Press release
Valby, 25 August, 2025

Lundbeck to present new data on bexicaserin at upcoming congress, highlighting long-term impact on seizure frequency in patients with rare epilepsy

- The full results of the open label extension (OLE) of the Phase 1b/2a PACIFIC trial investigating bexicaserin for the treatment of patients with Developmental and Epileptic Encephalopathies (DEEs), will be presented for the first time at the International Epilepsy Annual Congress[1]
- DEEs are the most severe rare epilepsies, characterized by drug-resistant seizures, frequent epileptic activity on EEG and developmental slowing or regression[2]
- Bexicaserin, which has been granted Breakthrough Therapy designation by the FDA, demonstrated reductions in countable and total motor seizure frequency in the extension study comparable to reductions seen in the Phase 1b/2a PACIFIC trial, reinforcing durability of response and validating its progression to Phase 3 trials[1]
- Additional data will be presented from the audiogenic seizure model and the GAERS absence epilepsy model, investigating sudden unexpected death in epilepsy (SUDEP), and seizure reduction respectively.[3,4]

Valby, Denmark, 25 August 2025 – H. Lundbeck A/S (Lundbeck) today announced that new data regarding bexicaserin, a novel treatment under investigation for seizures associated with Developmental and Epileptic Encephalopathies (DEEs), will be presented at the 36th International Epilepsy Congress (IEC) in Lisbon, Portugal (Aug 30 – Sept 3).

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

“Patients with DEEs represent a challenging group of rare epilepsies, with few effective approved treatment options,” said Johan Luthman, EVP and Head of Research and Development at Lundbeck. “As we are now in phase 3 trials with bexicaserin, we are optimistic about its potential. The clinical data so far suggests broad and durable anti-seizure activity across DEEs, and new preclinical data suggests modulation of the risk of sudden unexpected death in epilepsy (SUDEP). This marks a significant step forward in the potential to transform care for patients and address critical gaps in the treatment landscape,”

The full results of the open label extension (OLE) of the Phase 1b/2a PACIFIC trial will be presented. It was designed to evaluate the long-term (up to 52 weeks), safety, tolerability, and efficacy of bexicaserin in individuals with a DEE. During the OLE, a median reduction of 59.3% in countable motor seizure frequency was observed, with 55% of participants experiencing sustained reductions of ≥50% compared to baseline before the PACIFIC trial. Bexicaserin was well tolerated, with no new safety signals observed.

"I am encouraged by the 100% enrollment of eligible participants and the high completion rate of over 90% in the open-label extension study. Such high retention underscores the tolerability as well as the duration of effect of bexicaserin across developmental and epileptic encephalopathies," said Ingrid E. Scheffer, lead investigator and Laureate Professor of Pediatric Neurology, The University of Melbourne and Austin Health.

Lundbeck will also showcase preclinical data in an audiogenic seizure model of SUDEP, the most common cause of premature death in children and adults with epilepsy.[3,6] Bexicaserin significantly reduced seizures and respiratory arrest in the SUDEP model. Furthermore, preclinical data will be shared indicating the impact of bexicaserin on absence seizures, a type of seizure that is often more difficult to treat.[4,7]

Bexicaserin has entered late-stage clinical development through the global phase 3 program, DEEp, aimed at evaluating its safety, tolerability, and efficacy in the treatment of seizures in children and adults with DEEs. The DEEpSEA trial[8] is currently recruiting participants with Dravet syndrome and the DEEpOCEAN trial[9] is open to individuals with DEEs (including Lennox-Gastaut syndrome).

Both trials are randomized, double-blind, placebo-controlled and open for enrollment across the North America, Europe, Asia, Australia and Latin America, with additional sites being activated on a rolling basis.

Lundbeck's scientific presentations at IEC:

Long-term Safety, Tolerability, and Efficacy of Bexicaserin for the Treatment of Seizures in Participants With Developmental and Epileptic Encephalopathies: Primary Results of the 12-Month Phase 1b/2a PACIFIC Trial Open-Label Extension. **Poster presentation, 31 August 2025; 13:45-15:15 WEST**[1]

Activation of Central 5-HT2C Receptors by Bexicaserin Modulates Seizures and Respiratory Arrest in a Mouse Model of SUDEP. **Platform presentation, 31 August 2025; 14:30 – 15:00 WEST**[3]

Impact of Bexicaserin on Seizures and Interictal Spectral Power in the GAERS Absence Epilepsy Model. **Poster presentation, 31 August 2025; 13:45-15:15 WEST**[4]

Seizure Reductions and Tolerability in Participants With Developmental and Epileptic Encephalopathies Newly Exposed to Bexicaserin: Interim Results From the Phase 1b/2a PACIFIC Open-Label Extension. **Poster presentation, 1 September 2025; 13:45-15:15 WEST**[10]

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 risks of cardiovascular toxicity associated with nonselective serotonergic agents. 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 Developmental and Epileptic Encephalopathies (DEEs) for patients two years of age and older. Bexicaserin is an investigational compound that is not approved for marketing by any regulatory authority worldwide.

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.[11]

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 if they completed the 75-d RCT treatment period (titration and maintenance). The OLE duration was 52 weeks and included patients with Dravet syndrome (n=3), Lennox-Gastaut syndrome (n=20) and DEE Other (n=18), who completed the PACIFIC trial (n=41).

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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 approximately 5,700 employees in more than 50 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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