Press release
Valby, 3 September, 2026

Lundbeck to highlight mechanistic insights on bexicaserin's dual mode of action at the European Epilepsy Congress

- Preclinical data provide mechanistic insight into bexicaserin's dual mode of action, increasing inhibitory while decreasing excitatory neuronal activity, suggesting a broader antiseizure activity in preclinical models of focal, generalized motor and absence seizures across different etiologies.[1]
- Bexicaserin is currently being evaluated in the global Phase III DEEp Program for the treatment of seizures associated with developmental and epileptic encephalopathies (DEEs); Lundbeck will present clinical and preclinical research from the broader development program at the European Epilepsy Congress.[2,3]

Valby, Denmark, 3 September, 2026 – Lundbeck today announced that preclinical data on the dual mode of action of bexicaserin will be featured in an oral presentation at the European Epilepsy Congress in Athens, Greece, 5–9 September, alongside additional presentations of clinical and preclinical data from the bexicaserin development program. The oral presentation will highlight mechanistic data supporting the scientific rationale of bexicaserin's dual mode of action as an investigational, oral, highly-selective superagonist of the 5-HT2c receptor. Through this mechanism, bexicaserin has been shown in preclinical studies to increase inhibitory and decrease excitatory neuronal activity.[1]

Developmental and epileptic encephalopathies, or DEEs, are a diverse group of rare and serious epilepsies characterized by treatment-resistant seizures, frequent epileptiform activity and developmental slowing or regression.[3] People living with DEEs may experience multiple seizure types that evolve over time, while the conditions arise from a wide range of underlying etiologies.[3] There are currently no antiseizure medications approved across all DEEs, underscoring the need for new treatment approaches.[4]

"The data being presented at the European Epilepsy Congress highlight the strong scientific rationale for bexicaserin and its dual mode of action," said Tarek Samad, Executive Vice President and Head of Research & Development at Lundbeck. "DEEs are rare, serious and highly heterogeneous epilepsies, with a substantial unmet need for new treatment approaches. These presentations reflect our continued commitment to advancing the global Phase III DEEp program for people living with DEEs, and to deepen our scientific and mechanistic understanding of bexicaserin's mode of action. "

The preclinical data are relevant because many DEEs are associated with network hyperexcitability where an increase in excitation, decrease in inhibition, or both, can lead to seizures.[5] In hippocampal brain tissue, bexicaserin increases inhibitory while decreasing excitatory neuronal activity, suggesting broad-spectrum antiseizure activity in preclinical models of different seizure types from various etiologies. The high affinity and selectivity of bexicaserin for 5-HT2C receptor supports the conclusion that these effects are mediated through this receptor.[1]

Bexicaserin is being evaluated in the global Phase III DEEp Program. The program includes DEEp OCEAN in children and adults living with DEEs, including Lennox–Gastaut syndrome, and DEEp SEA in children and adults living with Dravet syndrome.[6,7]

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.

Lundbeck's scientific presentations at the European Epilepsy Congress

Data presentations	**Format**	**Date and time**
Analyses of Bexicaserin for the Treatment of Seizures in DEEs: Response Over Time and Responder Rates in the Phase 1b/2a PACIFIC Trial OLE[9]	Poster presentation and ILAE YES poster tour Presented by: Tolga Uz	Poster: Sunday, 6 September, 14:00–15:00 ILAE YES poster tour: Tuesday, 8 September, 14:30–15:00; specific slot 14:30–14:33
Bexicaserin for the Treatment of Seizures in Developmental and Epileptic Encephalopathies: Interim Analysis of an Expanded Access Program for Participants on Treatment for up to 2 Years[10]	Poster presentation Presented by: Mette Thrane Foged	Sunday, 6 September, 14:00–15:00
Effects of Bexicaserin on Neural Circuits in the DBA/1 Mouse Model of Sudden Unexpected Death in Epilepsy (SUDEP)[11]	Poster presentation Presented by: Sheryl Anne D. Vermudez	Tuesday, 8 September, 14:00–15:00
Bexicaserin, a 5-Hydroxytryptamine Type 2C Receptor Superagonist, Modulates Inhibitory and Excitatory Neuronal Function to Exert Antiseizure Effects Across Etiologies and Seizure Types[1]	Oral presentation Presented by: Jesper F. Bastlund	Sunday, 6 September, 12:15 – 13:45

About DEEs

Developmental and Epileptic Encephalopathies (DEEs) are a group of rare neurodevelopmental disorders that typically manifest in early childhood.[3] These heterogeneous and severe epilepsy syndromes are characterized by refractory seizures, frequent epileptiform activity on electroencephalogram (EEG), and developmental stagnation or regression.[3] According to the International League Against Epilepsy (ILAE), DEEs currently encompass more than 10 syndromes, including Early Infantile DEE (EIDEE), Infantile Epileptic Spasms 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 in the PACIFIC trial were somnolence, decreased appetite, constipation, diarrhea, lethargy, tremor, urinary tract infection, fatigue, pyrexia, agitation, and hypertension.

Bexicaserin acts via a dual mode of action, both increasing inhibitory and decreasing excitatory neuronal function, consistent with the reduction in seizures associated with DEEs arising from various etiologies.[1] 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.[2]

About 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.[6]

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.[7] The trial is currently enrolling participants globally.

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 and connect with us via LinkedIn.

References

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