Longboard Pharmaceuticals Completes Enrollment of Phase 1b/2a PACIFIC Study Evaluating LP352 for the Treatment of Developmental and Epileptic Encephalopathies

- Enrolled 52 participants with Developmental and Epileptic Encephalopathies (DEEs) into the PACIFIC Study
- Participants have a broad range of DEEs including Lennox-Gastaut syndrome, Dravet syndrome, SCN2A-related epilepsies, CDKL5 deficiency disorder, among others
- PACIFIC topline results remain on track for around year-end 2023

LA JOLLA, Calif., August 23, 2023 – Longboard Pharmaceuticals, Inc. (Nasdaq: LBPH), a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases, today announced that it has completed enrollment of its Phase 1b/2a clinical trial, the PACIFIC Study, which is evaluating LP352, an oral, centrally acting 5-HT2C receptor superagonist, in 52 participants with Developmental and Epileptic Encephalopathies (DEEs). The primary objectives of the study are to assess the safety and tolerability of LP352. The PACIFIC Study will also evaluate change in seizure frequency over the treatment period, and data are expected to inform the design and characteristics of the planned Phase 3 program for LP352. Participants who complete the PACIFIC Study are eligible to roll over into the ongoing open-label extension trial should they choose to do so.

“Completing enrollment of the PACIFIC Study is a tremendous milestone for Longboard and we are very pleased to see strong interest from the DEE patient community, underscoring the great unmet need that remains,” stated Dr. Randall Kaye, Longboard’s Chief Medical Officer. “We would like to thank the entire DEE community, including participants, their families and the advocates, as well as the investigators, sites and coordinators for their participation and continued collaboration. This achievement brings us one step closer to helping people living with Developmental and Epileptic Encephalopathies.”

“I am excited about the innovative approach of conducting clinical research in DEEs more broadly given the significant unmet need and limited access to novel and targeted therapies that exists in the majority of patients living with refractory epilepsies. I look forward to seeing the PACIFIC data and the potential of LP352,” said Dennis Dlugos, MD, MSCE, pediatric neurologist at Children's Hospital of Philadelphia, Vice President & Officer of the Epilepsy Study Consortium, and Principal Investigator of the PACIFIC Study.
“We are pleased to see Longboard’s commitment to advancing the rare and refractory epilepsy space. The inclusive nature of the PACIFIC Study is unique and exciting, especially given that people living with certain DEEs have not had access to newer therapies and clinical trials,” said Tracy Dixon-Salazar, PhD, Executive Director of the LGS Foundation. “There is a dire need for continued improvement of research and innovation for people living with these severe syndromes, and we are looking forward to the outcome of the PACIFIC Study.”

ABOUT THE PACIFIC STUDY

The PACIFIC Study is a Phase 1b/2a clinical trial evaluating participants with Developmental and Epileptic Encephalopathies (DEEs). The primary objectives of the study are to assess the safety and tolerability of LP352. The PACIFIC Study will also evaluate change in seizure frequency over the treatment period. The study enrolled 52 participants with a variety of treatment resistant seizures that fall into the category of DEE across approximately 30 study sites in the United States and Australia. The PACIFIC Study data are expected to inform the design and characteristics of the planned Phase 3 program for LP352. Participants who complete the PACIFIC Study are eligible to roll over into the ongoing open-label extension (OLE) trial should they choose to do so. The OLE is a Phase 2 multicenter, open-label, multiple-dose, long-term extension clinical trial designed to evaluate long-term safety of LP352 in participants with DEEs who have completed the PACIFIC Study.

ABOUT DEVELOPMENTAL AND EPILEPTIC ENCEPHALOPATHIES

DEEs refer to a group of severe heterogeneous epilepsies that are characterized by drug resistant seizures and significant developmental delay.

Importantly, if seizure control can be improved, developmental delay may slow. Most DEEs begin early in life, often starting in infancy. Children can have frequent and severe seizures which may be of multiple types. Epileptic spasms, tonic or atonic seizures and myoclonic seizures, among other seizure types, can be seen. In many cases, seizures are life long, although in some instances they can abate with time with certain syndromes or specific causes.

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 is evaluating LP352, an oral, centrally acting 5-hydroxytryptamine 2C (5-HT2C) receptor superagonist, with no detectable activity on 5-HT2B and 5-HT2A receptor subtypes, in development for the potential treatment of seizures associated with a broad range of Developmental and Epileptic Encephalopathies. 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 multiple neurological diseases.

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 “on track”, “target”, “objective”, “will”, “expect”, “plan”, “eligible to”, “goal”, “closer to”, “look forward to”, “potential”, “commitment”, “designed to”, “can”, “may”, “focused on”, “working to”, or the negative, plural or other tenses of these words or other comparable language, and they include, without limitation, statements about the following: the potential of LP352, including to advance into a Phase 3 program, treat seizures associated with a broad range of DEEs, or address an unmet need among people living with DEEs; the PACIFIC Study, including study participants completing the PACIFIC Study and rolling over into the OLE trial, the timing of topline results from the PACIFIC Study, and the potential for such results to inform a planned Phase 3 program for LP352; the potential for seizures to abate with time with certain syndromes or specific causes; the design, characteristics and potential of Longboard’s product candidates; and Longboard’s commitment, 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: Longboard’s product candidates, including LP352, are in the early to middle stages of a lengthy research, development, and regulatory review process, the timing, manner and outcome of which is uncertain, and Longboard’s product candidates may not advance in research or development or be approved for marketing; 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; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; topline data may not accurately reflect the complete results of a particular study or trial; enrolling participants in Longboard’s ongoing and intended clinical trials is competitive and challenging; other risks related to the development and commercialization of Longboard’s product candidates; 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; macroeconomic events stemming from the COVID-19 pandemic or evolving geopolitical developments such as the conflict in Ukraine, including but not limited to the impact on Longboard’s clinical trials and operations, the operations of Longboard’s suppliers, partners, collaborators, and licensees, and capital markets, which in each case remains uncertain; risks related to unexpected or unfavorable new data; 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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