

# PACIFIC Study Topline Data

JANUARY 2, 2024

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## Bexicaserin Has the Potential to Change the DEE Landscape

Median Reduction in Seizures\*

53.3%

- 72.1% J Dravet
- 48.1% 📕 LGS

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• 61.2% **JEE** 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

Screening Period	Randomization & Up-Titration	Maintenance*	Down- Titration	Follow-up Period	
5 Wks	Days 1-15	Days 16-75	Days 76- 80/90**	30 Days	
		<b>LP352</b> (n=43)			
	$6 \text{ mg} \rightarrow 9 \text{ mg} \rightarrow 12 \text{ mg}$	Participant remains on 6, 9 or 12 mg based on tolerability during up-titration			Open- Label Extension

### Key Inclusion Criteria:

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- 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:  $\geq$  12 to  $\leq$  65 yrs old

## No Echocardiograms Required in PACIFIC



Double-blind, placebocontrolled 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 4week period during 12 weeks before screening while on stable ASM treatment

	Dravet Syndrome	LGS	DEE Other
Onset	Between 3–19 months of age	Before 8 years of age	Unprovoked seizures before 5 years of age
Seizure Type	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
Developmental History	Initially normal, then delayed	Delayed	Delayed
EEG		Consistent with LGS diagnosis*	Slow or disorganized
Additional Criteria	One of the following: • Emergence of another seizure type after the first • Induced by warm temperatures, fevers, or visual stimuli • Genetic test consistent with Dravet	More than 1 type of generalized seizure for ≥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)
		Mean	23.8	26.7	24.3
Age (Years)		Standard Deviation	9.62	7.73	9.31
•		Median	23.0	23.0	23.0
		Min, Max	12, 55	19, 41	12, 55
<b>S</b> av		Male	21 (48.8)	7 (77.8)	28 (53.8)
Sex		Female	22 (51.2)	2 (22.2)	24 (46.2)
Waight (kg)		Median	55.20	72.76	59.36
Weight (kg)		Min, Max	29.2, 96.0	45.8, 110.7	29.2, 110.7
BMI (kg/m <sup>2</sup> )		Median	22.4	28.1	23.0
		Min, Max	17, 35	19, 34	17, 35
		Clobazam	21 (48.8)	2 (22.2)	23 (44.2)
Concomitant Medicat	ions	Cannabidiol	14 (32.6)	3 (33.3)	17 (32.7)
	10113	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

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S 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)

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## 86% of Bexicaserin Treated Participants Achieved 12 mg Dose

Highest tolerated dose achieved for the Maintenance Period

n(%)	Bexicaserin (LP352)	Placebo	Overall
	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)
	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)
	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)
	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)
	6 mg 9 mg 12 mg 6 mg 9 mg 12 mg 12 mg 12 mg 12 mg 12 mg 9 mg	35 $6 mg$ $1 (2.9)$ $9 mg$ $4 (11.4)$ $12 mg$ $30 (85.7)$ $3$ $6 mg$ $0$ $9 mg$ $1 (33.3)$ $12 mg$ $2 (66.7)$ $17$ $17$ $6 mg$ $0$ $9 mg$ $1 (5.9)$ $12 mg$ $16 (94.1)$ $15$ $15$ $6 mg$ $1 (6.7)$ $9 mg$ $2 (13.3)$	359 $6  mg$ $1 (2.9)$ $0$ $9  mg$ $4 (11.4)$ $0$ $9  mg$ $4 (11.4)$ $0$ $12  mg$ $30 (85.7)$ $9 (100)$ $6  mg$ $0$ $0$ $6  mg$ $0$ $0$ $9  mg$ $1 (33.3)$ $0$ $12  mg$ $2 (66.7)$ $0$ $12  mg$ $2 (66.7)$ $0$ $9  mg$ $1 (5.9)$ $0$ $9  mg$ $1 (6.74.1)$ $5 (100)$ $12  mg$ $16 (94.1)$ $5 (100)$ $12  mg$ $1 (6.7)$ $0$ $9  mg$ $2 (13.3)$ $0$

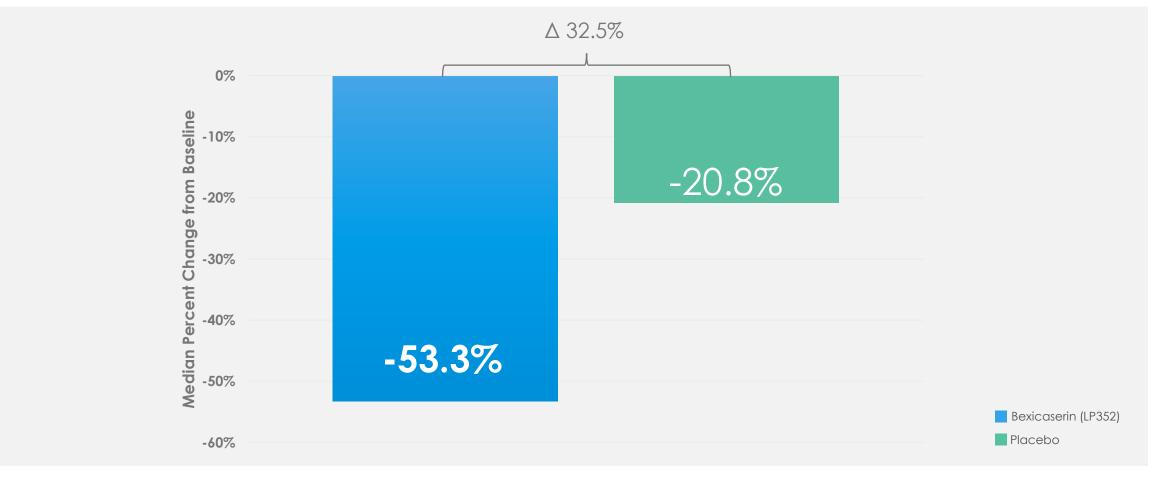
# Safety Results Summary

n(%)	Bexicaserin (N=43)	Placebo (N=9)	Overall (N=52)
	25 (01 4)	0 (00 0)	(2, (20, 7))
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



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# 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

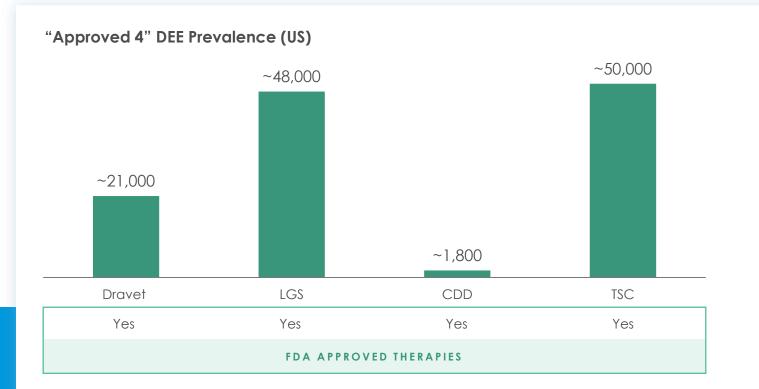
- No echocardiograms required in PACIFIC study
- Metabolized via UGT pathway potentially reduces risk of Drug-Drug Interactions

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



#### Other DEEs

- DUP15q
- SCN2A related epilepsies
- SCN8A related epilepsies
- KCNQ2 related epilepsies
- KCNQ3 related epilepsies
- Angelman syndrome
- Landau-Kleffner Syndrome
- Early Myoclonic Encephalopathy
- KCNT1 related epilepsies
- SynGAP1 related epilepsies

- Rett Syndrome
- Ohtahara Syndrome
- PCDH19
- EE w/ Continuous
  Spike-Wave
- West Syndrome
- Myoclonic Atonic Epilepsy
- Ring14
- Ring20
- Others

#### NO SPECIFICALLY APPROVED THERAPIES

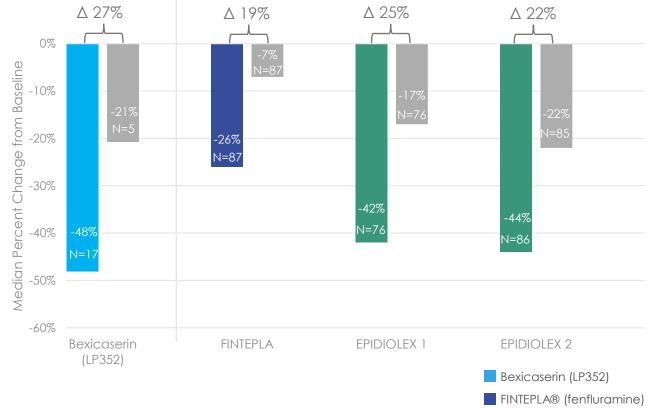
### The prevalence of all "Other DEEs" could exceed the total of the "Approved 4" combined

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

Dravet Syndrome<sup>1,3,4</sup>  $\Delta$  56%  $\Lambda 26\%$  $\Delta 22\%$ 0% Median Percent Change from Baseline -10% -20% -30% -39% 40% -49% N=67 -60% -72% -75% -70% N=40 -80% Bexicaserin FINTEPLA EPIDIOLEX 1 **EPIDIOLEX 2\*** (LP352)



Epidiolex (cannabidiol)

Placebo

### 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.

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 Fenfluramine - Lagae, et al The Lancet 2019; 2. Fenfluramine - Knupp, et al JAMA Neurology 2022; 3. Epidiolex HCP website <u>Dravet & LGS</u>, Miller et al JAMA Neurology 2020; 4. PACIFIC Study Topline Data
 \* Estimated percentage reduction in seizure frequency

Lennox-Gastaut Syndrome<sup>2,3,4</sup>

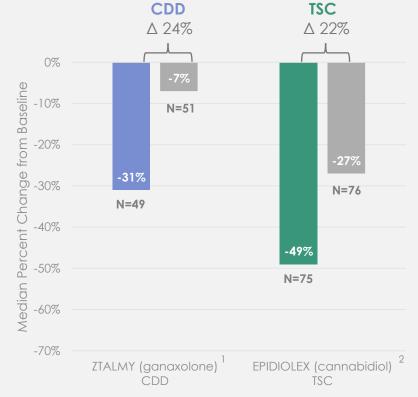
## Significant Unmet Need in DEEs (Beyond Dravet and LGS)

**DEE Other**  $\Delta 28\%$ 0% 0% from Baseline -20% Median Percent Change from Baseline -10% -20% -33% Percent Change fr -40% N=4 -30% -40% -61% 50% Median N=15 -60% -60% -70% -70% Bexicaserin (LP352) DEE Other

"DEE Other" in PACIFIC

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### "Other DEEs" with Specifically Approved Therapies



### "Other DEEs" With No Specifically Approved Therapies

- DUP15q
- SCN2A related epilepsies
- SCN8A related epilepsies
- KCNQ2 related epilepsies
- KCNQ3 related epilepsies
- Angelman syndrome
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- PCDH19
- EE w/ Continuous Spike-Wave
- West Syndrome
- Myoclonic Atonic Epilepsy
- Ring14
- Ring20
- Others

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# Thank you

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