

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 2, 2024

Longboard Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

1-40192  
(Commission File Number)

84-5009619  
(IRS Employer  
Identification No.)

4275 Executive Square, Suite 950  
La Jolla, CA  
(Address of Principal Executive Offices)

92037  
(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 789-9283

N/A  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	LBPH	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

In this report, "we" and "our" refer to Longboard Pharmaceuticals, Inc.

#### **Item 7.01 Regulation FD Disclosure.**

On January 2, 2024, Longboard Pharmaceuticals, Inc. ("Longboard") issued a press release announcing topline data from the PACIFIC Study. A copy of the press release is attached hereto as Exhibit 99.1.

Included as Exhibit 99.2 to this Form 8-K is a slide presentation titled PACIFIC Study Topline Data dated January 2, 2024, that is incorporated herein by reference. We intend to utilize this presentation and its contents in various meetings with securities analysts, investors and others, including during a conference call and live webcast with the investment community on January 2, 2024, at 8:30 a.m. ET.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01, including Exhibits 99.1 and 99.2, shall not be incorporated by reference into any filing we make with the U.S. Securities and Exchange Commission ("SEC"), whether before or after the date hereof, regardless of any general incorporation language in such filing.

#### **Item 8.01 Other Events**

On January 2, 2024, Longboard announced positive topline data from the PACIFIC Study evaluating bexicaserin (LP352) for participants with Developmental and Epileptic Encephalopathies ("DEEs").

In the innovative PACIFIC Study, 52 participants ages 12-65 years old with a DEE diagnosis were enrolled at 34 study sites across the United States and Australia to evaluate the safety, tolerability, efficacy and pharmacokinetics of oral bexicaserin (6 mg, 9 mg and 12 mg) three times daily versus placebo. Participant DEE diagnoses included Dravet syndrome ("DS"), Lennox-Gastaut Syndrome ("LGS"), and other qualifying DEEs ("DEE Other"). 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. Of the 52 participants enrolled in the study, 43 participants were randomized to bexicaserin (DS=4, LGS=24, DEE Other=15) and 9 to placebo (DS=0, LGS=5, DEE Other=4). The median number of countable motor seizures per 28-day period at baseline was 38.8 in the bexicaserin group compared to 20.8 in the placebo group. Participants were able to remain on a contemporary, stable polytherapy regimen of up to 4 anti-seizure medications ("ASMs") throughout the study, with the most common ASMs being clobazam, cannabidiol, lamotrigine and levetiracetam.

##### *Summary of Efficacy Data*

The median change in countable motor seizure frequency (primary efficacy endpoint) from baseline for the evaluable participants treated with bexicaserin (n=35) was a decrease of 53.3%, compared to a 20.8% decrease for those receiving placebo (n=9). Overall, this represents a placebo-adjusted reduction in seizure frequency of 32.5%. The median change in countable motor seizure frequency from baseline in the DS, LGS and DEE Other cohorts was a decrease of 72.1% (n=3), 48.1% (n=17) and 61.2% (n=15), respectively. This represents a placebo-adjusted reduction in seizure frequency of 27.3% and 28.6% in LGS and DEE Other, respectively.

##### *Summary of Safety Data*

Bexicaserin exhibited favorable safety and tolerability results. Most participants (85.7%) in the bexicaserin treated group (n=35) that started the maintenance period tolerated the highest dose (12 mg). The most common adverse events ("AEs") observed were somnolence, decreased appetite, constipation, diarrhea and lethargy. There were 3 participants that reported a serious adverse event ("SAE") (ankle fracture, constipation, increased seizures) and no deaths were reported in the study. Overall, 9 participants in the bexicaserin group discontinued due to an AE. Of note, 2 of these participants discontinued during the maintenance period (7 participants discontinued during the titration period). No participants in the placebo group discontinued or experienced an SAE.

100% of the participants who completed the PACIFIC Study elected to enroll in the ongoing 52-week open-label extension study.

##### *Planned Activities*

Additional data from the PACIFIC Study are intended to be presented at future medical meetings. Planning for a global Phase 3 program for bexicaserin is ongoing, with the PACIFIC Study results expected to inform the design and characteristics of the Phase 3 program.

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## Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this Current Report on Form 8-K that are not historical facts may be considered "forward-looking statements," including statements regarding Longboard's planned global Phase 3 program for bexicaserin and Longboard's plans to present additional data from the PACIFIC Study at future medical meetings. Forward-looking statements are typically, but not always, identified by the use of words such as "intend", "future", "plan", "expect" and other similar terminology.

Forward-looking statements are based on current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it, and are subject to risks and uncertainties. Such risks and uncertainties may cause actual results to differ materially from the expectations set forth in the forward-looking statements. Such risks and uncertainties include, but are not limited to, the risk that topline data may not accurately reflect the complete results of a particular study or trial and remain subject to audit, and that final data may differ materially from topline 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 that you and others may not agree with the manner in which 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; enrolling participants in Longboard's ongoing and intended clinical trials is competitive and challenging; 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's 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; macroeconomic events stemming from the COVID-19 pandemic or evolving geopolitical developments such as the conflicts in Ukraine and the Middle East, 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 principal stockholders or management selling some or all of their stock; 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, as well as the risks detailed in Longboard's recent filings on Forms 10-K and 10-Q with SEC. Longboard disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

## Item 9.01 Financial Statements and Exhibits. (d) Exhibits.

Exhibit No.	Description
99.1	<a href="#">Press release regarding PACIFIC Study Topline Data dated January 2, 2024</a>
99.2	<a href="#">Slide presentation titled "PACIFIC Study Topline Data" dated January 2, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Longboard Pharmaceuticals, Inc.

Date: January 2, 2024

By:

/s/ Kevin R. Lind

Kevin R. Lind  
President and Chief Executive Officer

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## **Longboard Pharmaceuticals Announces Positive Topline Data from the PACIFIC Study, a Phase 1b/2a Clinical Trial, for Bexicaserin (LP352) in Participants with Developmental and Epileptic Encephalopathies (DEEs)**

- *Bexicaserin achieved a median seizure reduction of 53.3% in countable motor seizures compared to 20.8% in the placebo group across the DEE study population*
- *A median seizure reduction of 72.1% in Dravet Syndrome (DS), 48.1% in Lennox-Gastaut Syndrome (LGS) and 61.2% in DEE Other was achieved*
- *Favorable safety and tolerability results*
- *Longboard is rapidly moving forward with preparations for its global Phase 3 program*
- *Conference call and webcast to be held today at 8:30am ET*

LA JOLLA, Calif., January 2, 2024 – Longboard Pharmaceuticals, Inc. (Nasdaq: LBPH), a clinical-stage biopharmaceutical company focused on developing novel, transformative medicines for neurological diseases, today announced positive topline data from the PACIFIC Study evaluating bexicaserin (LP352), a potentially best-in-class and highly selective, oral, novel 5-HT<sub>2C</sub> receptor superagonist for seizures associated with a broad range of Developmental and Epileptic Encephalopathies (DEEs).

### **The PACIFIC Study Topline Results:**

In the innovative PACIFIC Study, 52 participants ages 12-65 years old with a DEE diagnosis were enrolled at 34 study sites across the United States and Australia to evaluate the safety, tolerability, efficacy and pharmacokinetics of oral bexicaserin (6 mg, 9 mg and 12 mg) three times daily (TID) versus placebo. Participant DEE diagnoses included DS, LGS, and other qualifying DEEs (DEE Other). 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. Of the 52 participants enrolled in the study, 43 participants were randomized to bexicaserin (DS=4, LGS=24, DEE Other=15) and 9 to placebo (DS=0, LGS=5, DEE Other=4). The median number of countable motor seizures per 28-day period at baseline was 38.8 in the bexicaserin group compared to 20.8 in the placebo group. Participants were able to remain on a contemporary, stable polytherapy regimen of up to 4 anti-seizure medications (ASMs) throughout the study, with the most common ASMs being clobazam, cannabidiol, lamotrigine and levetiracetam.

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**Summary of Efficacy Data:**

The median change in countable motor seizure frequency (primary efficacy endpoint) from baseline for the evaluable participants treated with bexicaserin (n=35) was a decrease of 53.3%, compared to a 20.8% decrease for those receiving placebo (n=9). Overall, this represents a placebo-adjusted reduction in seizure frequency of 32.5%. The median change in countable motor seizure frequency from baseline in the DS, LGS and DEE Other cohorts was a decrease of 72.1%, 48.1% and 61.2%, respectively. This represents a placebo-adjusted reduction in seizure frequency of 27.3% and 28.6% in LGS and DEE Other, respectively.

**Summary of Safety Data:**

Bexicaserin exhibited favorable safety and tolerability results. Most participants (85.7%) in the bexicaserin treated group (n=35) that started the maintenance period tolerated the highest dose (12 mg). The most common adverse events (AEs) observed were somnolence, decreased appetite, constipation, diarrhea and lethargy. There were 3 participants that reported a serious adverse event (SAE) (ankle fracture, constipation, increased seizures) and no deaths were reported in the study. Overall, 9 participants in the bexicaserin group discontinued due to an AE. Of note, 2 of these participants discontinued during the maintenance period (7 participants discontinued during the titration period). No participants in the placebo group discontinued or experienced an SAE.

100% of the participants who completed the PACIFIC Study elected to enroll in the ongoing 52-week open-label extension study.

Additional data from the PACIFIC Study are intended to be presented at future medical meetings.

“These exciting PACIFIC Study results underscore our belief that bexicaserin’s differentiated profile will translate into a clinically and commercially best-in-class product and has the potential to redefine the standard of care in DEEs. We are pleased to see such strong seizure reduction across a wide range of DEE syndromes with varying etiologies coupled with favorable safety and tolerability results,” stated Dr. Randall Kaye, Longboard’s Chief Medical Officer. “We would like to thank the entire DEE community, including study participants, their caregivers and advocacy groups, as well as the investigators, sites and coordinators for their participation and continued partnership as we advance into a Phase 3 program. This tremendous milestone brings us one step closer to improving the lives of those living with these devastating diseases and their families.”

“The remarkable results from the PACIFIC Study give hope to patients and their loved ones who are in dire need of research and novel therapies in these severe syndromes. A tremendous unmet need remains not only for those living with LGS, but for the many other DEE patients who have not received the attention they deserve, and I applaud this innovative and inclusive approach that is designed to get therapies quickly and safely to even more people,” said Tracy Dixon-Salazar, PhD, Executive Director of the LGS Foundation.

“As the principal investigator, I am delighted to see these highly anticipated and, more importantly, clinically meaningful results from the PACIFIC Study. Physicians are looking for options with fewer side effects and less burden, and that are easy to add onto existing medications in these patients with highly refractory, treatment resistant seizures. This is an innovative and unique approach to clinical development in broadening research across the DEE population. I am looking forward to participating

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in the future development of this compound,” stated 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.

“Given the groundbreaking design of the PACIFIC Study and the broad efficacy of bexicaserin observed across DEEs in this study, we believe that bexicaserin provides us with the cornerstone to build a world-class epilepsy franchise and to explore development paths forward that may offer novel options to DEE patients that are vastly underserved. We are continuing our Phase 3 preparations as we evaluate the broader dataset. Given the broad efficacy of bexicaserin observed across DEEs in this study, we believe we have the opportunity to explore development paths forward that may offer novel options to DEE patients that are vastly underserved,” stated Kevin R. Lind, Longboard’s President and Chief Executive Officer.

#### **About the PACIFIC 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 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 program. The primary efficacy measure was median percent change from baseline in countable motor seizure frequency over the 75-day treatment period.

#### **Conference Call and Webcast Details**

Longboard will host a conference call today at 8:30am ET. Stockholders and other interested parties may participate in the call by following the instructions below. The live webcast can be accessed on the Events & Presentations portion of the investor page of Longboard’s website at <https://ir.longboardpharma.com>. A replay will be available on Longboard’s website shortly after completion of the event and will be archived for up to 30 days.

**Participant Webcast Link:** <https://edge.media-server.com/mmc/p/sqg9yxpf>

**Participant Call Link:** <https://register.vevent.com/register/B1b92b4a3dd66f44fdb3fcd202fca9caf>

#### **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 reported topline data from a Phase 1b/2a clinical trial for bexicaserin, the PACIFIC Study, evaluating participants ages 12 to 65 years old with a broad range of 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

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for the potential treatment of rare neuroinflammatory conditions. Longboard has initiated a Phase 1 single-ascending dose (SAD) clinical trial for LP659 in healthy volunteers, with topline data expected in the first half 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 “moving forward”, “to be held”, “focused on”, “potential”, “intended”, “belief”, “will”, “would”, “advance into”, “closer to”, “hope”, “designed to”, looking forward to”, “future”, “opportunity”, “may”, “working to”, “plans”, “expect” or the negative, plural or other tenses of these words or other comparable language, and they may include, without limitation, statements about the potential of bexicaserin (including to be best-in-class, to change the DEE landscape and to serve as the cornerstone of a world-class epilepsy franchise); Longboard’s planned global Phase 3 program for bexicaserin; Longboard’s clinical and preclinical product candidates and programs, including their advancement, timing of initiating dosing in clinical trials, timing of topline data from clinical trials, characteristics of clinical trial participants, their potential (including to be highly selective and the numbers and types of conditions they may address), and their design and characteristics; Longboard’s ability to develop product candidates and deliver medicines; Longboard’s focus and work; and Longboard’s plans to present additional data from the PACIFIC Study at future medical meetings. 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: topline 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 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 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; 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; enrolling participants in Longboard’s ongoing and intended clinical trials is competitive and challenging; 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; macroeconomic events stemming from the COVID-19 pandemic or evolving geopolitical developments such as the conflicts in Ukraine and the Middle East, 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 principal stockholders or management selling some or all of their stock; 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

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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.

**Corporate Contact:**  
Megan E. Knight  
Head of Investor Relations  
IR@longboardpharma.com  
858.789.9283

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# PACIFIC Study Topline Data

JANUARY 2, 2024

# Forward-Looking Statements

This presentation contains forward-looking statements about Longboard Pharmaceuticals, Inc. ("we," "Longboard" or the "Company"), including statements regarding: the potential of LP352 (including to be best-in-class, to change the DEE landscape, to serve as the cornerstone of a potential world-class epilepsy franchise, to have intellectual property protection through 2041, and to move rapidly into a global Phase 3 program); the competitive landscape, commercial opportunities and analogs; our development approach; the prevalence of unmet need associated with, and market opportunity for, DEEs; and other statements that are not historical facts, including statements that may include words such as "will", "may", "can", "would", "intend", "plan", "expect", "believe", "potential", "opportunity" and similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: topline data may not reflect the complete or final results of a particular study or trial, and are subject to change; nonclinical and clinical data are 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; our limited operating history; our history of incurring net losses and expectation that we will continue to incur net losses for the foreseeable future, and that we may never be profitable; our need for additional funding and related risks for our business, product development programs and future commercialization activities; the timing and success of clinical trials and preclinical studies we conduct; the ability to obtain and maintain regulatory approval to conduct our clinical trials (in the manner we propose or at all) and, ultimately, to market our product candidates; the ability to commercialize our product candidates; our ability to compete in the marketplace; risks regarding our license and dependencies on others; our ability to obtain and maintain intellectual property protection and freedom to operate for our product candidates; our ability to manage our growth; and other risks and factors disclosed in our filings with the U.S. Securities and Exchange Commission, including our most recently filed Annual Report on Form 10-K, subsequently filed Quarterly Reports on Form 10-Q, and in our other filings. We operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. The forward-looking events and circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Except as required by law, we assume no responsibility for the accuracy and completeness of the forward-looking statements, and we undertake no obligation to update any forward-looking statements after the date of this presentation to conform these statements to actual results or to changes in our expectations.

Certain information contained in this presentation and statements made orally during this presentation relate to or are based on studies, research, publications, surveys and other data obtained from third-party sources and Longboard's own internal estimates and research. While Longboard believes these third-party studies, research, publications, surveys and other data to be reliable as of the date of this presentation, they have not been independently verified, and Longboard makes no representations as to the adequacy, fairness, accuracy or completeness of any information obtained from third-party sources.

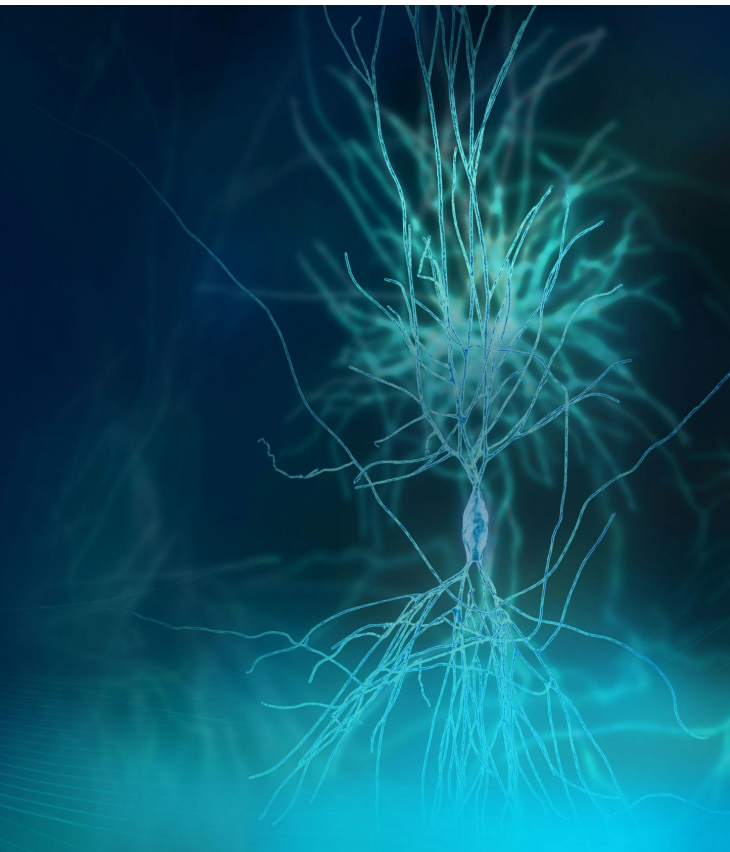
This presentation discusses product candidates that have not yet been approved for marketing by the U.S. Food and Drug Administration (the "FDA").





# PACIFIC Study Topline Data




JANUARY 2, 2024



# Bexicaserin Has the Potential to Change the DEE Landscape

 **53.3%**

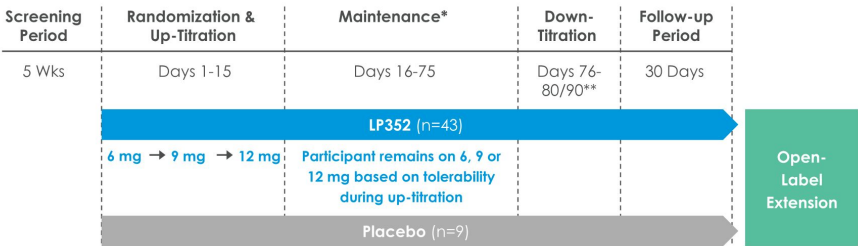
**Median Reduction in Seizures\***

- **72.1%**  **Dravet**
- **48.1%**  **LGS**
- **61.2%**  **DEE Other**

- **Bexicaserin provides the cornerstone to potentially build a world-class epilepsy franchise**
- Studies to date highlight bexicaserin as potentially **best-in-class**
- **Composition of matter IP protection through 2041\*\*** provides the opportunity to maximize the full potential of LP352
- Rapidly moving forward with preparations for a **global Phase 3 program**



# Bexicaserin (LP352) Ph 1b/2a PACIFIC Study in Participants with DEEs



**Key Inclusion Criteria:**

- DEEs with average of ≥ 4 motor seizures per 4-week period during the 12 weeks prior to screening and ≥ 4 motor seizures in the 4-week period of screening
- DEEs (multiple syndromes) including LGS, Dravet syndrome, SCN2A-related epilepsies, CDD, among others

**Key Exclusion Criteria:**

- Use of fenfluramine & lorcaserin

**Basic Information:**

- **Sites:** 34 sites
- **Ages:** ≥ 12 to ≤ 65 yrs old

No Echocardiograms Required in PACIFIC



Double-blind, placebo-controlled study to assess the safety, tolerability, pharmacokinetics and efficacy of bexicaserin

**Study Objectives:**

**Evaluate** reduction in countable motor seizures across a broad group of epilepsies

**Identify** potential indications for pivotal studies

**Analyze** concentration response to understand dosing in different seizure types and disorders

\* Maintenance Dose of bexicaserin (TID): 6 mg, 9 mg, 12 mg or placebo TID  
\*\* Up to a 15-day down-titration/taper period (reducing dose every 5 days) depending on the last maintenance dose  
Definitions: LGS = Lennox-Gastaut Syndrome, CDD = CDKL5 Deficiency Disorder

# Diagnostic Eligibility Criteria: Dravet Syndrome, Lennox-Gastaut Syndrome (LGS) and Other DEEs

All participants: Treatment-resistant countable motor seizures with average of  $\geq 4$  observed/countable motor seizures per 4-week period during 12 weeks before screening while on stable ASM treatment

	Dravet Syndrome	LGS	DEE Other
<b>Onset</b>	Between 3–19 months of age	Before 8 years of age	Unprovoked seizures before 5 years of age
<b>Seizure Type</b>	Generalized tonic-clonic, unilateral clonic or bilateral clonic seizures	Tonic or tonic/atonic seizures & more than 1 type of generalized seizure (tonic-clonic, tonic-atonic, atonic, tonic, myoclonic or drop)	Combined focal and generalized seizure types, or multiple generalized seizure types
<b>Developmental History</b>	Initially normal, then delayed	Delayed	Delayed
<b>EEG</b>		Consistent with LGS diagnosis*	Slow or disorganized
<b>Additional Criteria</b>	One of the following: <ul style="list-style-type: none"> <li>• Emergence of another seizure type after the first</li> <li>• Induced by warm temperatures, fevers, or visual stimuli</li> <li>• Genetic test consistent with Dravet</li> </ul>	More than 1 type of generalized seizure for $\geq 6$ months before screening	No history of idiopathic generalized seizures





# Topline Participant Disposition & Safety Results Summary



# Demographics, Baseline Characteristics & Concomitant Medications

Parameter	n(%)	Statistics	Bexicaserin (N=43)	Placebo (N=9)	Overall (N=52)
Age (Years)		Mean	23.8	26.7	24.3
		Standard Deviation	9.62	7.73	9.31
		Median	23.0	23.0	23.0
		Min, Max	12, 55	19, 41	12, 55
Sex		Male	21 (48.8)	7 (77.8)	28 (53.8)
		Female	22 (51.2)	2 (22.2)	24 (46.2)
Weight (kg)		Median	55.20	72.76	59.36
		Min, Max	29.2, 96.0	45.8, 110.7	29.2, 110.7
BMI (kg/m²)		Median	22.4	28.1	23.0
		Min, Max	17, 35	19, 34	17, 35
Concomitant Medications		Clobazam	21 (48.8)	2 (22.2)	23 (44.2)
		Cannabidiol	14 (32.6)	3 (33.3)	17 (32.7)
		Lamotrigine	13 (30.2)	4 (44.4)	17 (32.7)
		Levetiracetam	16 (37.2)	1 (11.1)	17 (32.7)



# Participant Disposition

n(%)	Overall		Dravet Syndrome		LGS		DEE Other	
	Bexicaserin	Placebo	Bexicaserin	Placebo	Bexicaserin	Placebo	Bexicaserin	Placebo
Safety Set	43 (100)	9 (100)	4 (9.3)	0	24 (55.8)	5 (55.6)	15 (34.9)	4 (44.4)
Full Analysis Set	35 (81.4)	9 (100)	3 (7.0)	0	17 (39.5)	5 (55.6)	15 (34.9)	4 (44.4)
Participants Completed	32 (74.4)	9 (100)	3 (7.0)	0	15 (34.9)	5 (55.6)	14 (32.6)	4 (44.4)
Participants Discontinued	11 (25.6)	0	1 (2.3)	0	9 (20.9)	0	1 (2.3)	0
Adverse Event	9 (20.9)	0	1 (2.3)	0	7 (16.3)	0	1 (2.3)	0
Consent withdrawn	1 (2.3)	0	N/A	N/A	1 (2.3)	0	N/A	N/A
Lost to follow-up	1 (2.3)	0	N/A	N/A	1 (2.3)	0	N/A	N/A

Definitions: LGS = Lennox-Gastaut Syndrome  
Note: Percentages are based on the number of subjects in the Enrolled (Safety) Set  
Safety Set includes all subjects who signed informed consent or those who had their legally authorized representative sign for them  
Full Analysis Set includes all subjects in the Safety Set who complete Part 1 (titration) and have at least 1 post-baseline seizure measurement during Part 2 (maintenance)



# 86% of Bexicaserin Treated Participants Achieved 12 mg Dose

Highest tolerated dose achieved for the Maintenance Period

	n(%)	Bexicaserin (LP352)	Placebo	Overall
All Participants		35	9	44
	6 mg	1 (2.9)	0	1 (2.3)
	9 mg	4 (11.4)	0	4 (9.1)
	12 mg	30 (85.7)	9 (100)	39 (88.6)
Dravet Syndrome		3	0	3
	6 mg	0	0	0
	9 mg	1 (33.3)	0	1 (33.3)
	12 mg	2 (66.7)	0	2 (66.7)
LGS		17	5	22
	6 mg	0	0	0
	9 mg	1 (5.9)	0	1 (4.5)
	12 mg	16 (94.1)	5 (100)	21 (95.5)
DEE Other		15	4	19
	6 mg	1 (6.7)	0	1 (5.3)
	9 mg	2 (13.3)	0	2 (10.5)
	12 mg	12 (80.0)	4 (100)	16 (84.2)



# Safety Results Summary

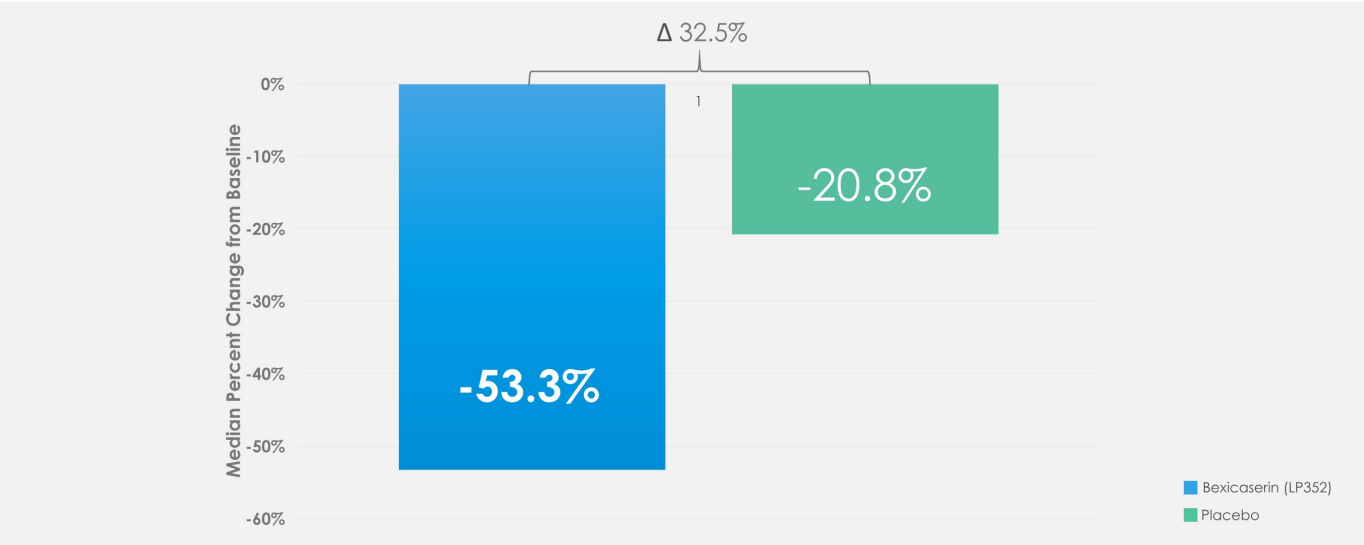
n(%)	Bexicaserin (N=43)	Placebo (N=9)	Overall (N=52)
Participants with any TEAEs	35 (81.4)	8 (88.9)	43 (82.7)
Drug-Related TEAEs	28 (65.1)	3(33.3)	31 (59.6)
TEAEs Leading to Discontinuation	9 (20.9)	0	9 (17.3)
TEAEs Leading to Discontinuation (Titration)	7 (16.3)	0	7 (13.5)
TEAEs Leading to Discontinuation (Maintenance)	2 (4.7)	0	2 (3.8)
Participants with any SAEs	3 (7.0)	0	3 (5.8)
Number of Deaths	0	0	0

- The most common AEs\* observed were somnolence, decreased appetite, constipation, diarrhea, lethargy, tremor, urinary tract infection, fatigue, pyrexia and agitation
- SAEs were ankle fracture, constipation and increased seizures
- Vast majority of participants stayed on bexicaserin once they achieved the maintenance phase
- **Favorable safety and tolerability results**

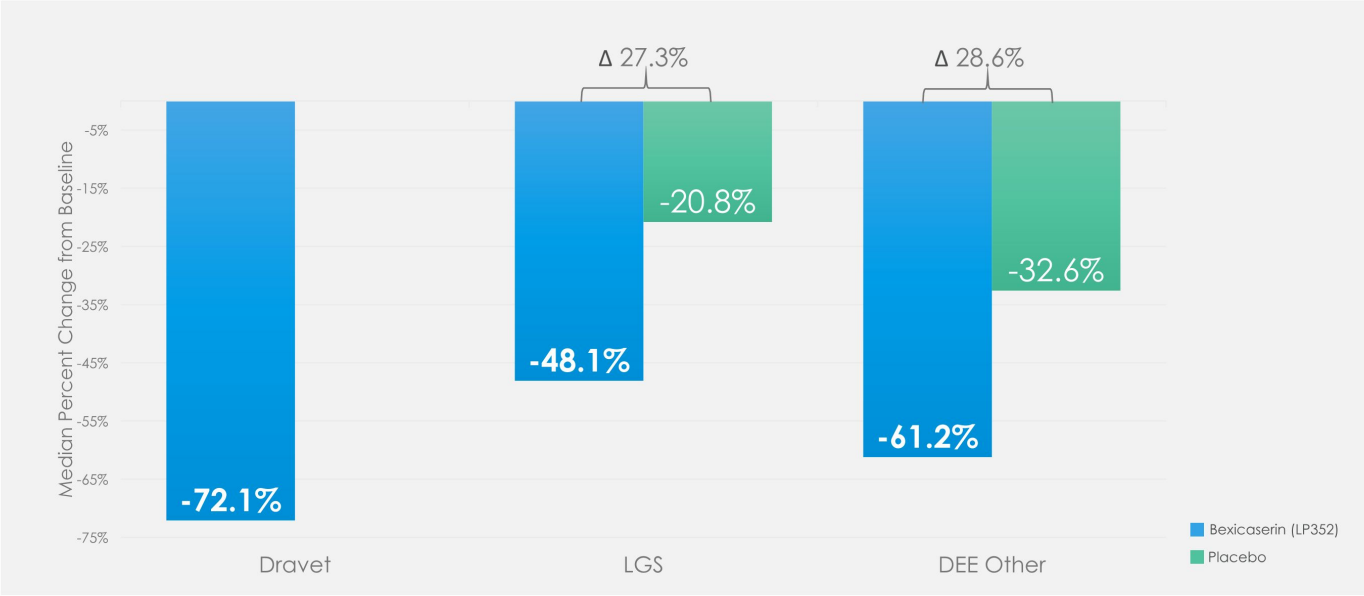
# Topline Efficacy Results



Bexicaserin Achieved Median Seizure Reduction of 53.3% in Countable Motor Seizures Compared to 20.8% for Placebo Across the DEE Study Population



# Bexicaserin Achieved Median Seizure\* Reduction Across Dravet, LGS, DEE Other Cohorts



# PACIFIC Results Pave the Way for Global Phase 3 Program

PACIFIC demonstrated meaningful efficacy results across a broad DEE population as well as in individuals with LGS and Dravet

**Bexicaserin (LP352) achieved a median percent reduction from baseline in seizure frequency during the treatment period of:**

- 53.3%** in broad DEE population (32.5% placebo-adjusted)
- 72.1%** in Dravet cohort
- 48.1%** in LGS cohort (27.3% placebo-adjusted)
- 61.2%** in DEE Other cohort (28.6% placebo-adjusted)

Results were demonstrated on top of a contemporary polytherapy background with multiple ASMs including cannabidiol **(32.7% of participants were receiving cannabidiol)**

Favorable safety and tolerability results

- No echocardiograms required** in PACIFIC study
- Metabolized via UGT pathway – potentially reduces risk of Drug-Drug Interactions

**100%** of PACIFIC participants who completed the study **entered the Open Label Extension Study**

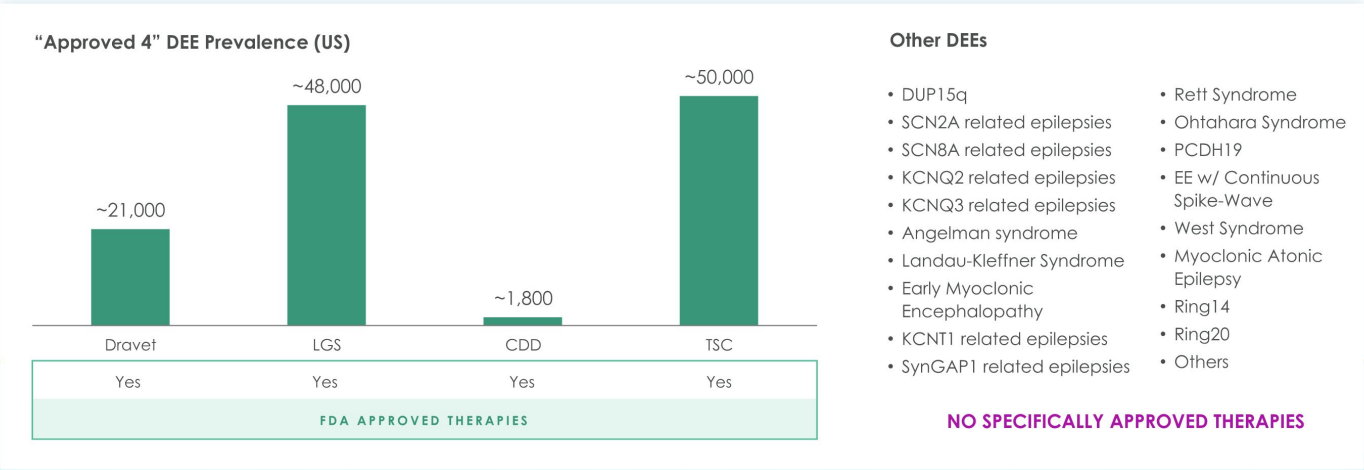
- Awaiting analysis of the full PACIFIC dataset
- Utilizing key learnings for incorporation into the global Phase 3 program



# Summary & Next Steps



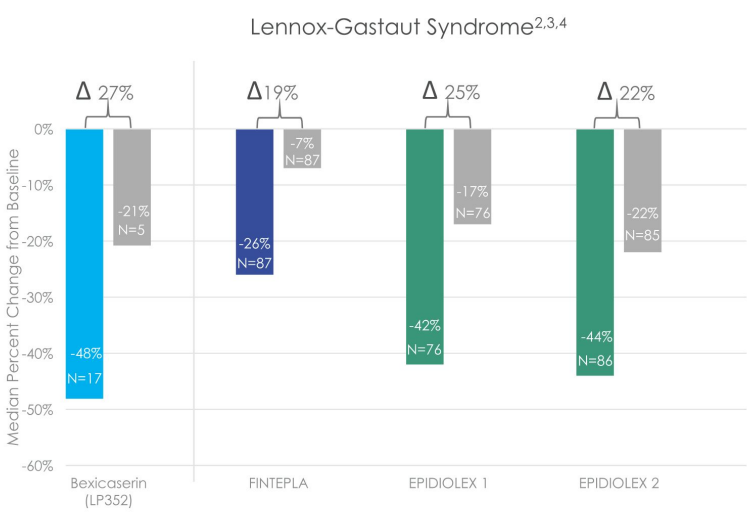
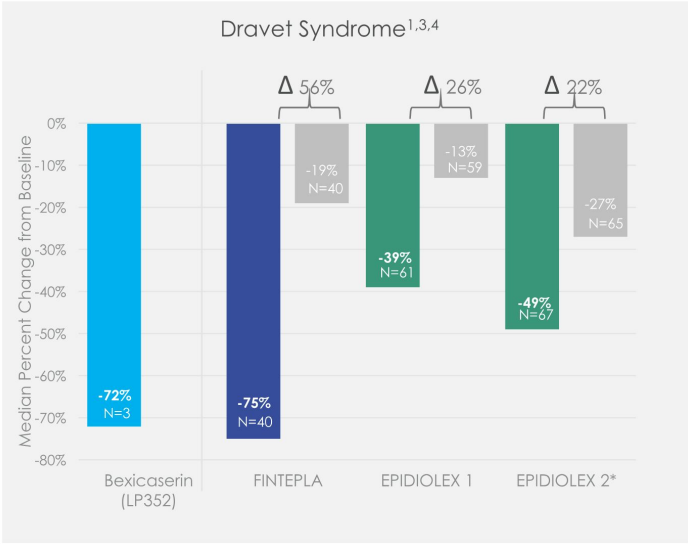
# 4 DEE Syndromes Have Approved Therapies; 20+ Have None



The prevalence of all "Other DEEs" could exceed the total of the "Approved 4" combined

Sources: Dravet Syndrome Foundation, LGS Foundation  
Definitions: LGS = Lennox-Gastaut Syndrome, CDD = CDKL5 Deficiency Disorder, TSC = Tuberous Sclerosis Complex; DEE = Developmental and Epileptic Encephalopathy

# Competitive Landscape: Median Seizure Reduction for Bexicaserin and Approved Compounds in Dravet and LGS



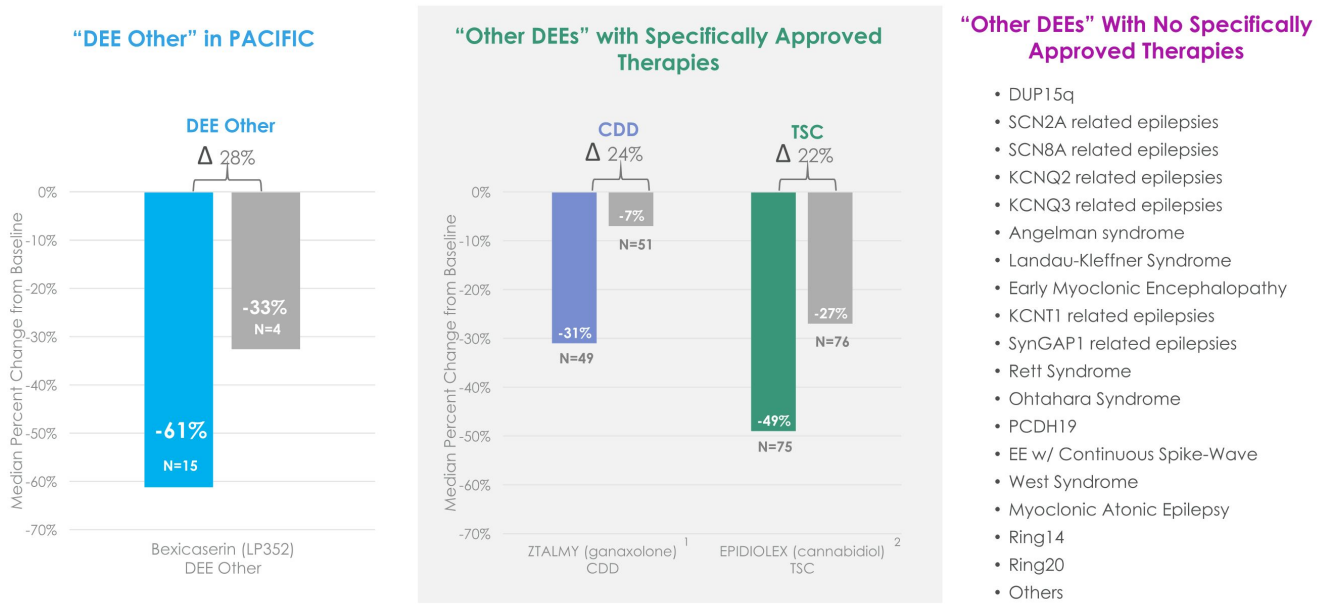
FOR ILLUSTRATIVE PURPOSES ONLY: Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.

■ Bexicaserin (LP352)  
■ FINTEPLA® (fenfluramine)  
■ Epidiolex (cannabidiol)  
■ Placebo

1. Fenfluramine - Lagae, et al The Lancet 2019; 2. Fenfluramine - Knupp, et al JAMA Neurology 2022; 3. Epidiolex HCP website [Dravet & LGS](#), Miller et al JAMA Neurology 2020; 4. PACIFIC Study Topline Data  
\* Estimated percentage reduction in seizure frequency



# Significant Unmet Need in DEEs (Beyond Dravet and LGS)






FOR ILLUSTRATIVE PURPOSES ONLY; Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.



# Bexicaserin Has the Potential to Change the DEE Landscape

 **53.3%**

**Median Reduction in Seizures\***

- **72.1%**  **Dravet**
- **48.1%**  **LGS**
- **61.2%**  **DEE Other**

- **Bexicaserin provides the cornerstone to potentially build a world-class epilepsy franchise**
- Studies to date highlight bexicaserin as potentially **best-in-class**
- **Composition of matter IP protection through 2041\*\*** provides the opportunity to maximize the full potential of LP352
- Rapidly moving forward with preparations for a **global Phase 3 program**



# Thank you

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