BMB-101

Novel 5-HT_{2C}
Selective Agonist

Bright Minds Biosciences Absence Epilepsy R&D Day

May 20, 2025

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Event speakers

Bright Minds Bio Participants

Ian McDonald

Chief Executive Officer, Director

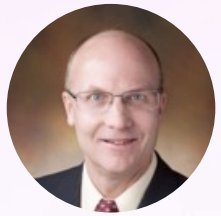
Jan T. Pedersen, PhD, MSc

Chief Scientific Officer, Director

Stephen Collins, MD, PhD

Chief Medical Officer

Key Opinion Leaders



Dennis Dlugos, MD

Professor of neurology and pediatrics at Children's Hospital of Philadelphia (CHOP) and the University of Pennsylvania School of Medicine. He is Director of the Section of Clinical Neurophysiology and the Epilepsy/Clinical Neurophysiology Fellowship. He holds the Tristram C. Colket, Jr. Endowed Chair in Pediatric Neurology.

Dr. Dlugos is a member of the American Academy of Pediatrics, the American Academy of Neurology, the American Epilepsy Society, the American Clinical Neurophysiology Society, and the Child Neurology Society. Dr. Dlugos is a frequent lecturer locally and at national medical meetings on topics related to pediatric neurology, epilepsy, and electroencephalograms. He has published papers in journals such as Neurology, Epilepsia, Archives of Neurology, Pediatric Neurology, and Journal of Child Neurology.

Wendyl D'Souza, MBChB, MPH, FRACP, PhD

Professor Wendyl D'Souza is a neurologist, epilepsy specialist and epidemiologist with over twenty years of experience managing people with seizures, suspected seizures, epilepsy, and their mimickers.

He was Head of Epilepsy Services at the Alfred Hospital from 2002-2007. He is currently, Head of Epilepsy Services, Director of Neurology Advanced Training and Deputy Director of Neurology, in the Department of Medicine, St Vincent's Hospital, The University of Melbourne.

His current research focus is on the idiopathic generalised epilepsies, psychogenic non-epileptic attacks, real-world studies in antiseizure medications and devices, autoimmune epilepsies, and the utilization of national privacy preserving data linkage techniques to map and improve epilepsy-related health outcomes.

Alexander Rotenberg, MD, PhD

Alexander Rotenberg is a neurologist and epileptologist, and Director of the Neuromoduation Program within the Department of Neurology. He is the recipient of the 2016 Dreifuss-Penry Epilepsy Award from the American Academy of Neurology. He is also the 2015-2016 president of the Greater Boston Epilepsy Society. Dr. Rotenberg leads local efforts to adapt methods for transcranial magnetic stimulation (TMS), transcranial direct current stimulation (tDCS) and other forms of noninvasive brain stimulation to the pediatric population, particularly to children with epilepsy. He also heads a basic science laboratory where experiments focus on translational applications of noninvasive brain stimulation in animal models of epilepsy and traumatic brain injury. Among his ongoing scientific studies are clinical trials aimed to test the capacity of TMS and related methods for brain stimulation to stop drug-resistant seizures, clinical studies of human brain plasticity in autism, and preclinical studies aimed to describe the neurobiology of a range of brain stimulation methods in order to improve their efficacy in clinical practice.

Topic	Themes	Speaker	Timing
Introduction		**Ian McDonald**	5 min
Overview of Absence Seizures & Syndromes	• Clinical and electrographic presentation (overview) • ILAE classification of the Idiopathic Generalized Epilepsy Syndromes • Current treatment paradigm • Absence seizures in DEEs	**Dennis Dlugos**	20 min
Burden of Absence seizures	• Long-term impact and the unmet need • Impact on cognition and sleep • Why we need better drugs • Use of 24h EEG to assess drug effects in this patient group	**Wendyl D'Souza**	20 min
Aspects of drug development for Absence seizures	• Burden of absence seizures • The need for novel, effective, safe, and well-tolerated drugs for absence seizures • Value of EEG and wearable devices	**Alex Rotenberg**	20 min
BMB Approach to Absence seizures	• Prevalence of absence epilepsy and commercial potential • Overview of BMB-101 • BMB approach for absence epilepsy	**Ian McDonald** **Jan Torleif Pedersen** **Stephen Collins**	15 min

BMB-101

Novel 5-HT_{2C}
Selective Agonist

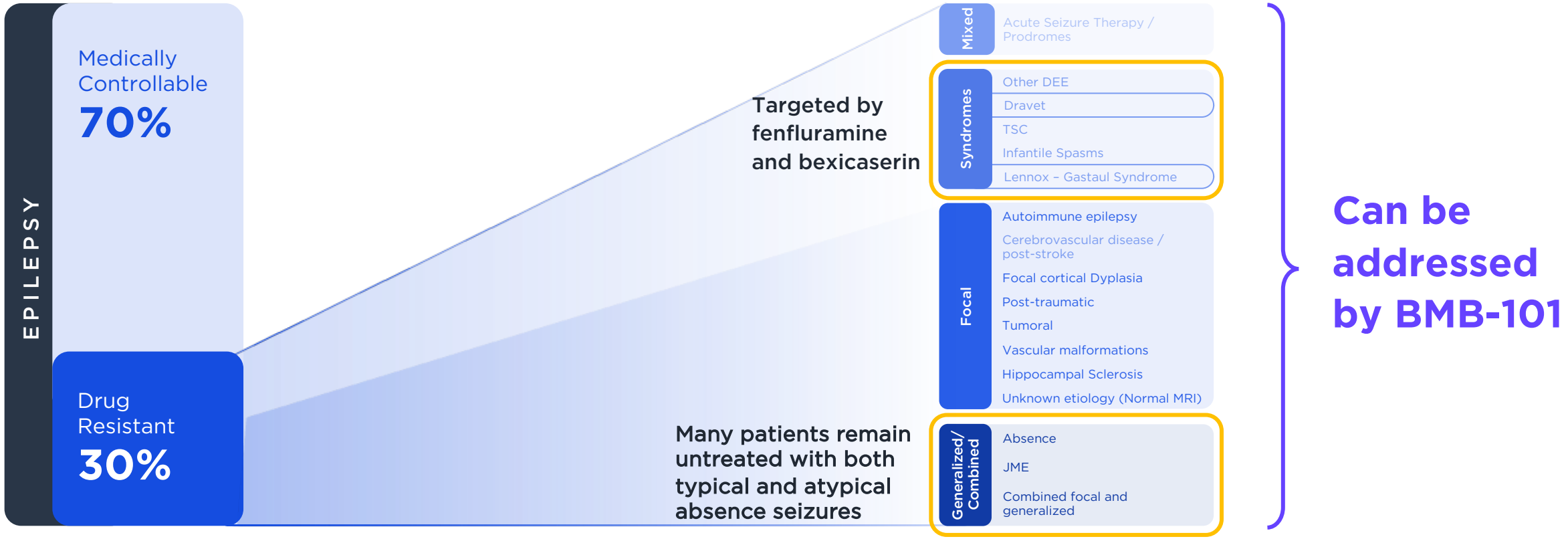
Breaking through

Drug resistant epilepsies

Absence seizures

High unmet need beyond Dravet

Addressable targets for BMB-101 range across multiple epilepsies



Today Suppression of seizures in Broad Epilepsy Population (~65 Million)

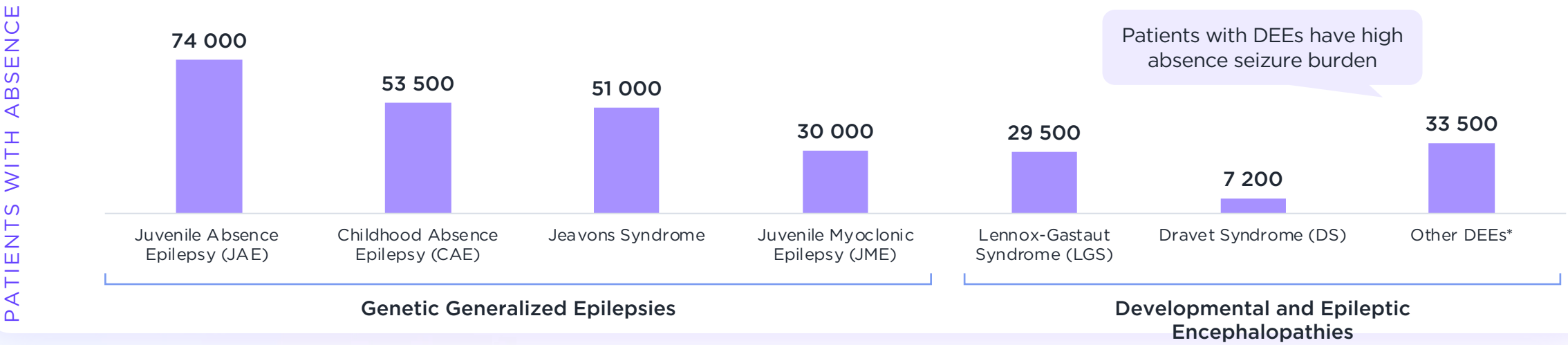
Future Focus on epilepsies without treatments

Semah F, et al. Is the underlying cause of epilepsy a major prognostic factor for recurrence? Neurology. 1998;(51):1256-1262
Brenner T et al. Prevalence of neurologic autoantibodies in cohorts of patients with new and established epilepsy. Epilepsia. 2013;54(6):1028–1035

Image credits: UCB

Estimates indicate a total absence prevalence of at least 280K in the USA only

US Prevalence of Absence Across Common Epilepsy Syndromes

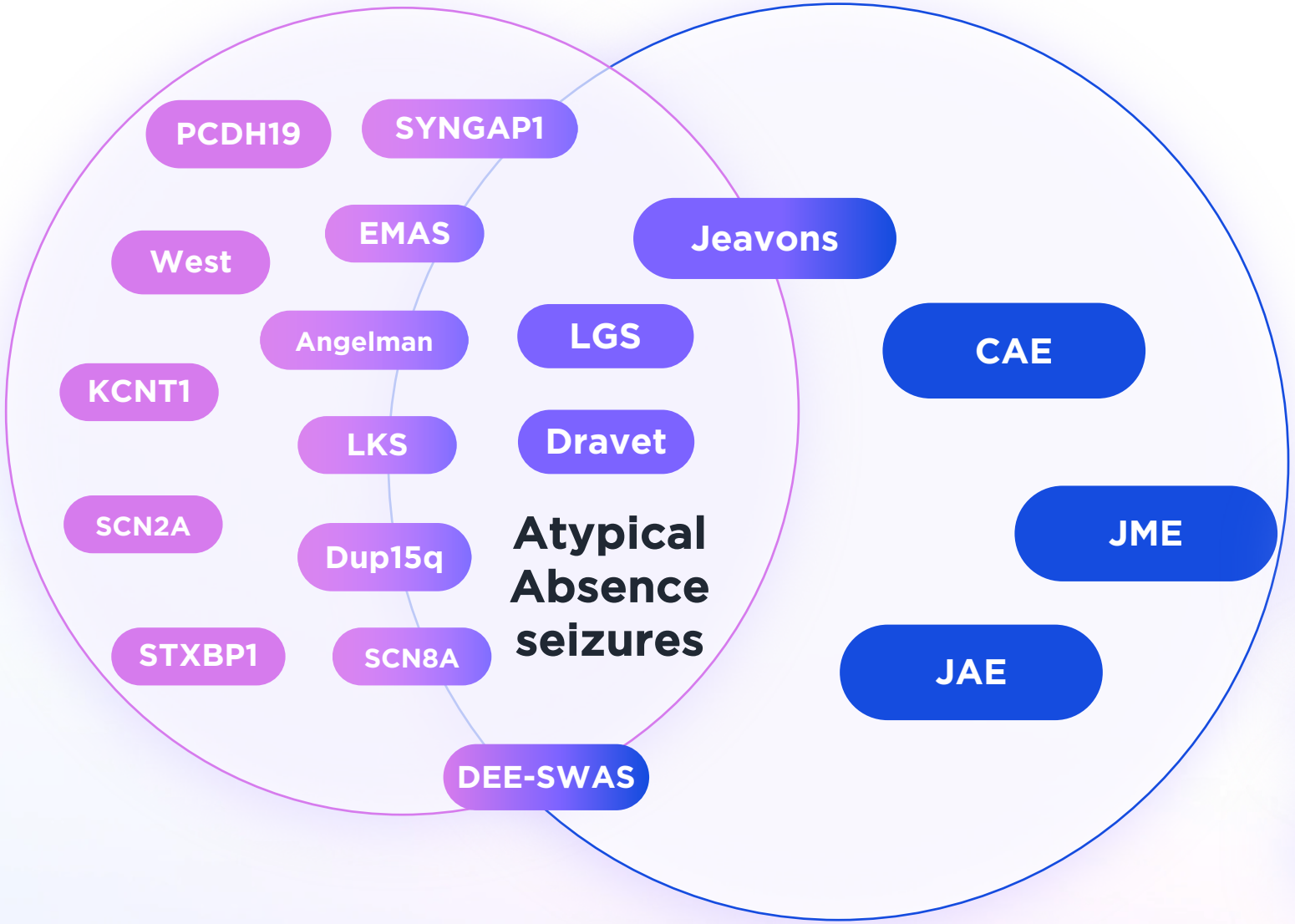


Indication	Prevalent Patients	% with Absence Seizures	Prevalent with Absence
Juvenile Absence Epilepsy (JAE)	74,000	100%	74,000
Childhood Absence Epilepsy (CAE)	53,500	100%	53,500
Juvenile Myoclonic Epilepsy (JME)	150,000	20%	30,000
Jeavons Syndrome (EEM)	64,000	80%	51,000
Lennox-Gastaut Syndrome (LGS)	49,000	60%	29,500
Dravet Syndrome (DS)	13,000	55%	7,200
Other DEEs*	--	--	33,500
Total	--	--	**278,700**

* Other DEEs included in this estimate are Dup15q, EMAS, Angelman Syndrome, SNYGAP1, DEE-SWAS, and SCN8A; ASM: Anti-seizure medication; EEM: Epilepsy with Eyelid Myoclonia
* Prevalence estimates are presented as median values, source: research from Trinity Life Sciences

Opportunity for BMB-101

DEEs



Typical Absence seizures

Efficacy of branded DEE drugs in Absence seizures is limited or unknown

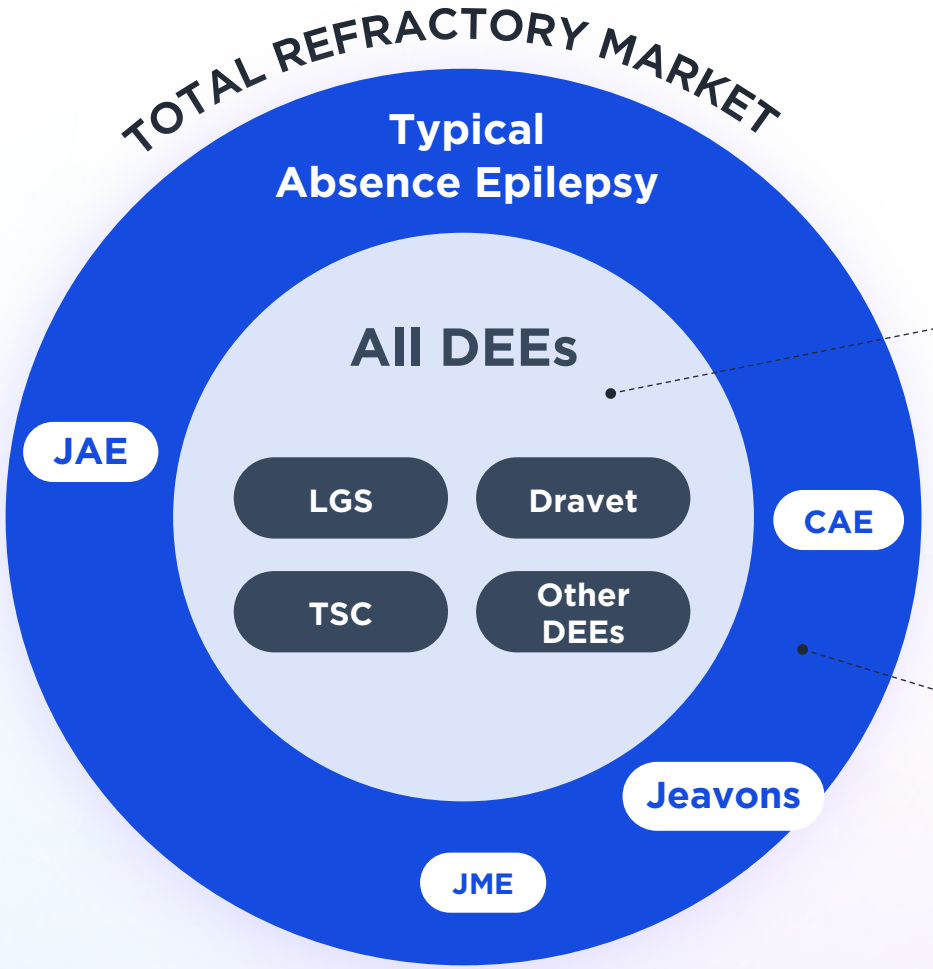
GABA modulation may worsen absence seizures

Epidiolex was reported to worsen seizures in Jeavons syndrome*

ABBREVIATIONS:
CAE: Childhood Absence Epilepsy; DEE: Developmental and Epileptic Encephalopathy; JAE: Juvenile Absence Epilepsy; JME: Juvenile Myoclonic Epilepsy; LGS: Lennox-Gastaut Syndrome; TSC: Tuberous Sclerosis Complex

*Sources: Perucca E, et al.. CNS Drugs. 2023, Zawar I, et al . Epileptic Disord. 2021

Potential for best-in-class drug in DEE and absence seizures



– Opportunity in All DEEs

– Opportunity with Absence

All DEE Refractory Market

~$16B

Absence Epilepsy Refractory Market

~$5.1B

~$21B
Total Refractory Market

Additional research needed to assign a product-specific peak sales estimate

ABBREVIATIONS:

CAE: Childhood Absence Epilepsy; **DEE:** Developmental and Epileptic Encephalopathy; **JAE:** Juvenile Absence Epilepsy; **JME:** Juvenile Myoclonic Epilepsy; **LGS:** Lennox-Gastaut Syndrome; **TSC:** Tuberous Sclerosis Complex

BMB-101 is uniquely positioned to address major unmet needs in epilepsy

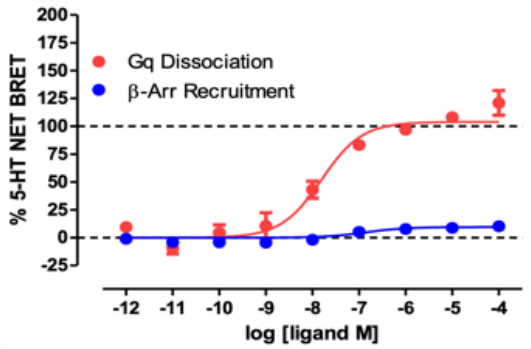
Highly selective 5-HT2C agonist

Compound	5-HT$_{2A}$	5-HT$_{2B}$	5-HT$_{2C}$
BMB-101	2280	>10000	16.2
Nor-Fenfluramine	82.8	11.6	2.5
Lorcaserin	50.1	67.4	2.4
Bexicaserin	>10000	>10000	120

Validated mechanism of action in DEEs

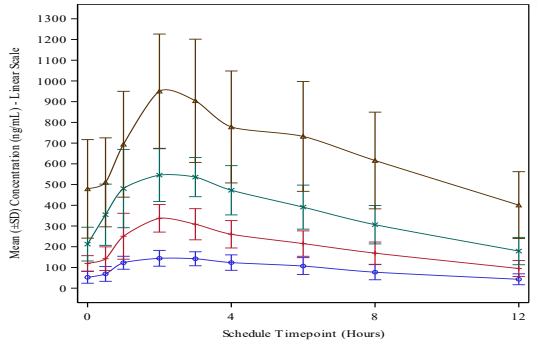
Improved safety profile

The only G protein-biased 5-HT2C agonist



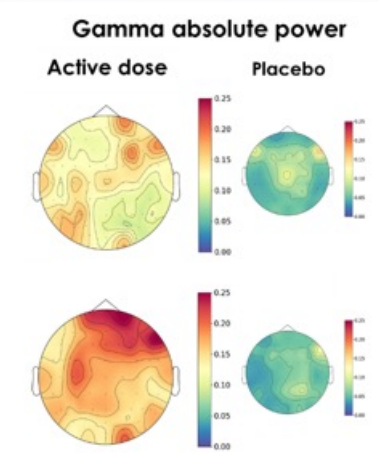
Sustained chronic effect via reduced tolerance

Safety and PK/PD properties validated in Phase 1



Potential for a more convenient once daily formulation

Proof of mechanism demonstrated in Ph.1 Increased gamma-power on qEEG



Additional behavioral/cognitive benefits

Preclinical validation in multiple seizure models

INDUCED *MODELS*	**BMB-101 and analogs**	Lorcaserin	Fenfluramine/ Norfenfluramine	Bexicaserin
Mice Electrical (6 Hz) *drug-resistant seizures*	✓	Not reported	✓	✓
Maximal Electroshock Seizure (MES) *rat/mice model*	✓*	Not reported	✓	Not reported
GENETIC *MODELS*				
Zebrafish *(scn1Lab) Drug-resistant-DEE*	✓	✓	✓	✓
Mice (*DBA/2*) *Reflex & SUDEP*	✓	Not reported	Not reported	Not reported
Rat (*GAERS*) *Absence*	Not reported	✓	Not reported	Not reported

Society for Neuroscience 2024 Annual Meeting (Chicago), Satellite NIH Forum. Poster: Selective 5-HT2C Agonists for the Treatment of Rare Epileptic Disorders
Data from UCB, Eisai, and Longboard Pharma

Proven mechanism of 5-HT2C agonists in absence epilepsy populations

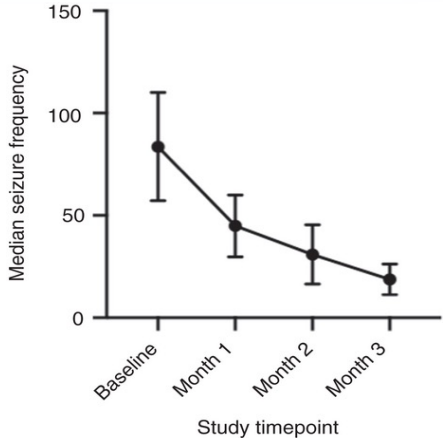
Preclinical

- ✓ Lorcaserin in GAERS (rat model of absence epilepsies)

Clinical

Fenfluramine in Sunflower Syndrome (form of absence epilepsy):

- ✓ Seizure reduction of >70% in the first cohort
- ✓ Cognitive improvements (mean 18-point increase in IQ scores)
- ✓ Reduction in epileptiform activity seen on EEG



Median hand-waving episode frequency Fenfluramine study with Sunflower Syndrome

Lagae et al. Lancet 2019 Dec 21;394(10216):2243-2254
Geenen KR, Doshi SP, Patel S, Sourbron J, Falk A, Morgan A, Vu U, Bruno PL, Thiele EA. Fenfluramine for seizures associated with Sunflower syndrome. Dev Med Child Neurol. 2021 Dec;63(12):1427-1432.
Patel S, Geenen KR, Dowless D, Bruno PL, Thiele EA. Follow-up to low-dose fenfluramine for Sunflower syndrome: A non-randomized controlled trial. Dev Med Child Neurol. 2023 Jul;65(7):961-967.

Venzi M, David F, Bellet J, Cavaccini A, Bombardi C, Crunelli V, Di Giovanni G. Role for serotonin2A (5-HT2A) and 2C (5-HT2C) receptors in experimental absence seizures. Neuropharmacology. 2016 Sep;108:292-304.
Silenieks LB, Carroll NK, Van Niekerk A, Van Niekerk E, Taylor C, Upton N, Higgins GA. Evaluation of Selective 5-HT2C Agonists in Acute Seizure Models. ACS Chem Neurosci. 2019 Jul 17;10(7):3284-3295.

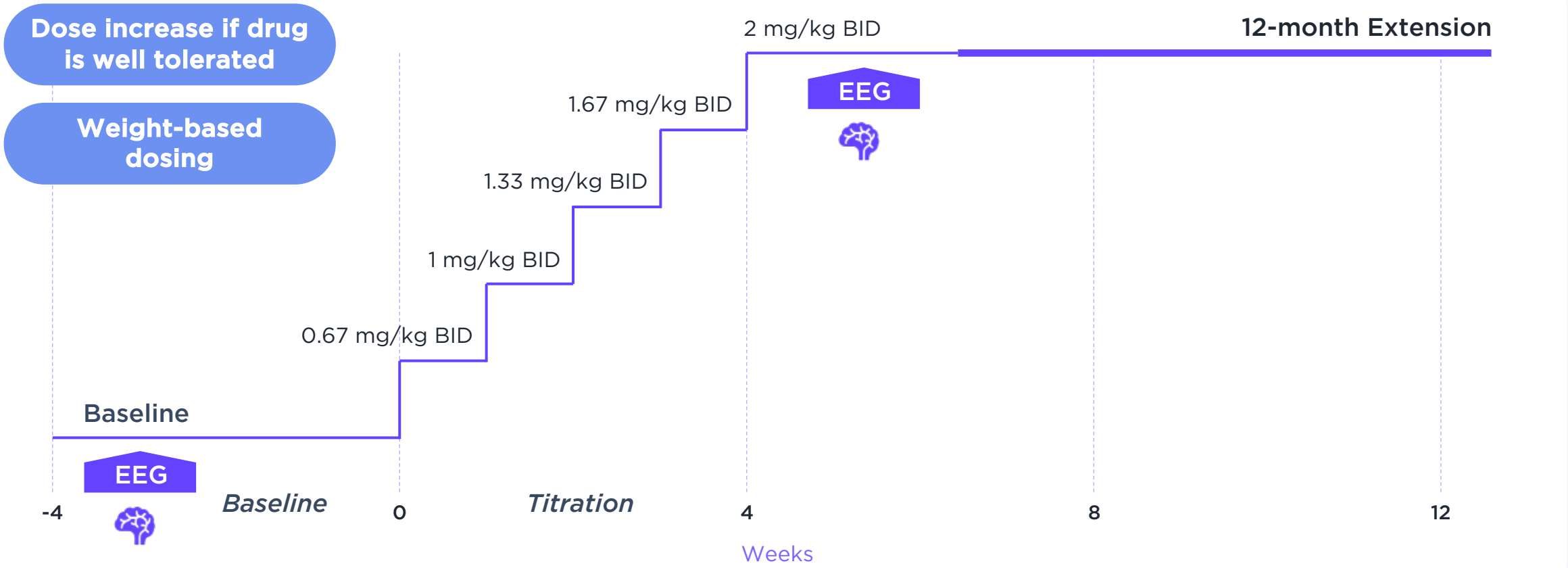
BREAKTHROUGH – Open Label Phase 2 study

To Evaluate the Efficacy, Safety and Tolerability of BMB-101 in Adults

	Absence Epilepsy Cohort	Developmental and Epileptic Encephalopathy (DEE) Cohort
Efficacy primary endpoints	**<u>24h EEG:</u>** Number and duration of electroclinical seizures (generalized spike-wave discharges)	**<u>Seizure diary:</u>** Major motor seizure frequency (generalized tonic-clonic, tonic, clonic and atonic)
Efficacy secondary endpoints	Seizure diary: Seizure frequency Quality of Life (QOLIE-31) Wearable EEG device for seizure counts (exploratory)	24h EEG: Number of electroclinical seizures Quality of Life (QOLIE-31) Wearable EEG device for seizure counts (exploratory)

Absence Epilepsy Trial Design

Improved approach to measure absence seizures uses 24h ambulatory EEG

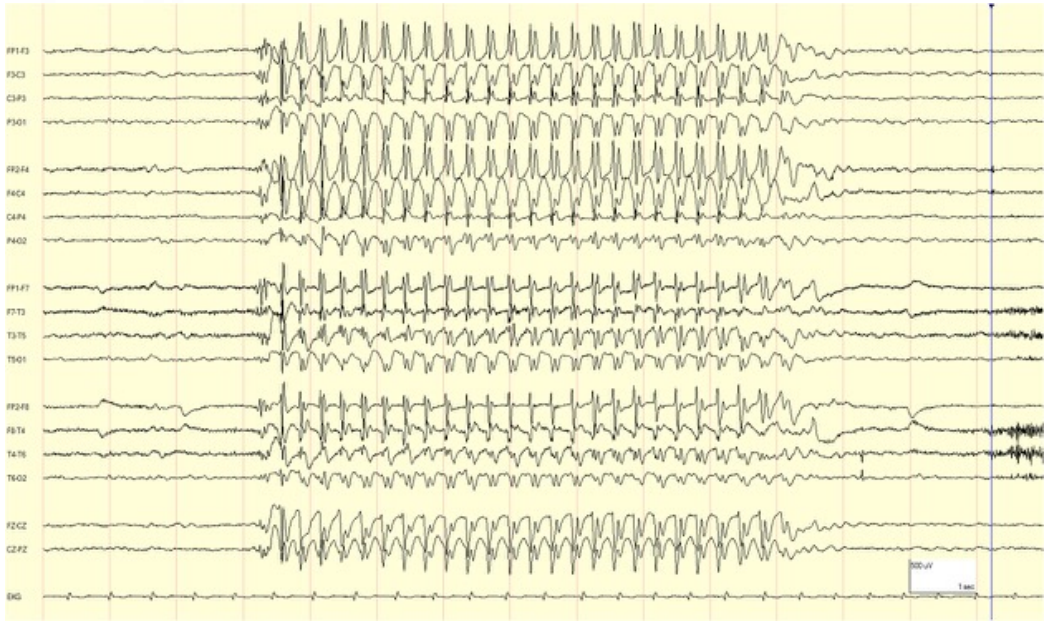


Seizure diary
Wearable EEG device

What is an absence seizure?

Absence seizure is defined as:

- A distinct 3/s spike-and-wave discharge – an abnormal, and unique paroxysmal pattern of a high velocity spike followed by a slower dome shaped wave on the background of a normal EEG.
- The 3/s spike-and-wave on EEG is the clinically accepted proof of absence seizure, has extremely high specificity and sensitivity, and has been so defined for over 70 years



Source: ILAE https://www.epilepsydiagnosis.org/seizure/absence-typical-eeg.html

Egenasi CK, Moodley AA, Steinberg WJ, Adefuye AO. Current norms and practices in using a seizure diary for managing epilepsy: A scoping review. South African Fam Pract Off J South African Acad Fam Pract Care 2022;64:e1–9. https://doi.org/10.4102/safp.v64i1.5540.

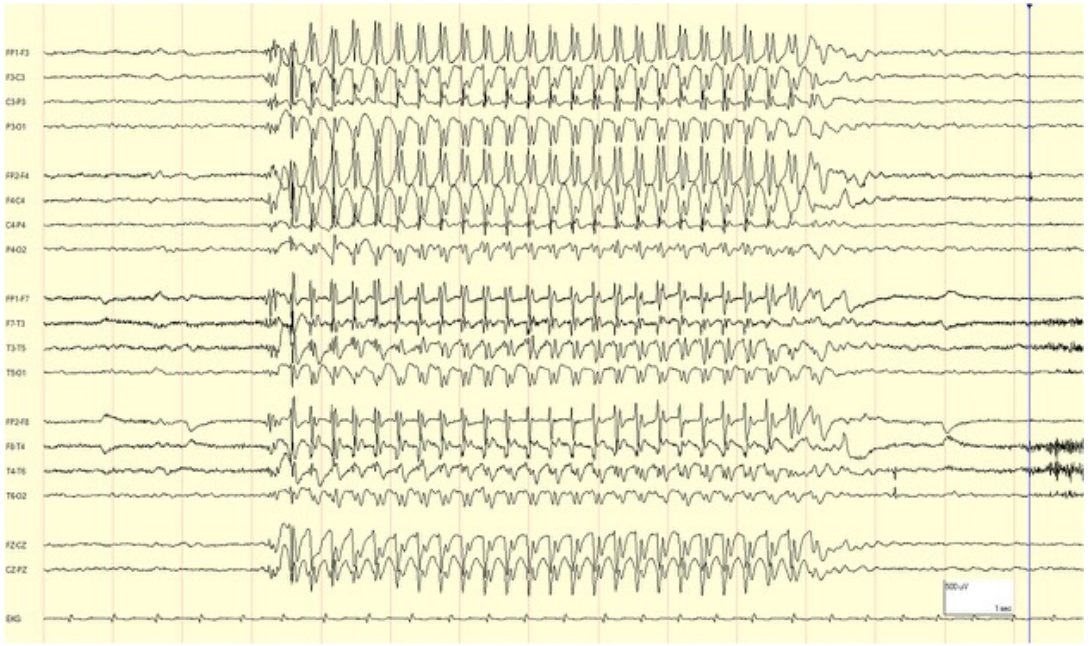
Buchhalter J, Neuray C, Cheng JY, D'Cruz O, Datta AN, Dlugos D, French J, Haubenberger D, Hulihan J, Klein P, Komorowski RW, Kramer L, Lothe A, Nabbout R, Perucca E, der Ark PV. EEG parameters as endpoints in epilepsy clinical trials - An expert panel opinion paper. Epilepsy Res. 2022 Nov;187:107028.

Porter, R. J. (1993). The Absence Epilepsies. Epilepsia, 34, S42–S48

How are we documenting absence seizures?

Primary Method

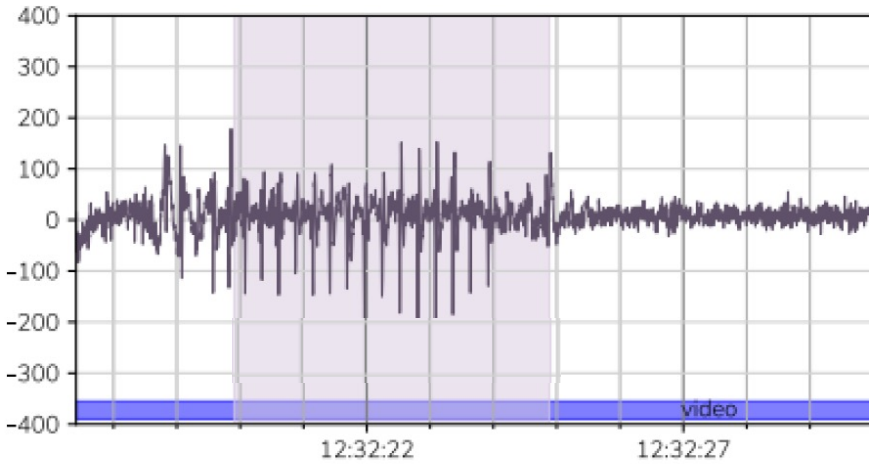
24h EEG Ambulatory



- ✓ Quantitative seizure detection
- ✓ Potential for sleep assessment

Exploratory Method

Wearable EEG device



- ✓ Designed and validated for absence seizure detection
- ✓ Convenient absence seizure monitoring

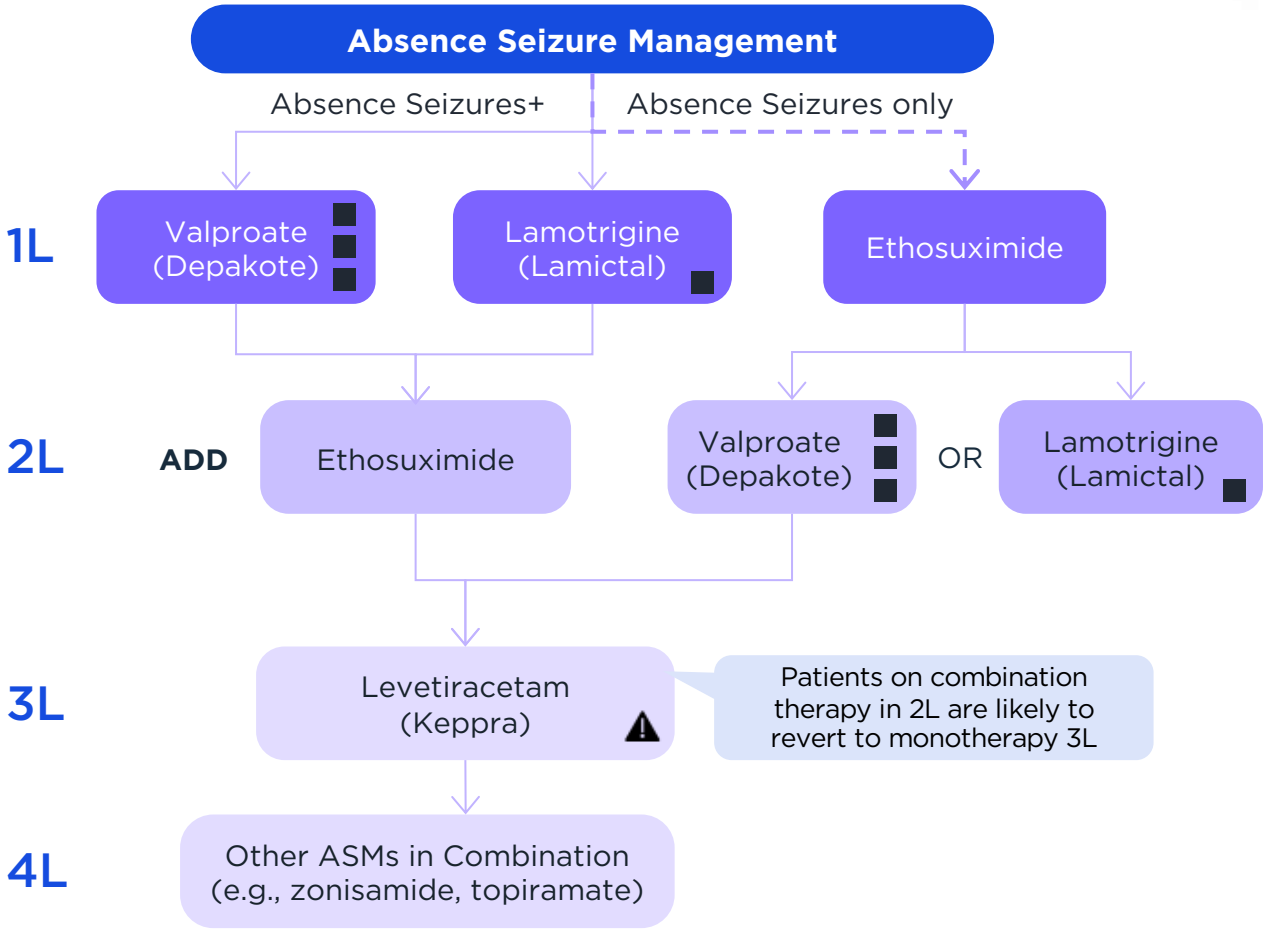
Source: ILAE https://www.epilepsydiagnosis.org/seizure/absence-typical-eeg.html

Why are we developing novel drugs for absence seizures?

Absence epilepsies have high unmet need

- Current drugs don’t effectively treat all patients and have tolerability and potentially even severe safety issues
- The unmet need is in both people with typical absence and those with mixed seizure disorders, including DEE’s. All of these patients need an effective, wide-spectrum, safe and well-tolerated therapy.

Limited treatment options represent significant opportunity for new branded agent in the absence treatment paradigm



Ethosuximide

- Standard-of-care drug for CAE - only manages absence seizures (narrow-spectrum)
- Associated with GI disturbance

Valproate (three FDA black boxes) ■ ■ ■

- Not preferred for first-line in females due to its association with birth defects
- Also associated with hepatotoxicity, it requires liver monitoring which adds additional burden for patients

Lamotrigine (one FDA black box) ■

- more limited in effectiveness against absence seizures
- often selected in 2L, particularly in females due to lack of terratogenicity

Levetiracetam (FDA warning – DRESS) ⚠

- often used later-line and not preferred in patients with co-morbid behavioral issues

4L+ options are limited due few antiseizure medicines with proven efficacy against typical and atypical absence seizures

■ A “black box” warning, also known as a boxed warning, is the strictest and most serious warning issued by the FDA for prescription drugs. This warning is displayed alert healthcare providers and patients to serious or life-threatening risks associated with the medication

⚠ DRESS - Drug Reaction with Eosinophilia and Systemic Symptoms

Kessler SK, McGinnis E. A practical guide to treatment of childhood absence epilepsy. Paediatr Drugs Internet. 2019
Albuja A, Ighodaro E, Khan GQ. Absence Seizure Internet. In: StatPearls. Treasure Island (FL): StatPearls Publishing; 2024

BMB-101 - Potential to reduce the absence seizure burden regardless of epilepsy type

- Novel mechanism for the treatment of absence seizures
- Potential for best-in-class drug in DEE and first-in-class in absence seizures
- Opportunity for once-a-day drug with improved safety
- Goal is to improve the absence seizure burden in all forms of epilepsy

Phase 2 study updates

- Study is ongoing and recruitment is on track
- No serious adverse events seen to date

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Drug resistant epilepsies

Q&A session