Longboard Pharmaceuticals Initiates Phase 3 DEEp OCEAN Study Evaluating Bexicaserin in Developmental and Epileptic Encephalopathies (DEEs)

November 12, 2024

- *DEEp OCEAN is the first pivotal clinical trial designed to study DEEs broadly*
- *Initial sites activated with additional sites expected to be activated in the coming weeks*

LA JOLLA, Calif.--(BUSINESS WIRE)--Nov. 12, 2024-- Longboard Pharmaceuticals, Inc. (Nasdaq: LBPH), a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases, today announced that it has initiated its global Phase 3 DEEp OCEAN Study evaluating its investigational drug bexicaserin for the treatment of seizures associated with Developmental and Epileptic Encephalopathies (DEEs) in participants two years of age and older.

“The initiation of our second global Phase 3 clinical trial, DEEp OCEAN in DEEs, is a significant milestone for Longboard and the entire DEE community. As the first pivotal trial of its kind to study DEEs broadly with the goal of achieving an indication for seizures associated with DEEs, DEEp OCEAN has the ability to address a crucial unmet need,” stated Chad Orevillo, Longboard’s Executive Vice President, Head of Operations. “The strong sense of urgency and excitement for DEEp OCEAN from the community is profound, and we are thrilled that this trial will provide hope and access for individuals living with underserved syndromes.”

“I am truly excited about the impact that DEEp OCEAN could have for the DEE community. The majority of people living with DEEs lack access to innovative medications, and have not had the opportunity to participate in clinical trials tailored to their condition. It’s encouraging to see strides being made in DEE research aimed at benefiting a broader population of patients who are suffering with refractory seizures and related health challenges. I’m also pleased that we are moving towards greater equity and access for underserved patients and their families to engage in clinical research,” stated Gabrielle Conecker, MPH, Executive Director & Co-Founder of Decoding Developmental Epilepsies, home of the International SCN8A Alliance, DEE-P Connections, and The Inchstone Project.

About the DEEp OCEAN Study

The DEEp OCEAN Study (LP352-301) is a global Phase 3 double-blind, placebo-controlled clinical trial to evaluate the efficacy of bexicaserin in Developmental and Epileptic Encephalopathies (DEEs) as assessed by countable motor seizures in ~320 participants between the ages of two and 65 years old. An important secondary objective is to evaluate the safety and tolerability of bexicaserin. Following a 5-week screening period and baseline evaluations, study participants initiate dose titration over a 3-week period and subsequently continue on the highest tolerated dose throughout the maintenance period of 12 weeks. Following the maintenance period, eligible participants will be given the opportunity to enroll in the 52-week DEEp Open-Label Extension (DEEp OLE Study, LP352-303). The Phase 3 DEEp OCEAN Study is part of the broader DEEp Program which includes ~480 participants with a range of Developmental and Epileptic Encephalopathies (DEEs).

ABOUT LONGBOARD PHARMACEUTICALS

Longboard Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases. Longboard is working to advance centrally acting product candidates designed to be highly selective for specific G protein-coupled receptors (GPCRs). Longboard’s small molecule product candidates are based on more than 20 years of GPCR research. Bexicaserin (LP352), an oral, centrally acting 5-hydroxytryptamine 2C (5-HT2C) receptor superagonist, with no observed impact on 5-HT2B and 5-HT2A receptor subtypes, 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 the FDA or any other regulatory authority.

FORWARD-LOOKING STATEMENTS

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. In some cases, you can identify forward-looking statements by words such as “designed to”, “potential”, “focus”, “will”, “opportunity”, “aimed at”, “moving towards”, “objective”, “subsequent”, “working to”, “expected”, or the negative, plural or other tenses of these words, references to future dates or time periods, or other comparable language, and they may include, without limitation, statements about the following: Longboard’s product candidates and programs (including statements about bexicaserin, FDA designations for bexicaserin, the DEEp Program and DEEp SEA, DEEp OCEAN and DEEp OLE Studies, participating sites and their activation, and participant enrollment), plans, focus and work. For such statements, Longboard claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Longboard’s expectations. Factors that could cause actual results to differ materially from those stated or implied by Longboard’s forward-looking statements include, but are not limited to, the following: risks related to the satisfaction or waiver of the conditions to closing the proposed acquisition of Longboard by Lundbeck (including the failure to obtain necessary regulatory approvals) in the anticipated timeframe or at all, including the possibility that the proposed acquisition does not close; Longboard’s product candidates are in a lengthy research and development process, the timing, manner and outcome of research, development and regulatory review is uncertain, and Longboard’s product candidates, including bexicaserin, may not advance in research or development or be approved for marketing; enrolling participants in clinical trials is competitive and challenging; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; topline or interim data may not accurately reflect the complete results of a particular study or trial and remain subject to audit, and final data may differ materially from topline or interim data; risks related to unexpected or unfavorable new data; nonclinical and clinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Longboard or others, request additional information, have additional

recommendations or change their guidance or requirements before or after approval; the standards for Breakthrough Therapy and other designations are not the same as the standard for drug approval, Breakthrough Therapy designation is based on preliminary clinical evidence, and not all drugs designated as Breakthrough Therapies ultimately will be shown to have substantial improvement over available therapies; the FDA may later decide to rescind a designation if it determines the designation is no longer supported by subsequent data; risks related to Longboard's limited operating history, financial position and need for additional capital; Longboard will need additional managerial and financial resources to advance all of its programs, and you and others may not agree with the manner Longboard allocates its resources; risks related to the development and commercialization of Longboard's product candidates; risks related to relying on licenses or collaborative arrangements; other risks related to Longboard's dependence on third parties; competition; product liability or other litigation or disagreements with others; government and third-party payor actions, including relating to reimbursement and pricing; risks related to regulatory compliance; and risks related to Longboard's and third parties' intellectual property rights. Additional factors that could cause actual results to differ materially from those stated or implied by Longboard's forward-looking statements are disclosed in Longboard's filings with the Securities and Exchange Commission (SEC). These forward-looking statements represent Longboard's judgment as of the time of this release. Longboard disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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