aims to neutralize pathological increases in ACTH and thereby affect downstream chronic cortisol excess, as reflected in UFC levels.

The data, presented as an oral presentation at the 2026 Endocrine Society's Annual Meeting, (ENDO), taking place June 13–16 in Chicago, U.S., showed UFC normalization in 7 out of 8 evaluable patients following individualized intravenous (IV) dose titration of asedebart.[1]

"The data from the ongoing Phase II study highlight the potential of direct ACTH neutralization as a novel therapeutic approach in Cushing's disease, a neuroendocrine condition where major unmet medical needs remain," said Johan Luthman, EVP and Head of Research & Development at Lundbeck. "The UFC normalization observed in most evaluable patients is very encouraging and strengthens our confidence in asedebart's continued development in CD. The next steps include evaluating a subcutaneous formulation."

The asedebart program reflects how Lundbeck has expanded upon its neuroscience heritage by pursuing biological drug targets within neurohormonal signaling. This area offers the potential to develop differentiated therapeutics for rare endocrine disorders, supported by biomarker-driven patient studies that enable decisive and early development decisions.

Preliminary Phase II Part A results
At ENDO 2026, preliminary Part A data were presented from Lundbeck's ongoing multi-center, open-label Phase II dose-titration study evaluating multiple IV and subcutaneous (SC) doses of asedebart in adults with ACTH-driven CD of pituitary origin.

At the data cut-off, 12 patients had been enrolled and 8 out of 9 who began the IV dosing phase completed individualized dose titration. In the responder analysis, 7 out of 8 of these patients achieved normalization of UFC (≤170 nmol/24 hours). 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. Serious adverse events were reported in 3 patients, including one death due to an unrelated event. No hypersensitivity events were reported. Glucocorticoid deficiency events were observed in two participants and managed with short-term hydrocortisone treatment.

Part B of the ongoing Phase II study is investigating SC administration of asedebart in adults with CD.[1] This next step, Part B, is designed to further evaluate direct ACTH neutralization, including effects on cortisol reduction, safety and tolerability, pharmacokinetics and patient experience with SC dosing.

Asedebart is an investigational drug not approved for marketing by any regulatory authority worldwide, and the efficacy and safety of asedebart have not been established.

About asedebart

Asedebart is a humanized anti-ACTH monoclonal antibody designed to specifically recognize ACTH with high affinity. It blocks the binding of ACTH to the melanocortin 2 receptor in the adrenal glands and thereby inhibits the neurohormonal signaling of ACTH. This inhibition causes a decreased secretion of glucocorticoids, mineralocorticoids and androgens from the adrenal glands.[3,4] ACTH plays a key role in the biosynthesis of adrenal steroids[5] and is therefore considered a potential therapeutic target in conditions characterized by elevated ACTH levels.[4]

Asedebart has received Orphan Drug Designation (ODD) for congenital adrenal hyperplasia (CAH) in the European Union and the United States as well as ODD in Japan for the treatment of patients with CD and CAH.

About Cushing's disease

CD is a rare endocrine disorder caused by a pituitary adenoma that secretes excess ACTH, leading to chronic overproduction of cortisol.[2] The condition is associated with significant morbidity and increased mortality, and patients may experience a wide range of physical and neuropsychiatric symptoms.[6] First-line treatment is surgical removal of the tumor; however, not all patients are eligible, achieve sustained remission, or benefit fully from currently available treatment options, highlighting an ongoing unmet need for effective and well-tolerated therapies.

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About H. Lundbeck A/S

Lundbeck is a biopharmaceutical company focusing exclusively on brain health. With more than 70 years of experience in neuroscience, we are committed to improving the lives of people with neurological and psychiatric diseases.

Brain disorders affect a large part of the world's population, and the effects are felt throughout society. With the rapidly improving understanding of the biology of the brain, we hold ourselves accountable for advancing brain health by curiously exploring new opportunities for treatments.

As a focused innovator, we strive for our research and development programs to tackle some of the most complex neurological challenges. We develop transformative medicines targeting people for whom there are few or no treatments available, expanding into neuro-specialty and neuro-rare from our strong legacy within psychiatry and neurology.

We are committed to fighting stigma and we act to improve health equity. We strive to create long term value for our shareholders by making a positive contribution to patients, their families, and society as a whole.

Lundbeck has more than 5,000 employees in more than 20 countries and our products are available in more than 80 countries. For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us via LinkedIn.

References:

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