Press release
Valby, 24 November, 2026

Lundbeck to present new clinical trial analyses and broader bexicaserin research at AES 2026

- DEEp OCEAN baseline data will characterize the diversity of the Phase III population across multiple etiologies and seizure types in developmental and epileptic encephalopathies (DEEs).[1]
- New clinical analyses from the PACIFIC Phase II trial and the open-label extension (OLE) will provide insights into days without countable motor seizures and the durability of these effects over 12 months of treatment.[2]
- Expanded access program (EAP) data from PACIFIC patients provide further insights into the durability of the effect on seizure frequency, safety and tolerability of bexicaserin in DEEs, following up to three years of use.[3]
- At AES 2026, Lundbeck will present nine scientific posters, including three late-breaking clinical presentations, as well as a scientific symposium and exhibition, covering the comprehensive bexicaserin development program and the burden of DEEs.[1–9]

Valby, Denmark, 24 November, 2026 – H. Lundbeck A/S (Lundbeck) today announced plans to present new data characterizing the broad DEE representation in the DEEp OCEAN Phase III trial population and clinical analyses of seizure outcomes over time with bexicaserin from the PACIFIC Phase II trial and OLE at the American Epilepsy Society (AES) Annual Meeting in Denver, Colorado, 4–8 December 2026. The nine-poster program will also feature preclinical research into bexicaserin's proposed dual mode of action, clinical pharmacology findings and analyses of the healthcare burden associated with DEEs. The company will also host a scientific symposium and exhibit at the congress.

"The research presented at AES reflects our commitment to provide a better understanding of the investigational compound bexicaserin and the patient population enrolled in clinical trials," said Tarek Samad, Executive Vice President and Head of Research & Development at Lundbeck. "From further exploring its proposed dual mode of action to examining seizure outcomes over time and the population represented in our Phase III program, these studies provide complementary perspectives on the development of bexicaserin. Together, they reflect our commitment to advancing research for people living with these severe epilepsies."

The three late-breaking clinical presentations share new insights on the range of seizure types included in the DEEp OCEAN Phase III trial, analyses of countable motor seizure-free days from the PACIFIC extension trial, and duration of effect on seizure frequency over the long term in people receiving up to three years of bexicaserin for seizures associated with DEEs under the expanded access program.[1-3]

The six additional posters provide scientific insights into the proposed mechanism of action and pharmacology of bexicaserin and document the healthcare and medication burden associated with DEEs.

New preclinical research findings on bexicaserin's pharmacology, proposed dual mode of action, effect on seizure activity and SUDEP are also featured at AES 2026.[4,5]

Two Phase I studies, each involving 24 healthy participants, report data on bexicaserin exposure affected by food and interactions with carbamazepine, a common anti-seizure medication in DEE management.[6,7]

Two retrospective US claims analyses examine healthcare resource use, direct costs, comorbidity burden and medication patterns associated with DEEs.[8,9]

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

Lundbeck's scientific program at AES 2026

Poster presentations			
Category	**Scientific question addressed by poster**	**Format / author**	**Details**
Late-breaking poster	Reporting of baseline characteristics of the DEEp OCEAN Phase III trial population. [1]	Poster presentation Presented by: Ingrid E. Scheffer	Monday, December 7, Author-present Time: 12:00 to 14:00 (MT) Poster session #3.499
Late-breaking poster	The PACIFIC Open-Label Extension Trial provides documentation of the long-term effects of bexicaserin on motor seizure-free days in DEE patient population.[2]	Poster presentation Presented by: David G. Vossler	Sunday, December 6, Author-present Time: 12:00 to 14:00 (MT) Poster session #2.511
Late-breaking poster	The expanded access program for former PACIFIC participants evaluates the durability of bexicaserin's anti-seizure effect.[3]	Poster presentation Presented by: Terence J. O'Brien	Sunday, December 6, Author-present Time: 12:00 to 14:00 (MT) Poster session #2.508
Poster	Complementary action of bexicaserin as a super 5HT2C receptor agonist is further characterized in preclinical research. [4]	Poster presentation Presented by: Charlotte Hougaard	Saturday, December 5, Author-present Time: 12:00 to 14:00 (MT) Poster session #1.050
Poster	Bexicaserin's action on brainstem neural activity known to be associated with sudden unexpected death in epilepsy (SUDEP) explored in animal models.[5]	Poster presentation Presented by: Sheryl Anne D. Vermudez	Saturday, December 5, Author-present Time: 12:00 to 14:00 (MT) Poster session #1.049
Poster	Impact of food on bexicaserin exposure in healthy human participants is reported.[6]	Poster presentation Presented by: Rosa Chan	Saturday, December 5 Author-present Time: 12:00-14:00 (MT) Poster session #1.224
Poster	Bexicaserin's potential for drug-drug interactions with carbamazepine, an established anti-seizure medication for specific subtypes of DEE.[7]	Poster presentation Presented by: Jonathan Williams	Saturday, December 5 Author-present Time: 12:00-14:00 (MT) Poster session #1.089
Poster	A comparative evaluation of healthcare utilization among DEE patients vs other patients with epilepsy is presented.[8]	Poster presentation Presented by: Scott Demarest	Saturday, December 5, Author-present Time: 12:00 to 14:00 (MT) Poster session #1.389
Poster	A detailed look at the types of polypharmacy often needed to manage comorbidities in people living with DEEs is shared.[9]	Poster presentation Presented by: Gauri Dixit	Saturday, December 5, Author-present Time: 12:00 to 14:00 (MT) Poster session #1.388

Sponsored scientific symposium and scientific exhibition			
Activity	**Title / content**	**Speakers / staff**	**Details**
Lundbeck-sponsored scientific symposium	Advancing management of developmental and epileptic encephalopathies (DEEs): Mechanistic perspectives and the potential of 5-HT_{2C} receptor targeting	Ingrid Scheffer (chair and speaker); Lieven Lagae; Raman Sankar	Friday, 4 December 6:00–9:00 PM Bluebird 1C, Colorado Convention Center
Scientific exhibition	Bexicaserin: A Novel Investigational Molecule in Development for the Treatment of DEEs	Sponsored by Lundbeck	Sunday, 6 December 8:00–11:00 AM Bluebird 2E–F

About DEEs

Developmental and Epileptic Encephalopathies (DEEs) represent a heterogeneous group of severe epileptic disorders characterized by early-onset seizures and developmental impairment, including developmental delay or regression and intellectual and functional disabilities that may persist into adulthood.[10] DEEs may have genetic, structural, metabolic, or unknown etiologies. Seizures associated with DEEs include multiple types such as generalized tonic-clonic, tonic, atonic, and focal seizures.[10]

About bexicaserin

Bexicaserin is an investigational, oral, highly selective superagonist of the 5-HT_{2C} receptor subtype. Through its unique and selective binding to 5-HT_{2C}, the potential for adverse effects linked with other receptor subtypes may be minimized.[11] Bexicaserin is believed to act with a dual mode of action that modulates both inhibitory and excitatory neuronal pathways to reduce neuronal hyperexcitability associated with seizures in DEEs arising from various etiologies.[4] The precise mode of action of bexicaserin is not established.

The most common treatment-emergent adverse events (TEAEs) reported in the PACIFIC trial were somnolence, decreased appetite, constipation, and diarrhea.[12]

Bexicaserin is being evaluated in a global Phase III 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 been granted Breakthrough Therapy Designation in China for the treatment of seizures associated with DEEs.[13]

About the PACIFIC trial

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.[12] 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).[12,14]

About the DEEp OCEAN trial

DEEp OCEAN (NCT:06719141) is a Phase III interventional, randomized, double-blind, parallel-group, placebo-controlled trial evaluating bexicaserin in children and adults with DEEs, including LGS.[15]

The trial comprises a screening period of up to 35 days, followed by a 15-week treatment period consisting of a 3-week titration phase and a 12-week maintenance phase. Participants are randomized to receive either bexicaserin or placebo three times daily, with weight-based dosing used for pediatric participants. Following treatment, participants complete a taper period and safety follow-up or may transition into the 52-week DEEp open-label extension study (OLE). The aim of the trial is to evaluate the efficacy, safety, and tolerability of bexicaserin in reducing countable motor seizure frequency in patients with DEEs, including LGS.

About the DEEp SEA trial

DEEp SEA (NCT:06660394) is a Phase III interventional, randomized, double-blind, parallel-group, placebo-controlled trial evaluating bexicaserin in children and adults with Dravet syndrome.[16]

The trial comprises a screening period of up to 35 days, followed by a 15-week treatment period consisting of a 3-week titration phase and a 12-week maintenance phase. Participants are randomized to receive either bexicaserin or placebo three times daily, with weight-based dosing used for pediatric participants. Following treatment, participants complete a taper period and safety follow-up or may transition into the 52-week DEEp OLE. The aim of the trial is to evaluate the efficacy, safety, and tolerability of bexicaserin in reducing countable motor seizure frequency in patients with Dravet syndrome.

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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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