Press release
Valby, 20 July 2026

Lundbeck announces last patient randomized in DEEp OCEAN, a large Phase III trial in developmental and epileptic encephalopathies (DEEs)

- DEEp OCEAN is a global trial designed to evaluate the investigational molecule bexicaserin for the treatment of seizures associated with DEEs, a diverse group of childhood-onset epilepsies[1]
- Broadest pivotal trial to date, enrolling patients with a wide range of DEE syndromes, the majority of which have limited treatment options where significant unmet need exists[1]
- Headline results are expected at the end of Q4 2026 or Q1 2027
- In the DEEp SEA trial for Dravet syndrome, the second pivotal study within the DEEp clinical program, recruitment is progressing well with expected completion of randomization in the next few months

Valby, Denmark, 20 July 2026 – H. Lundbeck A/S (Lundbeck) today announced that the last patient has been randomized in DEEp OCEAN (NCT06719141), 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 developmental and epileptic encephalopathies (DEEs).

DEEs are a group of severe, childhood-onset epilepsies characterized by frequent seizures, developmental impairment, and substantial unmet medical need.[1] DEEs are a highly heterogeneous group of syndromes arising from a wide range of underlying etiologies.[1]

Clinical development has historically focused on a limited number of individual DEE syndromes, such as Dravet syndrome (DS), Lennox–Gastaut syndrome (LGS). There are currently no antiseizure medications (ASMs) approved across all DEE subtypes, leaving many patients without suitable treatment options.[2] The DEEp OCEAN trial was designed with the intention of addressing this gap.

“The DEEp OCEAN trial represents a comprehensive pivotal program in DEEs, with the most diverse DEE population studied to date,” said Professor Ingrid Scheffer, lead investigator of the DEEp OCEAN trial. “By including a broad range of DEE syndromes and more than 60 different genetic DEEs, this study is designed to reflect the real-world heterogeneity of these devastating conditions.”

The DEEp OCEAN trial will evaluate the safety, tolerability and efficacy of bexicaserin on countable motor seizures in people living with DEEs. The placebo-controlled, randomized multicenter trial enrolled over 350 participants aged two to 65 years and will be succeeded by an open-label extension for eligible participants.

The breadth of DEEp OCEAN positions Lundbeck to generate meaningful insights, not only into seizure control, but also into the potential best-in-class benefit-risk profile of bexicaserin across diverse DEE populations.

Bexicaserin is an oral, highly selective superagonist of the 5-HT2C receptor, a serotonin receptor subtype involved in seizure modulation. Acting via a dual mode of action, bexicaserin increases both inhibitory neuron activity while decreasing excitatory neuron function. This is consistent with the observed reduction in multiple seizure types across a broad range of DEE syndromes with various etiologies in the Phase IIa PACIFIC trial.

"The completion of randomization in DEEp OCEAN is an important milestone for the bexicaserin pivotal program, made possible by the commitment of patients, families, investigators, and advocacy communities. We look forward to headline results by the end of 2026 or early 2027," said Johan Luthman, Executive Vice President and Head of Research and Development at Lundbeck. "Additionally, we remain equally committed to the DEEp SEA trial in Dravet syndrome where we are seeing good progress in recruitment of patients and according to plan. We expect to close randomization within a few months."

Bexicaserin has received Breakthrough Therapy Designation in the U.S. and China for the treatment of seizures associated with DEEs. With randomization now complete, the multicenter DEEp OCEAN trial will continue as planned, with participants progressing through the double-blind treatment period followed by the optional open-label extension.

About DEEs

Developmental and Epileptic Encephalopathies (DEEs) are a group of rare neurodevelopmental disorders that typically manifest in early childhood.[1] 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.[3] 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.[3]

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 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.

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 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.[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.

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

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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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