Press release
Valby, 15 September, 2026

Lundbeck announces last patient randomized in DEEp SEA, a Phase III trial of bexicaserin in Dravet syndrome

- DEEp SEA is a global Phase III trial evaluating efficacy, safety and tolerability of the investigational molecule bexicaserin in children and adults with Dravet syndrome[1]
- Completion of randomization marks another important milestone for the global Phase III DEEp program, with randomization now complete in both pivotal trials
- Dravet syndrome is a rare severe childhood-onset epilepsy and is classified as a developmental and epileptic encephalopathy (DEE)[2]

Valby, Denmark, 15 September, 2026 – H. Lundbeck A/S (Lundbeck) today announced that the last patient has been randomized in DEEp SEA (NCT06660394), a global Phase III clinical trial evaluating the efficacy, safety and tolerability of bexicaserin for the treatment of seizures in children and adults living with Dravet syndrome.

"Completing randomization in DEEp SEA is an important milestone in our work to evaluate bexicaserin in people living with Dravet syndrome. This marks another step forward for the broader Phase III DEEp program and supports our ongoing efforts to advance research for people living with these severe epilepsies," said Tarek Samad, Executive Vice President and Head of Research & Development at Lundbeck. "This milestone reflects the extraordinary commitment of patients and their families, investigators, study teams and advocacy communities around the world. We are deeply grateful for their continued contribution as the study progresses."

DEEp SEA is focused specifically on Dravet syndrome, a rare and severe childhood-onset epilepsy classified as a developmental and epileptic encephalopathy (DEE). Dravet syndrome is associated with treatment-resistant seizures[3], highlighting the continued challenge of seizure control for people living with the condition and the need for continued research in this area. DEEs encompass a diverse group of severe epilepsies that typically begin in childhood and are characterized by refractory seizures and developmental stagnation or regression.[2]

The trial is evaluating the efficacy of bexicaserin, assessed through the reduction in countable motor seizure frequency in children and adults with Dravet syndrome, and is designed as a randomized, double-blind, placebo-controlled multicenter trial. The DEEp SEA trial enrolled over 100 participants aged two to 65 years, and eligible participants may transition into the 52-week DEEp open-label extension (OLE).[1] DEEp SEA is one of two pivotal trials in the global Phase III DEEp program. The second, DEEp OCEAN (NCT06719141), is evaluating bexicaserin in children and adults with DEEs, including Lennox-Gastaut syndrome, but excluding Dravet syndrome,[4] and completed randomization in July 2026.

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.

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 and developmental stagnation or regression. 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 (LGS) as well as etiology-specific syndromes such as CDKL5-DEE and KCNQ2-DEE. The etiology is unknown in approximately 50% of cases of DEE.

About bexicaserin

Bexicaserin is an investigational, oral, highly selective superagonist of the 5-HT2C receptor subtype.[5] Through its unique and selective binding to 5-HT2C, the potential for adverse effects linked with other receptor subtypes may be minimized. Bexicaserin acts via a dual mode of action, both increasing inhibitory and decreasing excitatory neuron function, consistent with the reduction in seizures associated with DEEs arising from various etiologies.[5]

Bexicaserin is being evaluated for the treatment of seizures in participants with any type of DEE in a global Phase III clinical program (the DEEp program). The FDA has granted Breakthrough Therapy designation to 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.

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About DEEp SEA trial

DEEp SEA (NCT06660394) is a Phase III interventional, randomized, double-blind, parallel-group, placebo-controlled trial evaluating bexicaserin in children and adults with Dravet syndrome.[1]

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.

About DEEp OCEAN trial

DEEp OCEAN (NCT06719141) is a Phase III interventional, randomized, double-blind, parallel-group, placebo-controlled trial evaluating bexicaserin in children and adults with DEEs, including LGS.[4]

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.

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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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