Longboard Pharmaceuticals Announces Positive Interim Results from the Open-Label Extension (OLE) of the Phase 1b/2a PACIFIC Study Evaluating Bexicaserin in Participants with Developmental and Epileptic Encephalopathies (DEEs)

June 10, 2024

- *Bexicaserin achieved an overall median seizure reduction of 56.1% in countable motor seizures over an approximate 6-month treatment period; participants randomized to the PACIFIC placebo group achieved a median seizure reduction of 57.3%*
- *Favorable safety and tolerability results observed*
- *100% of participants who completed the PACIFIC Study entered the OLE*
- *End of Phase 2 Meeting scheduled for this summer*

LA JOLLA, Calif.--(BUSINESS WIRE)--Jun. 10, 2024-- Longboard Pharmaceuticals, Inc. (Nasdaq: LBPH), a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases, today announced positive interim results from its ongoing 52-week open-label extension of the PACIFIC Study evaluating bexicaserin (LP352) in participants ages 12-65 years old with Developmental and Epileptic Encephalopathies.

“We are thrilled to see a sustained, durable response in seizure reduction and a favorable safety and tolerability profile across a broad range of DEE patients. Additionally, we saw compelling seizure reduction in the PACIFIC placebo patients who transitioned to bexicaserin in the OLE. These data provide further support to bexicaserin’s potential to offer a highly differentiated and best-in-class profile,” stated Dr. Randall Kaye, Longboard’s Chief Medical Officer.

“Given the tremendous unmet need in patients living with DEEs, we are committed to rapidly advancing the development of bexicaserin. We expect to provide additional analyses of these participants as they progress in the OLE Study and transition to our Expanded Access Program,” Dr. Kaye continued. “With an End of Phase 2 meeting scheduled this summer, we remain on track to initiate our global Phase 3 program for bexicaserin later this year.”

PACIFIC OLE Study Interim Analysis Results:

The PACIFIC OLE Study is a 52-week Phase 2, open-label, long-term safety study of bexicaserin in participants with a range of DEEs, including Dravet syndrome (n=3), Lennox-Gastaut syndrome (n=20) and DEE Other (n=18), who completed the PACIFIC Study (n=41). The study objectives are to investigate the safety and tolerability of multiple doses of bexicaserin in participants with DEEs, and to analyze the effect of bexicaserin on the frequency of observed countable motor seizures and other seizure types. The interim analysis was conducted when participants reached the approximate 6-month point in the OLE Study.

Summary of Efficacy Results:

The median change in countable motor seizure frequency for participants in the OLE Study over an approximate 6-month treatment period was a decrease of 56.1% (n=40) from their baseline entering the PACIFIC Study.

The median change in countable motor seizure frequency from baseline for:

- participants randomized to the bexicaserin-treated group in the PACIFIC Study was a decrease of 54.9% (n=31)
- participants randomized to the placebo group in the PACIFIC Study that transitioned to bexicaserin in the OLE was a decrease of 57.3% (n=9)

Summary of Safety and Tolerability Results:

Favorable safety and tolerability results were observed in this study. 100% of PACIFIC Study completers elected to enroll in the OLE with 95.1% (39 out of 41) remaining in the ongoing open-label study. One participant discontinued due to the adverse event (AE) of lethargy and one participant discontinued by withdrawal of consent. The most common treatment emergent AEs in the overall group (n=41) occurring in >5% of patients were upper respiratory tract infections, COVID-19, pneumonia, sinusitis, seizures, and decreased appetite.

ABOUT THE PACIFIC STUDY AND THE OLE STUDY

The PACIFIC Study is a Phase 1b/2a double-blind, placebo-controlled clinical trial to assess the safety, tolerability, efficacy and pharmacokinetics of bexicaserin (LP352) in 52 participants between the ages of 12 and 65 years old with DEEs at 34 sites across the United States and Australia. Following a 5-week screening period and baseline evaluations, 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. Following the maintenance period, participants were then titrated down, and eligible participants were given the opportunity to enroll in a 52-week open-label extension study.

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 a portfolio of 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. Longboard plans to advance 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, into a global Phase 3 program. Longboard recently reported positive topline data from a Phase 1b/2a clinical trial (the PACIFIC Study) evaluating bexicaserin in participants ages 12 to 65 years old with Developmental and Epileptic Encephalopathies (DEEs), including Lennox-Gastaut syndrome, Dravet syndrome and other DEEs. Longboard is also evaluating LP659, an oral, centrally acting, sphingosine-1-phosphate (S1P) receptor subtypes 1 and 5 modulator, which is in development for the potential treatment of rare neuroinflammatory conditions. Longboard is conducting a Phase 1 single-ascending dose (SAD) clinical trial for LP659 in healthy volunteers, with topline data expected in the second quarter of 2024.

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 "focus", "potential", "expect", "committed to", "scheduled", "remain on track", "working to", "designed to", "plans", "will", 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 clinical and preclinical product candidates and programs, including their potential (including for bexicaserin to be differentiated and to have a best-in-class profile), advancement, timing of initiating clinical trials (including a global Phase 3 program for bexicaserin), timing of topline data from clinical trials (including the Phase 1 SAD data for LP659), , the end of Phase 2 meeting, the ability of patients to progress in the OLE Study and transition to an expanded access program, and their design and characteristics; Longboard's ability to develop product candidates and deliver medicines; and Longboard's 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: risk that topline or interim data may not accurately reflect the complete results of a particular study or trial, and that final data may differ materially from topline or interim data; PACIFIC Study participants' diagnoses are as of time of screening and are subject to change; risks related to Longboard's limited operating history, financial position and need for additional capital; Longboard's need for 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; Longboard's product candidates are in the early to middle phases of a lengthy research and development process, the timing, manner and outcome of research, development and regulatory review is uncertain, and Longboard's product candidates may not advance in research or development or be approved for marketing; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; enrolling participants in Longboard's ongoing and intended clinical trials is competitive and challenging; 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; macroeconomic events and their impact on Longboard's clinical trials and operations, the operations of Longboard's suppliers, partners, collaborators, and licensees, and capital markets; 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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