Press release
Valby, 13 October 2025

Lundbeck's bexicaserin receives Breakthrough Therapy Designation in China for the treatment of seizures in severe rare epilepsies

- Accelerated pathway underscores urgent need for innovative solutions for patients with devastating, childhood-onset epilepsies
- Novel 5HT2C mechanism designed to reduce drug-resistant seizures in children and adults living with Developmental Epileptic Encephalopathies (DEEs) and improve quality of life for patients and their caregivers[1]
- Dual Breakthrough Therapy Designation (BTD) in China and the U.S. underscores Lundbeck's mission to advance brain health and transform lives of patients with rare neurological diseases

Valby, Denmark, 13 October 2025 – Lundbeck today announced that its investigational drug bexicaserin, for the treatment of seizures associated with Developmental and Epileptic Encephalopathies (DEEs), has been granted Breakthrough Therapy Designation (BTD) by China's Center for Drug Evaluation (CDE).

DEEs are a heterogeneous group of severe, childhood-onset, rare epilepsies marked by drug-resistant seizures and developmental stagnation or regression.[2] Affecting more than 1 in 2,000 live births, DEEs carry a mortality rate of 17–50%.[3] Survivors are often left with profound neurological disabilities, creating a heavy burden for families and society and underscoring the urgent need for new treatment options.[4]

"We are honored that bexicaserin has been granted Breakthrough Therapy Designation, recognizing the potential of our innovative approach to advancing treatment in one of the most challenging areas of epilepsy," said Johan Luthman, EVP and Head of Research & Development at Lundbeck. "Drawing on our expertise in neuroscience, and past experiences with epilepsy therapies, we are deeply committed driving the global Phase 3 clinical program forward. Obtaining BTD for the program in China supports us in bringing Bexicaserin to patients living with DEEs as quickly as possible."

Bexicaserin (LP352) is a novel investigational, oral therapy that selectively targets the 5-HT2C receptor while avoiding activity at the 5-HT2B and 5-HT2A subtypes, a profile designed to reduce cardiovascular risk. The medicine has also been granted BTD by the U.S. Food and Drug Administration (FDA) for the treatment of seizures associated with DEEs.

"Bexicaserin's Breakthrough Therapy Designation is an important step forward for Lundbeck in China and reflects our dedication to addressing the urgent needs of patients living with DEEs," said Zhang Yifan, Managing Director of Lundbeck China. "This recognition strengthens our commitment to bringing innovative neuroscience solutions to China, working hand in hand with partners to advance brain health and improve the lives of patients and their families."

The BTD procedure is designed to accelerate the development and review of innovative medicines for serious or life-threatening diseases with no adequate treatment options, or where early evidence shows substantial advantages over existing therapies. The CDE prioritizes resource allocation, communication, enhanced guidance, and development promotion for drugs included in the BTD drug procedure.

About Bexicaserin

Bexicaserin (LP352) is an oral, centrally acting 5-hydroxytryptamine 2C (5-HT2C) receptor agonist with no engagement of the 5-HT2B and 5-HT2A receptor subtypes, potentially minimizing the risks of cardiovascular toxicity.[1] 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.[5] 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.

About DEEs

Developmental and Epileptic Encephalopathies (DEEs) are a group of rare neurodevelopmental disorders that typically manifest in early childhood. 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 Spams Syndrome (IESS), Dravet Syndrome, and Lennox-Gastaut Syndrome with various etiologies among those mainly genetic (e.g., CDKL5, STXBP1, KCNT1, SCN2A). Some of these conditions have been included in the first and second batches of the Rare Disease Catalog released by the National Health Commission.

Contacts

Anders Crillesen
Head of Media Relations, Corp. Communication
AECE@lundbeck.com
+45 27 79 12 86

Jens Høyer
Vice President, Head of Investor Relations
JSHR@lundbeck.com
+45 30 83 45 01

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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