Press release
Valby, 6 December, 2025

Lundbeck announces positive Phase 2 long-term data for bexicaserin in rare childhood-onset epilepsies, at American Epilepsy Society (AES) Annual Meeting

- New long-term data presented at AES 2025 indicate reductions in seizure frequency are maintained for up to two years after treatment initiation with bexicaserin in patients with Developmental and Epileptic Encephalopathies (DEEs)[1]
- DEEs are a group of devastating, rare epilepsies characterized by unpredictable, drug-resistant seizures combined with developmental and intellectual disabilities[2]
- Durable and consistent effects were observed across a diverse range of DEEs with a favorable safety and tolerability profile[1]
- Bexicaserin is an investigational compound in development for the treatment of seizures associated with a broad range of DEEs

Valby, Denmark, 6 December 2025 – H. Lundbeck A/S (Lundbeck) today announced results from a long-term follow-up in patients who have received bexicaserin (LP352) for up to two years. Bexicaserin is a novel, investigational drug for the treatment of seizures associated with Developmental and Epileptic Encephalopathies (DEEs). The data, presented at the 2025 American Epilepsy Society Congress in Atlanta, USA (Dec 5 – 9), indicate that patients who achieved an early reduction in seizure frequency following bexicaserin treatment initiation, continue to maintain this reduction long-term.[1]

DEEs are a group of severe, rare epilepsies that begin in childhood and demand lifelong care.[2,3] Characterized by drug-resistant seizures and developmental or intellectual disabilities, these conditions leave patients heavily dependent on caregivers.[3] In most cases, DEEs are resistant to conventional anti-seizure medications (ASMs) and there are currently no ASMs approved across all DEE subtypes, leaving many patients without suitable treatment options.[4-6] The unpredictable nature of the seizures adds to the daily distress faced by families, highlighting the pressing need for innovative solutions to improve treatment outcomes and enhance quality of life.

“The constant management of DEEs place a heavy emotional and financial burden on families, underscoring the urgent need for better seizure control. We are increasingly hopeful that bexicaserin can address this need,” said Johan Luthman, EVP and Head of Research and Development at Lundbeck. “The data so far show durable seizure reductions, an encouraging safety profile and minimal risk of drug-drug interactions, reinforcing bexicaserin’s potential as a first-in-class therapy across a broad range of DEEs.”

At the AES congress, long-term data were showcased in patients who completed the Phase 1a/2b PACIFIC trial followed by a 12-month Open Label Extension (OLE) and have now received up to two years of bexicaserin treatment via Expanded Access, which enables continued access to investigational drugs where no satisfactory alternative therapy options are available.

During this two-year follow up, patients receiving bexicaserin experienced a median reduction in countable motor seizures of -60.2% at ~18 months (n=30), and -53.7% at ~24 months (n=17), compared to the start of the PACIFIC trial.[1] Notably, the reductions were consistent across DEE types and similar to the results of the PACIFIC trial and OLE. This indicates that patients of all DEE types, who experience an early, clinically meaningful response, continue to maintain this response long-term.[1] No new safety concerns were observed during the two-year treatment phase with a tolerability and safety profile similar to the PACIFIC trial and OLE (further safety information detailed below).

The full results of the PACIFIC trial were recently published in *Epilepsia*, a leading neurology journal, marking a significant milestone in advancing research within the field of DEEs.[7]

With seven additional presentations at AES 2025, Lundbeck demonstrates the breadth of its R&D program and dedication to improving outcomes for children and families affected by rare epilepsies.

Bexicaserin is an investigational compound that is not approved for marketing by any regulatory authority worldwide. The efficacy and safety of bexicaserin have not been established.

About DEEs

Developmental and Epileptic Encephalopathies (DEEs) are a group of rare neurodevelopmental disorders that typically manifest in early childhood.[2] These heterogeneous and severe epilepsy syndromes are characterized by refractory seizures, frequent epileptiform activity on electroencephalogram (EEG), and developmental stagnation or regression.[2] According to the International League Against Epilepsy (ILAE), DEEs currently encompass more than 10 syndromes, including Early Infantile DEE (EIDEE), Infantile Epileptic Spams Syndrome (IESS), Dravet Syndrome, and Lennox-Gastaut Syndrome with various etiologies among those mainly genetic (e.g., CDKL5, STXBP1, KCNT1, SCN2A).

About bexicaserin

Bexicaserin (LP352) is an oral, centrally acting 5-hydroxytryptamine 2C (5-HT2C) receptor superagonist with no engagement of the 5-HT2B and 5-HT2A receptor subtypes, potentially minimizing the risk of cardiovascular toxicity.[8] The most common TEAEs associated with bexicaserin the PACIFIC trial were somnolence, decreased appetite, constipation, diarrhea, lethargy, tremor, urinary tract infection, fatigue, pyrexia, agitation, and hypertension.

Bexicaserin is being evaluated in a global Phase 3 clinical program (the DEEp Program). The FDA has granted Breakthrough Therapy designation for bexicaserin for the treatment of seizures associated with DEEs for patients two years of age and older. Bexicaserin has also recently been granted Breakthrough Therapy Designation in China for the treatment of seizures associated with DEEs.

About the PACIFIC trial and 2 year Follow-Up

The PACIFIC trial was a Phase 1b/2a randomized, double-blind, placebo-controlled clinical trial to assess the safety, tolerability, efficacy, and pharmacokinetics of bexicaserin in 52 participants between the ages of 12 and 65 years old with any type of DEE (Dravet syndrome,

Lennox-Gastaut syndrome and DEE other) at 34 sites across the United States and Australia. Participants who had ≥4 countable motor seizures during the 28-day baseline period, while on a stable regimen of 1 to 4 concomitant antiseizure medications were included.[7] Three participants in the bexicaserin group reported a serious adverse event (ankle fracture x 2, constipation, and increased seizures). During the titration period, 16.3% of bexicaserin-treated patients discontinued due to an adverse event, while during the maintenance period, 4.7% of bexicaserin-treated participants discontinued due to an adverse event.

Following a 28-d baseline period, study participants initiated a dose titration over a 15-day period and subsequently continued on the highest tolerated dose throughout the maintenance period of 60 days. Eligible participants were given the opportunity to enroll in a 52-week open-label extension (OLE) if they completed the 75-d RCT treatment period (titration and maintenance). The OLE included patients with Dravet syndrome (n=3), Lennox-Gastaut syndrome (n=20) and DEE Other (n=18), who completed the PACIFIC trial (n=41).[7]

Of 38 participants who completed the OLE, 36 continued their maintenance dosing regimen via Expanded Access application. At approximately 18 months treatment (OLE + Extended Access period), one participant was lost to follow-up, and one participant was reported as deceased unrelated to study drug; the remaining 34 participants on bexicaserin received approximately 24 months of treatment.[1]

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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.

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