



**Healing mental health disorders so that everyone everywhere can live a more fulfilled life**

**Corporate Presentation – January 2025**



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The forward-looking statements included in this presentation are made only as of the date hereof. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor our advisors nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Neither we nor our advisors undertake any obligation to update any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations, except as may be required by law. You should read this presentation with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Unless otherwise indicated, information contained in this presentation concerning our industry, competitive position and the markets in which we operate is based on information from independent industry and research organizations, other third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and other third-party sources, as well as data from our internal research, and are based on assumptions made by us upon reviewing such data, and our experience in, and knowledge of, such industry and markets, which we believe to be reasonable. In addition, projections, assumptions and estimates of the future performance of the industry in which we operate or of any individual competitor and our future performance are necessarily subject to

uncertainty and risk due to a variety of factors, including those described above. These and other factors could cause results to differ materially from those expressed in the estimates made by independent parties and by us. Industry publications, research, surveys and studies generally state that the information they contain has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and uncertainties as the other forward-looking statements in this presentation.

This presentation contains excerpts of testimonials from individuals who have been treated with compounds or derivatives of the compounds underlying our product candidates in the context of third-party studies or otherwise that are solely intended to be illustrative and not representative of the potential for beneficial results of such compounds. Our product candidates are in preclinical or clinical stages of development and none of our product candidates have been approved by the FDA or any other regulatory agency.

When discussing patents in this presentation, “issued” is to be understood to mean one or more issued or granted claims in one or more country, and “pending” is understood to mean one or more claims pending in a patent application in one or more country. Patent protection is a highly fact-sensitive inquiry, varying from country-to-country, and provides for enforceable protection to the extent (a) covered by a given claim, and (b) issued in such country or countries. No generalized descriptions of patents made herein should be relied upon; rather, a detailed discussion of our intellectual property and related risk factors can be found in our most recently filed Annual Report on Form 10-K, available on the SEC’s website at [www.sec.gov](http://www.sec.gov).

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# atai is addressing significant unmet patient needs in mental health disorders so that everyone, everywhere can live a more fulfilled life

- 1 Significant unmet need:** mental health disorders are one of the largest global health burdens; it is estimated that one out of every two people in the world will develop a mental health disorder in their lifetime<sup>1</sup>
- 2 Novel approach:** our objective is to enable patients to achieve clinically meaningful improvements by developing innovative therapeutics with rapid-onset, durable effects and a focus on interventional treatment approaches
- 3 5 clinical-stage programs:** four psychedelic programs and one non-psychedelic program, each with a robust package of prior clinical evidence
- 4 Multiple Phase 2 readouts expected over the next 12 months:** several anticipated clinical trial readouts across our drug development programs and strategic investments
- 5 Runway into 2026:** cash and cash equivalents, marketable securities, and committed term loan funding expected to provide funding into 2026<sup>2</sup>

1. McGrath et al, "Age of onset and cumulative risk of mental disorders: a cross-national analysis of population surveys from 29 countries", The Lancet Psychiatry, 2023.

2. Marketable securities includes money market funds, U.S. Treasury securities, commercial paper, corporate notes/bonds, U.S. government agencies securities, and public equities; term loan funding from Hercules Capital of up to \$175M includes \$45M capital that can be drawn not subject to milestones

# Our vision is being delivered through a robust pipeline of development programs and strategic investments across a range of compounds and psychiatric indications

Programs	Primary Indication	Preclin	Phase 1	Phase 2	Phase 3
<b>VLS-01</b> DMT	Treatment Resistant Depression	█			
<b>EMP-01</b> R-MDMA	Social Anxiety Disorder	█			
<b>IBX-210</b> Ibogaine	Opioid Use Disorder	█			
<b>Novel 5-HT<sub>2A</sub> Receptor Agonists</b> (incl. non-hallucinogenic neuroplastogens)	Undisclosed	█			
<b>STRATEGIC INVESTMENTS</b>					
<b>BPL-003<sup>1</sup></b> 5-MeO-DMT	Treatment Resistant Depression	█			
<b>ELE-101<sup>1</sup></b> Psilocin	Major Depressive Disorder	█			
<b>RL-007<sup>2</sup></b> Pro-cognitive neuromodulator	Cognitive Impairment Associated with Schizophrenia	█			

Abbreviations: DMT = N,N-Dimethyltryptamine; R-MDMA = R enantiomer of 3,4-Methylenedioxymethamphetamine; 5-MeO-DMT = 5-methoxy-N,N-dimethyltryptamine

1. Strategic Investment in Beckley Psytech

2. Majority ownership stake in Recognify Life Sciences

# Multiple near-term milestones

## ACHIEVED AND ANTICIPATED UPCOMING MILESTONES<sup>1,2</sup>

Q4'24

Q1'25

Q2'25

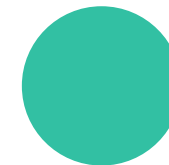
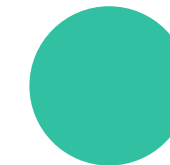
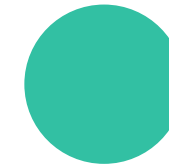
Q3'25

Q4'25

Q1'26

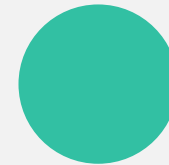
### BPL-003

5-MeO-DMT

Ph 2a (AUD)  
topline OL dataPh 2b (TRD)  
topline dataPh 2a (TRD)  
topline SSRI OL data

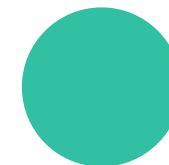
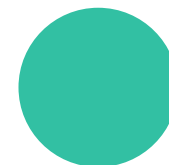
### VLS-01

DMT

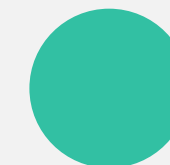
Ph 2 (TRD)  
trial initiationPh 2 (TRD)  
topline data

### EMP-01

R-MDMA

Ph 2a (SAD)  
trial initiationPh 2a (SAD)  
topline data

### RL-007<sup>3</sup>

Pro-cognitive  
neuromodulatorPh 2b (CIAS)  
topline data

Abbreviations: OL = Open-label; TRD = Treatment Resistant Depression; SAD = Social Anxiety Disorder;; AUD = Alcohol Use Disorder; CIAS = Cognitive Impairment in Schizophrenia

1. All dates provided are as estimated

2. Trial initiation defined as central regulatory and ethics approval

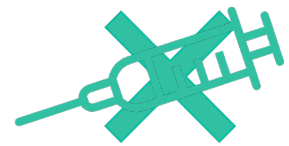
3. Majority ownership stake in Recognify Life Sciences

**VLS-01**  
**(Buccal Film DMT)**  
**for TRD**

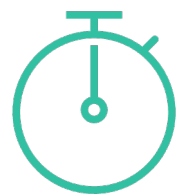
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# VLS-01 (buccal film DMT) is a patent-protected formulation, designed to fit into established **~2-hour interventional psychiatry treatment paradigm** for TRD



**Optimized transmucosal buccal film formulation:** Phase 1 study demonstrated favorable safety & tolerability and an IV-like PK profile, which may support a more scalable patient / provider experience



**Short duration psychedelic effect:** Phase 1 data suggests subjective effects experienced for ~2 hours, potentially enabling VLS-01 to fit into interventional psychiatry paradigm established by Spravato®



**Potential for rapid onset and durable efficacy:** Prior clinical evidence with DMT has generated sustained, clinically meaningful improvement on depressive symptoms<sup>1</sup>



**Patent protected formulation:** Issued patents and pending applications covering compositions and methods of use (expiry anticipated 2042<sup>2</sup>)

Abbreviations: DMT = N,N-Dimethyltryptamine; TRD= Treatment Resistant Depression; PK = Pharmacokinetic;

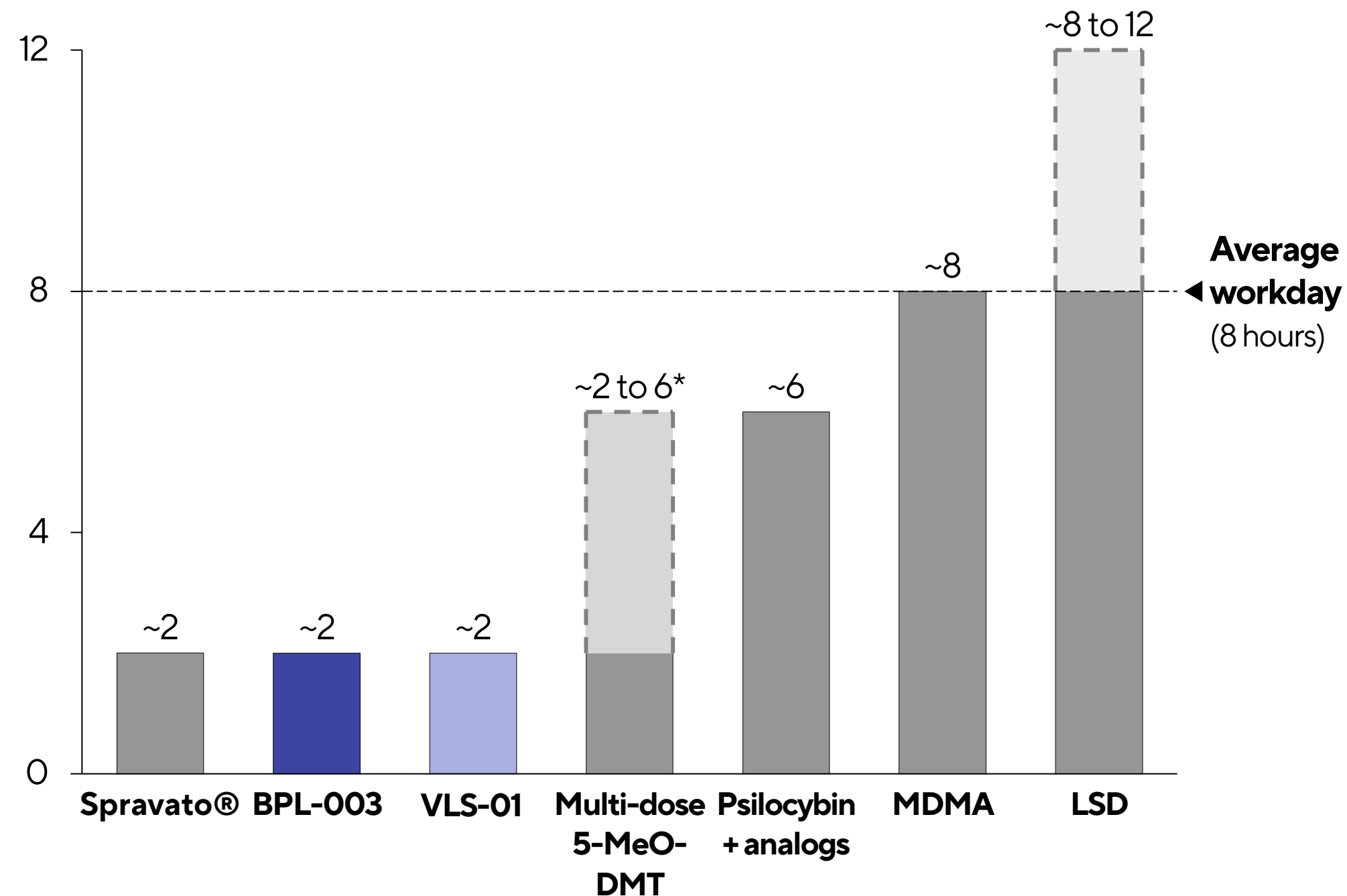
1. Palhano-Fontes F et al, Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression: a randomized placebo-controlled trial. *Psychol Med.* 2019

2. Exclusive of possible patent term adjustments or extensions or other forms of exclusivity. For additional detail please see the most recent 10-K filing

# BPL-003 and VLS-01 have the potential to leverage Spravato® 2-hour in-clinic treatment paradigm in depression

## ANTICIPATED TIME TO RESOLUTION OF SUBJECTIVE EFFECTS<sup>1</sup>

(in hours) *Illustrative*



## Key Takeaways

- 1 Predictable 2-hour treatment:** the potential to fit into the 2-hour in-clinic treatment paradigm established by Spravato
- 2 Established infrastructure and reimbursement:** potential to immediately leverage Spravato's reimbursement pathways and >4,500 certified clinics<sup>2</sup>
- 3 Extended durability reduces patient burden:** 1-2 doses of a psychedelic therapy provides a sustained effect, simplifying the dosing schedule compared to esketamine's once-weekly regimen
- 4 Significantly improved use of infrastructure:** lower dosing frequency compared to esketamine will lower provider burden, and improve payer receptivity

1. Subject to further validation through future clinical studies and real-world evidence

2. [www.spravatohcp.com/#find-a-center](http://www.spravatohcp.com/#find-a-center)

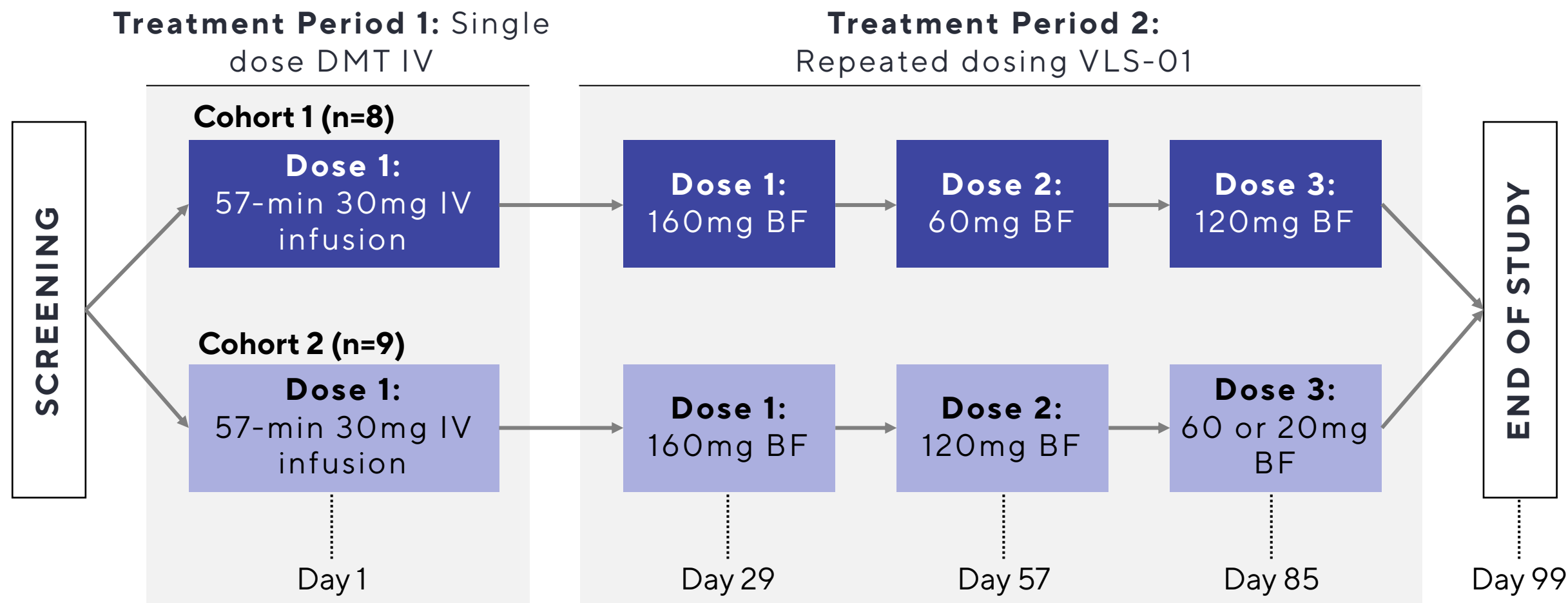
\* If multi-dose required



## VLS-01: Phase 1b clinical trial design

# Phase 1b trial investigating the PK, PD, safety and tolerability of optimized buccal film formulation compared to DMT IV

### VLS-01 PHASE 1B STUDY DESIGN



#### Study Design:

- Open-label, dose ranging study of an optimized buccal film formulation of VLS-01 in healthy volunteers
- Enrolled 17 healthy participants
- Tested 160mg, 120mg, 60mg, or 20mg of VLS-01

#### Primary Endpoint:

- Plasma and urine PK characteristics

#### Key Secondary Endpoints:

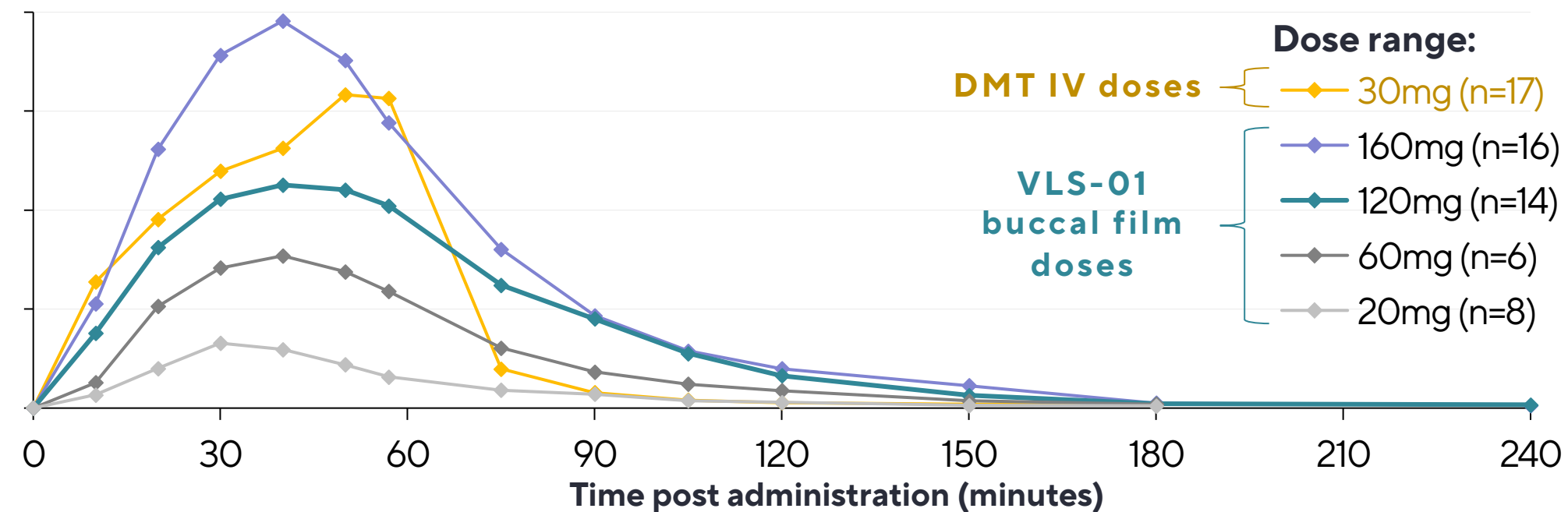
- Safety and tolerability
- Subjective acute PD drug effects

## VLS-01: Phase 1b results

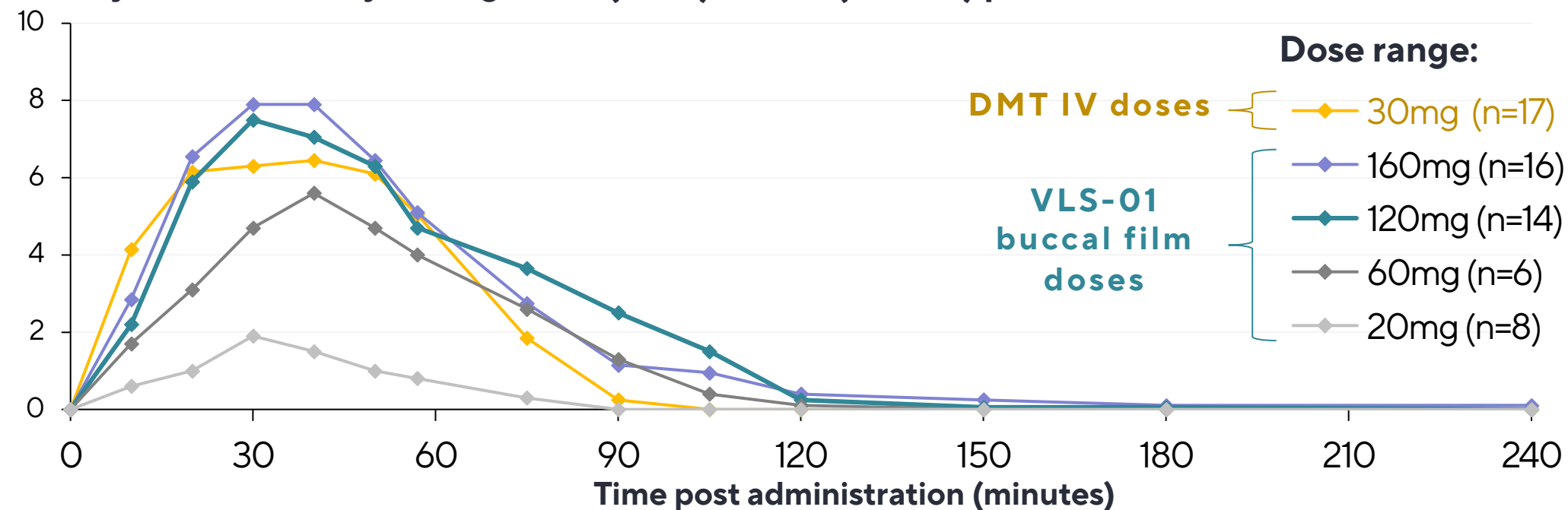
Higher doses demonstrated plasma concentrations comparable to DMT IV and robust subjective effects that resolved in ~2 hours

### VLS-01 PHASE 1B – PRELIMINARY PK/PD RESULTS

#### DMT plasma concentration over time (ng/ml) post administration



#### Subjective Intensity Rating Scale (SIRS) scores (0 to 10) post administration



Abbreviations: IV = Intravenous; PK / PD = Pharmacokinetic / Pharmacodynamic; C-Max = maximum (or peak) serum concentration; T-Max = time it takes for a drug to reach the maximum concentration (C-Max)  
Draft Delivery Version 0.1 [Data cut-off: 2024-06-17]. Study data has been source data verified by the study monitor and queries resolved prior to creating the draft tables but the database is not yet locked and results may change

### Key Takeaways

#### Pharmacokinetics (PK)

- C-Max was dose-proportional and comparable between the higher VLS-01 doses (120mg and 160mg) and the 30mg DMT IV dose
- VLS-01 rapidly reached peak plasma concentration (T-Max) within 30-45 minutes

#### Pharmacodynamics (PD)

- Dose-dependent effects, with robust subjective effects seen at the VLS-01 120mg and 160mg doses
- 13/14 participants in the 120mg cohort achieved SIRS scores greater than 7
- Perceptual effects generally fully resolved within 90-120 mins

## VLS-01: Phase 1b results

Well-tolerated safety profile, with most adverse events classified as either mild or moderate, and most resolving on the day of dosing

### VLS-01 PHASE 1B PRELIMINARY SAFETY RESULTS<sup>a,b</sup>

No. of participants with drug-related TEAE (>10%):	DMT IV	VLS-01 (buccal film)				Total (N=62)
	30mg (N=17)	160mg (N=16)	120mg (N=14)	60mg (N=7)	20mg (N=8)	
Headache	1 (6%)	5 (31%)	4 (29%)		1 (13%)	11 (18%)
Dissociation	1 (6%)	5 (31%)	3 (21%)			9 (15%)
Euphoric mood	1 (6%)	3 (19%)	3 (21%)			7 (11%)
Nausea		5 (31%)	1 (7%)	1 (14%)		7 (11%)
Emotional distress	1 (6%)	3 (19%)				4 (6%)
Feeling drunk			2 (14%)		1 (13%)	3 (5%)
Feeling hot	2 (12%)					2 (3%)
Anxiety	2 (12%)					2 (3%)
Dizziness		1 (6%)		1 (14%)		2 (3%)
Vomiting		2 (13%)				2 (3%)
Myocardial ischemia <sup>1</sup>					1 (13%)	1 (2%)
Abdominal pain				1 (14%)		1 (2%)
At least one severe TEAE						0
At least one serious TEAE						0
At least one TEAE leading to discontinuation	1 (6%)					1 (2%)

1. Myocardial ischemia, mild, probably related to study drug has been added based on feedback from the FDA.

a. Treatment Emergent Adverse Events (TEAEs) are defined as adverse events that occurred following the first administration of study medication

b. Draft Delivery Version 0.1 [Data cut-off: 2024-06-17]. Study data has been source data verified by the study monitor and queries resolved prior to creating the draft tables but the database is not yet locked and results may change

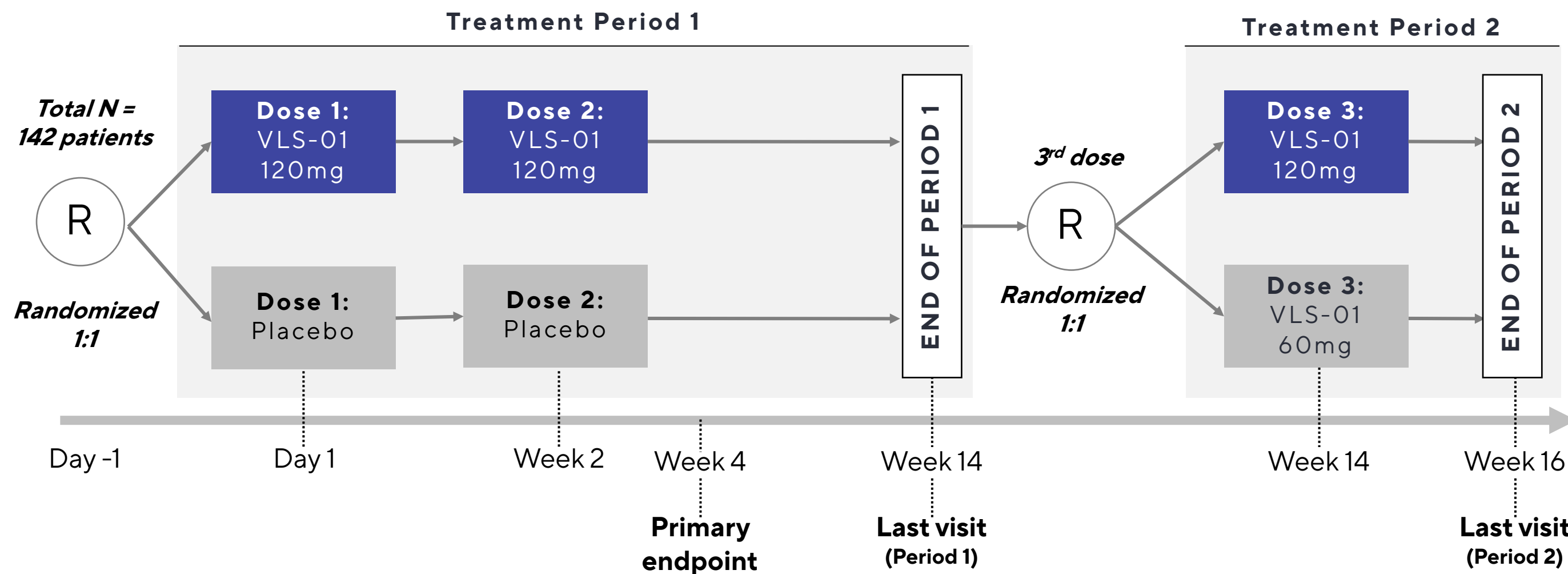
### Key Takeaways

- 1 The most common TEAEs were headache, dissociation, euphoric mood and nausea; adverse events were transient with most resolving on the day of dosing
- 2 Blood pressure and heart rate increases were transient and mostly resolved within 90 min without intervention. None were considered clinically significant
- 3 Results from the C-SSRS showed participants experienced no increase in suicidal thoughts, intentions or behaviours
- 4 Overall impressions from healthy volunteers in the 120mg group was that VLS-01 was well-tolerated and psychologically meaningful with reports of increased self-reflection

## VLS-01: Phase 2 study design

VLS-01 randomized, double-blind, placebo-controlled, Phase 2 study to assess the efficacy of repeated doses of VLS-01 in patients with TRD

### VLS-01 PHASE 2 STUDY DESIGN (PRELIMINARY)



### Study Design:

- Moderate to severe TRD
- Patient must be willing to discontinue current antidepressants
- No use of psychedelics within 6 months of screening<sup>1</sup>
- Psychological support pre- and post-dose

### Primary Endpoint:

- Change from Baseline in MADRS total score at Week 4

### Other Secondary Endpoints:

- Change from Baseline in MADRS total score at Week 6 and Week 14
- Response and remission rates
- Safety and tolerability

**Trial status:** First patient screened in December 2024  
Topline data anticipated Q1 2026

Abbreviations: MADRS = Montgomery-Asberg Depression Rating Scale

1. Patients are also excluded if they report any lifetime use of DMT or DMT-containing drugs, or report a history of > 2 lifetime administrations of any other psychedelic drug

**EMP-01  
(R-MDMA) for  
Social Anxiety  
Disorder**

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# EMP-01 (R-MDMA), a moiety that is **pharmacologically distinct** from both racemic MDMA and S-MDMA



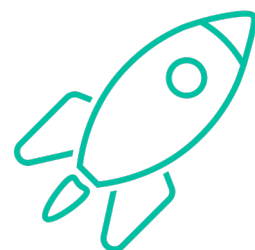
**Unexpected subjective effects:** in a Phase 1 trial, EMP-01 was found to be significantly more psychedelic-like than MDMA, with a more "inward focused" experience.



**Beneficial psychological effects:** EMP-01 administration in healthy volunteers resulted in dose-dependent increases in emotional breakthroughs and measures of self-compassion, both factors associated with reduction in anxiety symptoms.



**Well tolerated:** EMP-01 was generally well tolerated, with no severe or serious adverse events observed. Third-party animal studies indicate that R-MDMA may have fewer adverse effects compared to racemic MDMA<sup>2</sup>.



**First-to-market potential:** no other companies in the psychedelic or psychedelic-like space are targeting the SAD indication.

Abbreviations: SAD = Social Anxiety Disorder; PTSD = Post Traumatic Stress Disorder; PCT = Patent Cooperation Treaty

1. All dates provided for expected milestones are estimated. Trial initiation defined as central regulatory and ethics approval

2. Curry DW, Young MB, Tran AN, Daoud GE, Howell LL. Separating the agony from ecstasy: R(-)-3,4-methylenedioxymethamphetamine has prosocial and therapeutic-like effects without signs of neurotoxicity in mice. *Neuropharmacology*. 2018 Jan

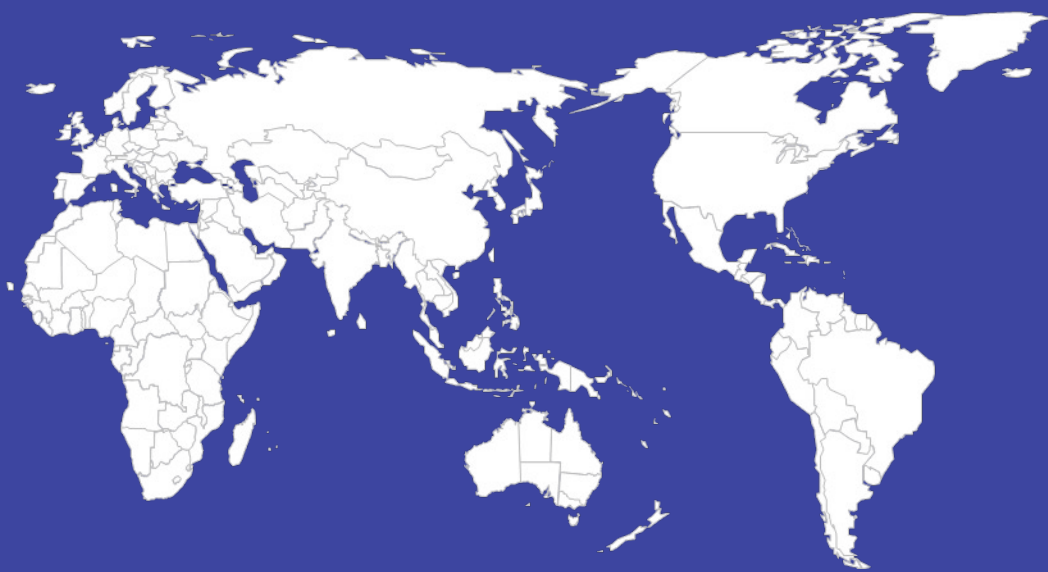
# EMP-01: Disease Overview

## Anxiety Disorders

Anxiety disorders develop when feelings of apprehension and unease persist over an extended period and potentially worsen over time



### Anxiety in numbers



**~40m**  
Suffer from anxiety disorders in the US<sup>1</sup>

**#1**  
Most common mental health disorder in the US<sup>2</sup>

**~\$42bn**  
Annual societal cost of anxiety disorders in the US<sup>3</sup>

### URGENT NEED FOR INNOVATION

- ~18m**

**SAD patients in the US**

Approximately 7.1% of US adults, or ~18 million individuals, suffered from Social Anxiety Disorder (SAD) in the past year<sup>4</sup>
- 69%**

**Moderate to severe impairment is common**

Of adults with SAD in the past year, 30% had serious impairment, 39% had moderate impairment, and 31% had mild impairment<sup>4</sup>
- 35%**

**Low recovery rate**

Only 35% of patients with SAD recovered after 10 years of prospective follow-up<sup>5</sup>
- 0**

**No novel molecules approved for SAD in over 20 years**

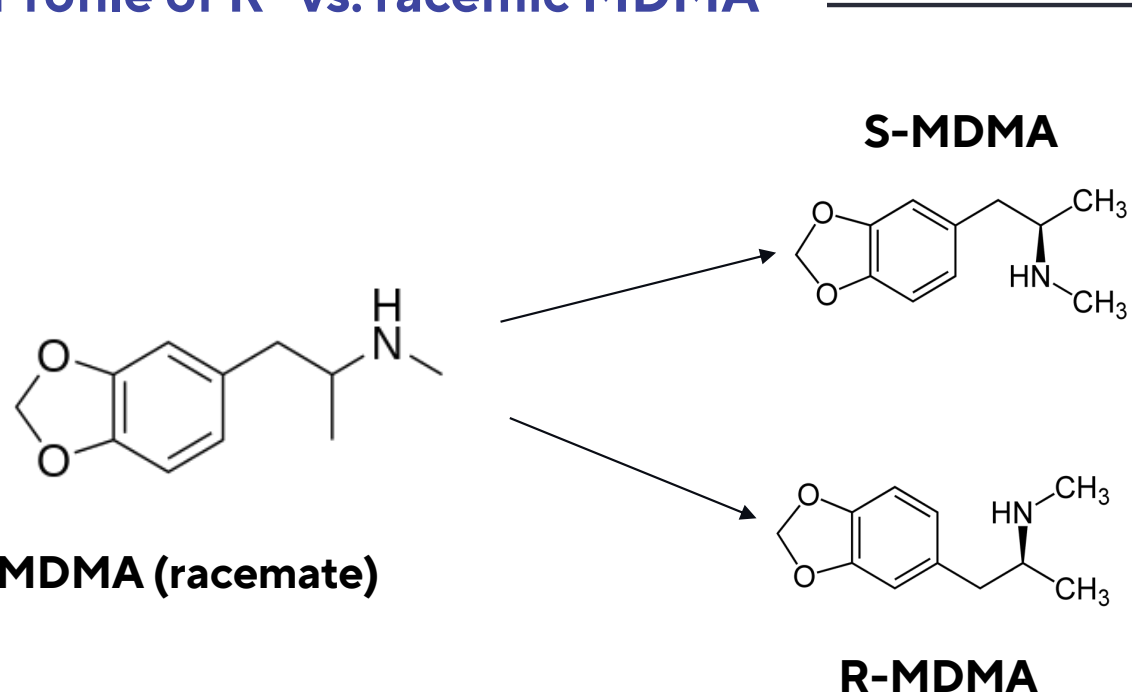
Most recent FDA approvals of novel molecules for SAD were Effexor (2003), Zoloft (2002) and Paxil (1999)<sup>6</sup>

1. Anxiety and Depression Association of America (2021)  
 2. National Alliance on Mental Illness (2021)  
 3. DeVane et al., "Anxiety Disorders in the 21st Century: Status, Challenges, Opportunities, and Comorbidity With Depression", AJMC (2005)  
 4. National Institute of Mental Health  
 5. Keller MB. Social anxiety disorder clinical course and outcome: review of Harvard/Brown Anxiety Research Project (HARP) findings. J Clin Psychiatry. 2006  
 6. GlobalData (as of 06.26.2024).

# EMP-01: Unique Profile of R-MDMA

## R-MDMA unique pharmacological benefits to racemic MDMA, and with a lower risk for adverse effects

### Profile of R- vs. racemic MDMA



Similar to the racemic MDMA, R-MDMA has been shown to **significantly increase social interaction in both animal models and exploratory human studies**<sup>1,2</sup>

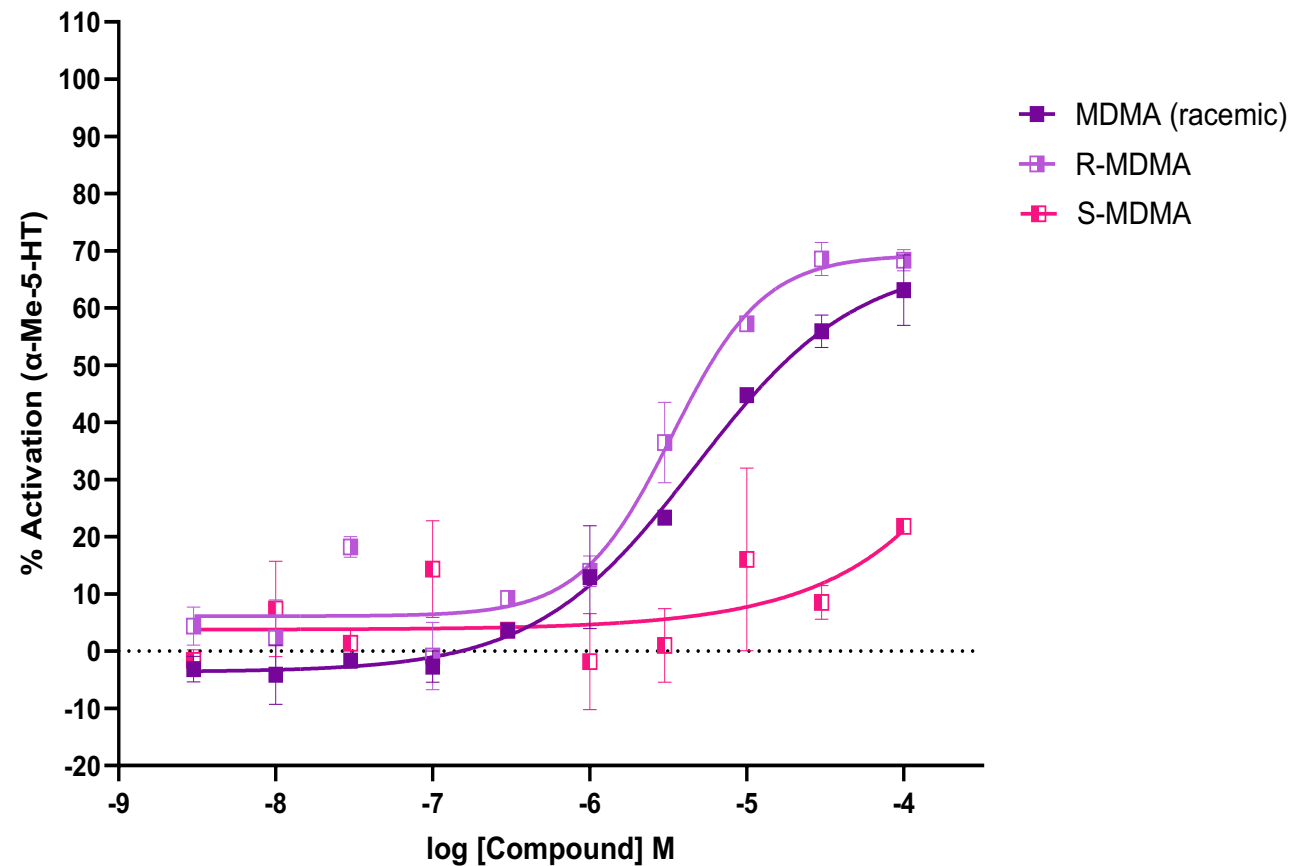
Yet, unlike racemic MDMA, it does not appear to increase locomotor activity, produce signs of neurotoxicity, or increase body temperature in animal models<sup>1</sup>

Differences are hypothesized to arise from:

- R-MDMA has reduced amphetamine-like pharmacology than S-MDMA
- R-MDMA is a partial agonist at 5-HT2A receptors

### Validated unique pharmacology

#### Human 5-HT2A receptor activation study<sup>3</sup>

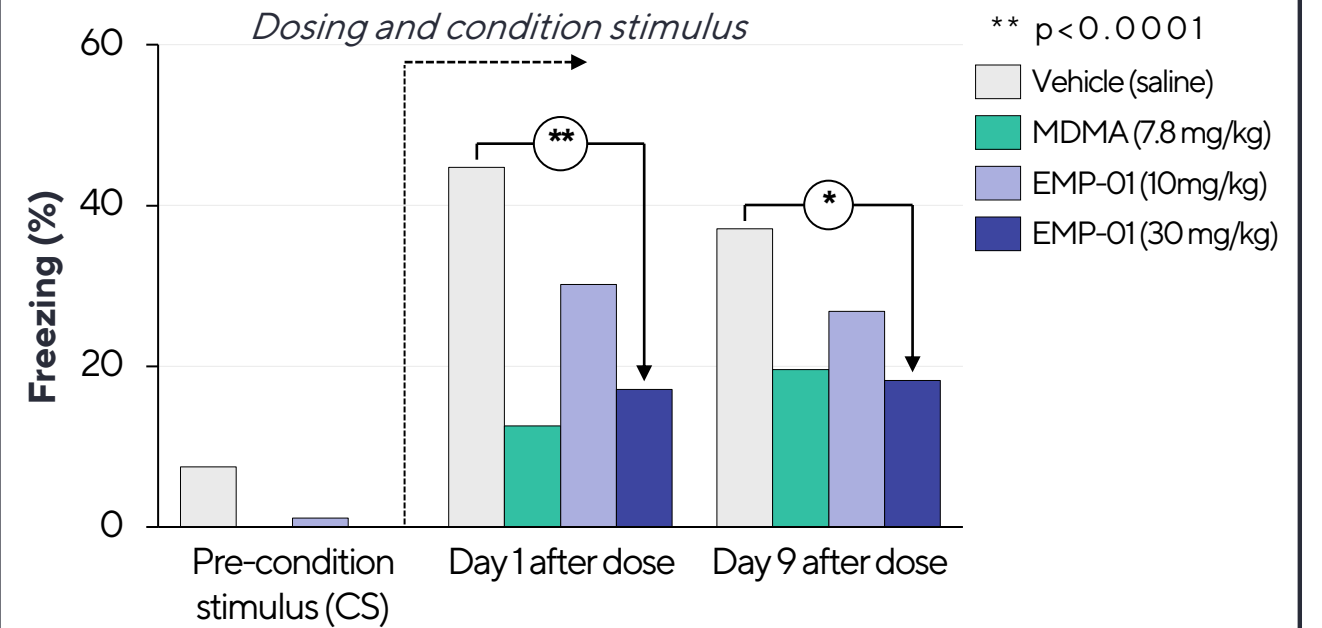


R-MDMA (EMP-01) shows significantly greater activity at the 5-HT2a receptor compared to racemic MDMA and S-MDMA

EMP-01 also demonstrated inducement of a mouse head twitch response, suggesting R-MDMA may generate a more psychedelic-like, internal subjective experience

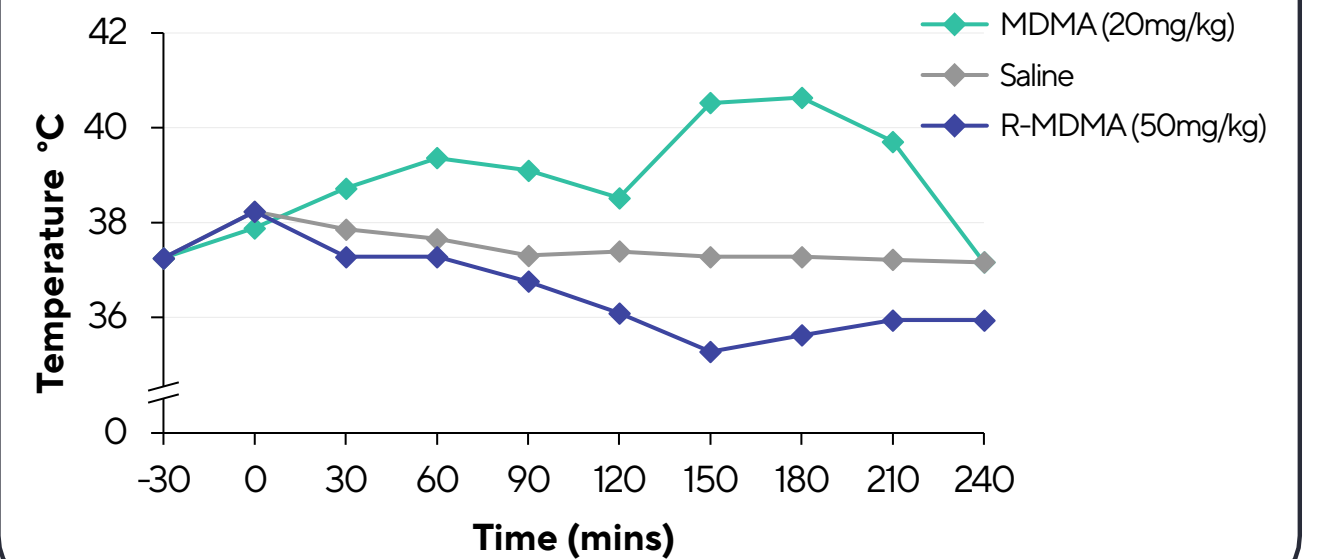
### Efficacy signals with fewer adverse effects

#### Fear Extinction Mice model<sup>4</sup>



#### Effects of racemic MDMA and R-MDMA on body temp<sup>1</sup>

(Third party study)



1. Curry DW, Young MB, Tran AN, Daoud GE, Howell LL. Separating the agony from ecstasy: R(-)-3,4-methylenedioxymethamphetamine has prosocial and therapeutic-like effects without signs of neurotoxicity in mice. *Neuropharmacology*. 2018 Jan  
 2. Danforth AL, Grob CS, Struble C, Feduccia AA, Walker N, Jerome L, Yazar-Klosinski B, Emerson A. Reduction in social anxiety after MDMA-assisted psychotherapy with autistic adults: a randomized, double-blind, placebo-controlled pilot study. *Psychopharmacology (Berl)*. 2018  
 3. CHO-K1 overexpressing human 5-HT2a receptors are incubated with test compound for 1 hour at 37°C, with lithium chloride causing IP1 accumulation upon 5-HT2a agonism  
 4. Fear extinction test models the ability of the compound to facilitate the therapeutic effect of exposure-based therapy; exposure-based therapy is sometimes used in the clinical management of social anxiety disorder



## EMP-01: Phase 1 Results

EMP-01 was generally well tolerated with no severe or serious adverse events observed in a Phase 1 study

### EMP-01 PHASE 1 SAFETY RESULTS<sup>1</sup>

	Placebo N=8	EMP-01 dose (N=24)				Total N=32
		75mg (N=6)	125mg (N=6)	175mg (N=6)	225mg (N=6)	
Participants with at least one drug-related TEAEs <sup>2</sup>	1	2	1	4	6	14
Nausea	1		1	3	3	8
Headache		1			1	2
Vomiting				1	1	2
Fatigue		1		1		2
Pain in jaw				1		1
Dizziness					1	1
Tremor				1		1
Chills					1	1
Feeling hot					1	1
Palpitations		1				1
Bruxism					1	1

### Key Takeaways

- 1 Single-ascending dose, double-blinded, placebo-controlled Phase 1 study enrolling 32 healthy participants and testing EMP-01 or placebo in a 6+2 design
- 2 Observed changes in both pulse and blood pressure were in the expected range and were only slightly dose dependent
- 3 Body temperature remained in the normal range across all cohorts (hyperthermia is a known side effect of racemic MDMA)
- 4 Results from the C-SSRS showed participants experienced no increase in suicidal thoughts, intentions or behaviours
- 5 Only 1/24 participants (4%) experienced bruxism, grinding of teeth, which is a common side effect of racemic MDMA

1. Treatment Emergent Adverse Events (TEAEs) are defined as adverse events that occurred following the first administration of study medication. If a participant has multiple occurrences of a TEAE, the participant is presented only once in the Participant count (n) column for a given Preferred Term.

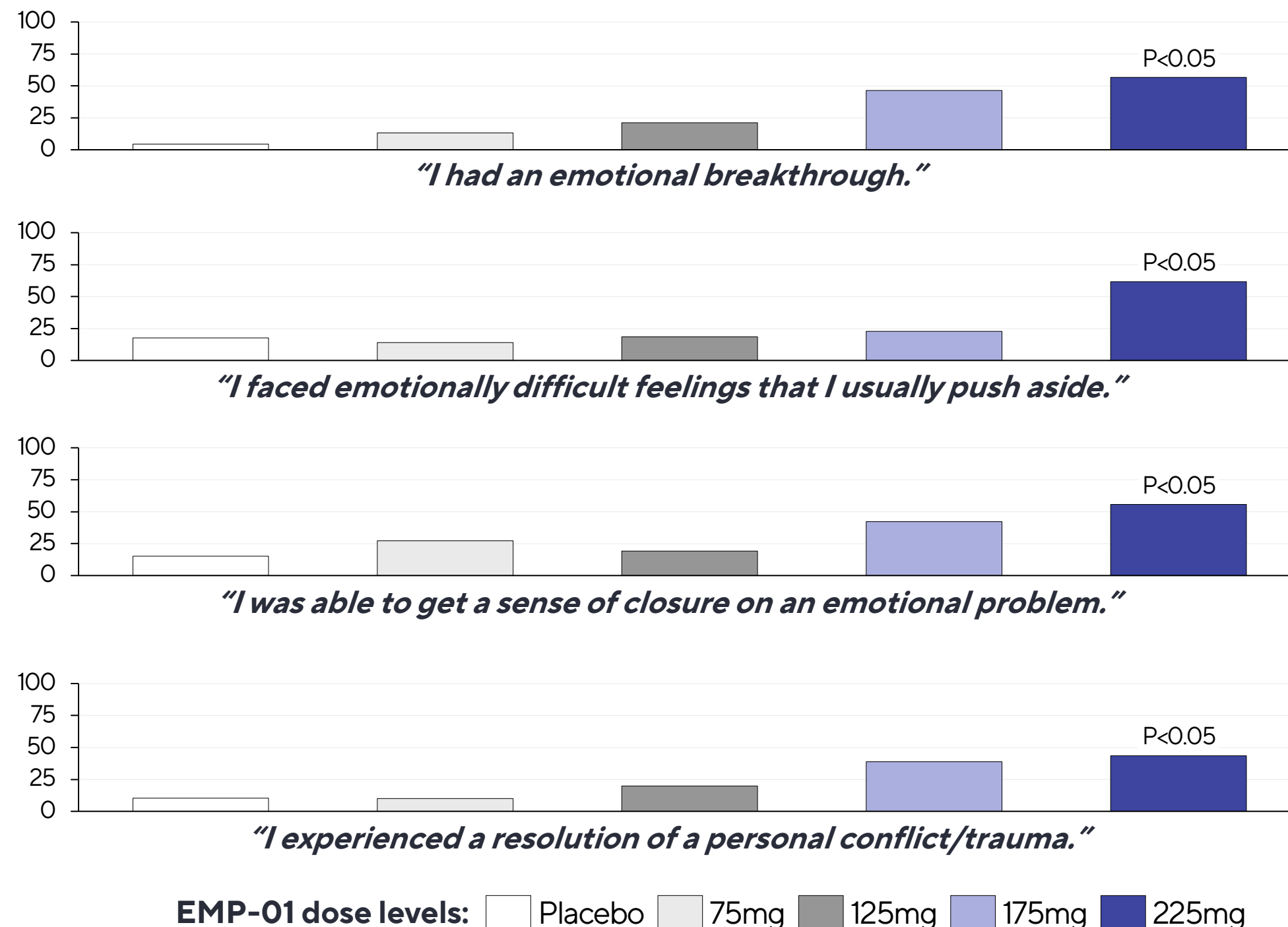
2. Drug related TEAEs defined as any TEAE that was deemed to have either a "possible", "probable" or "definite" relationship to the study drug

## EMP-01: Phase 1 Results

# Dose-dependent increases in acute emotional breakthroughs and increased measures of self-compassion observed at Week 1

### EMP-01 PHASE 1 PHARMACODYNAMIC (PD) RESULTS

Average Emotional Breakthrough Inventory (EBI) scoring on Day 2 after EMP-01 dosing



### Key Takeaways

1

225mg dose of EMP-01 showed statistically significant increases in emotional breakthroughs.

Emotional breakthroughs have been shown to mediate efficacy in depression and anxiety studies involving classical psychedelics<sup>1</sup>

2

Some measures of **self-compassion also significantly increased** with the 225mg dose of EMP-01 at the 1-week follow-up visit

SAD patients report lower levels of self-compassion than healthy controls and social anxiety symptom severity is correlated with lower self-compassion<sup>2</sup>

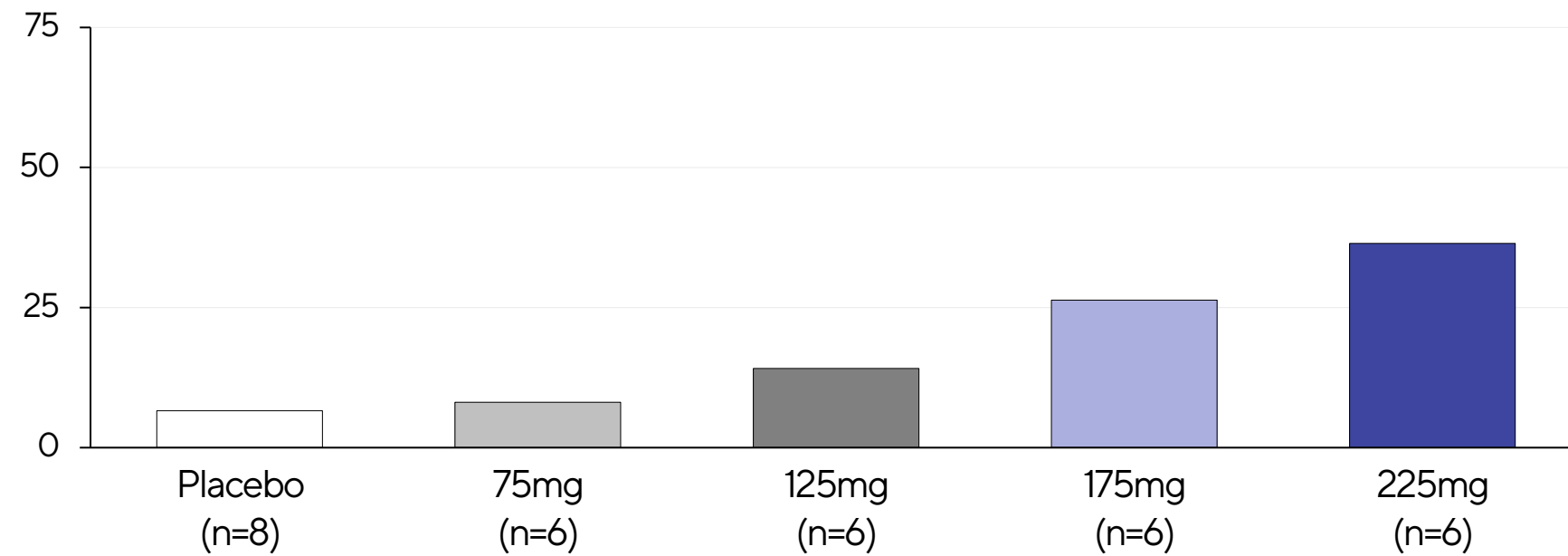
1. GM Goodwin et al, 2022, Roseman et al, 2019, <https://med.uth.edu/psychiatry/2024/04/01/fda-grants-breakthrough-status-to-ldf-formula-and-opens-a-new-frontier-in-the-generalized-anxiety-disorder-gad-treatment/>  
 2. Werner et al, 2012, Blackie and Kovovski, 2018, Madaki and Koszycki, 2020

## EMP-01: Phase 1 Results

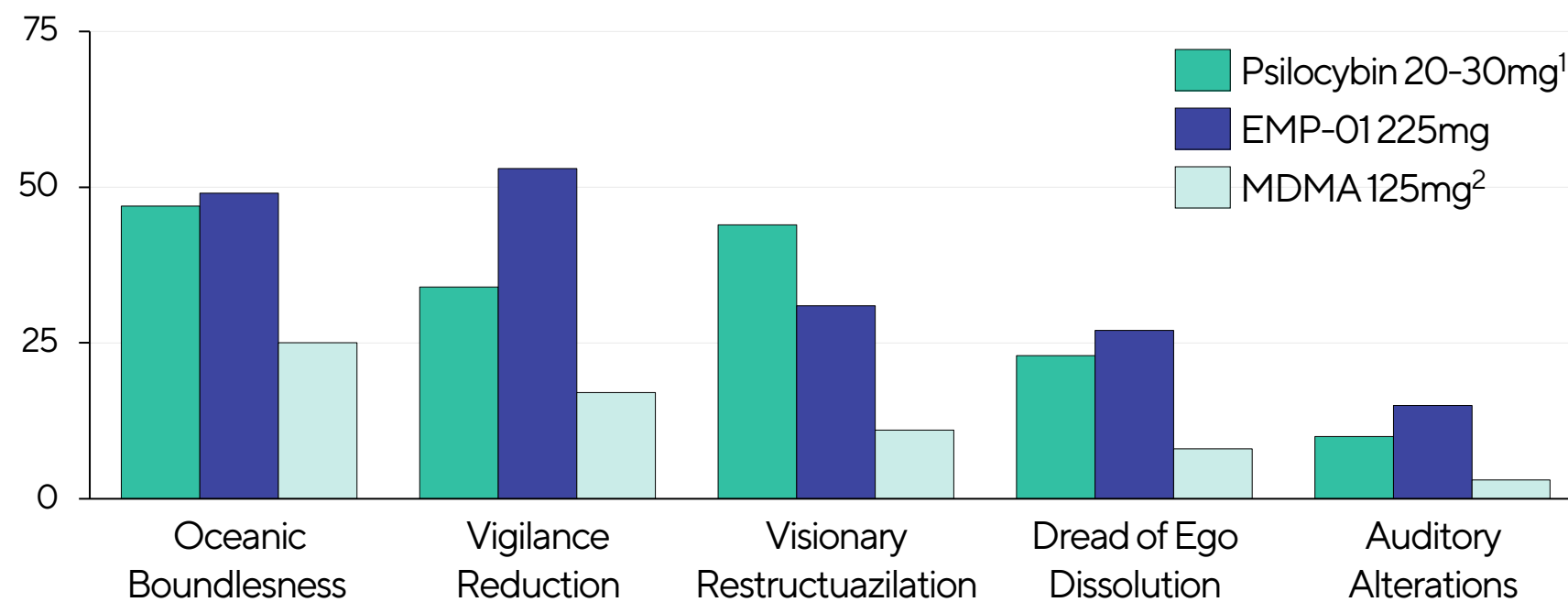
Demonstrated a dose-dependent, psychedelic-like experience with a subjective effect profile more like classical psychedelics than MDMA

### EMP-01 PHASE 1 PHARMACODYNAMIC (PD) RESULTS

Total score on 5D-ASC psychedelic experience questionnaire per dose level



Average score on 5D-ASC psychedelic experience questionnaire per dimension



### Key Takeaways

- 1 EMP-01 demonstrated a unique, dose-dependent subjective effect profile
- 2 The qualitative profile of the effects (based on 5D-ASC questionnaire) were generally found to be more like classical psychedelics (i.e., psilocybin or LSD) than MDMA  
  
Classic psychedelics have also been shown to be effective in treating the symptoms of anxiety<sup>3</sup>, as has MDMA<sup>4</sup>
- 3 Study facilitators reported that EMP-01 appeared to produce a more inward-focused and "peaceful" experience in participants compared to their experience facilitating MDMA therapies

1. Hasler et al, 2004, Vollenweider et al, 2007

2. Holze et al., 2020; Schmid et al., 2021; Angerer et al., 2023; Hysek et al., 2011; Hysek et al., 2012; Hysek et al., 2012

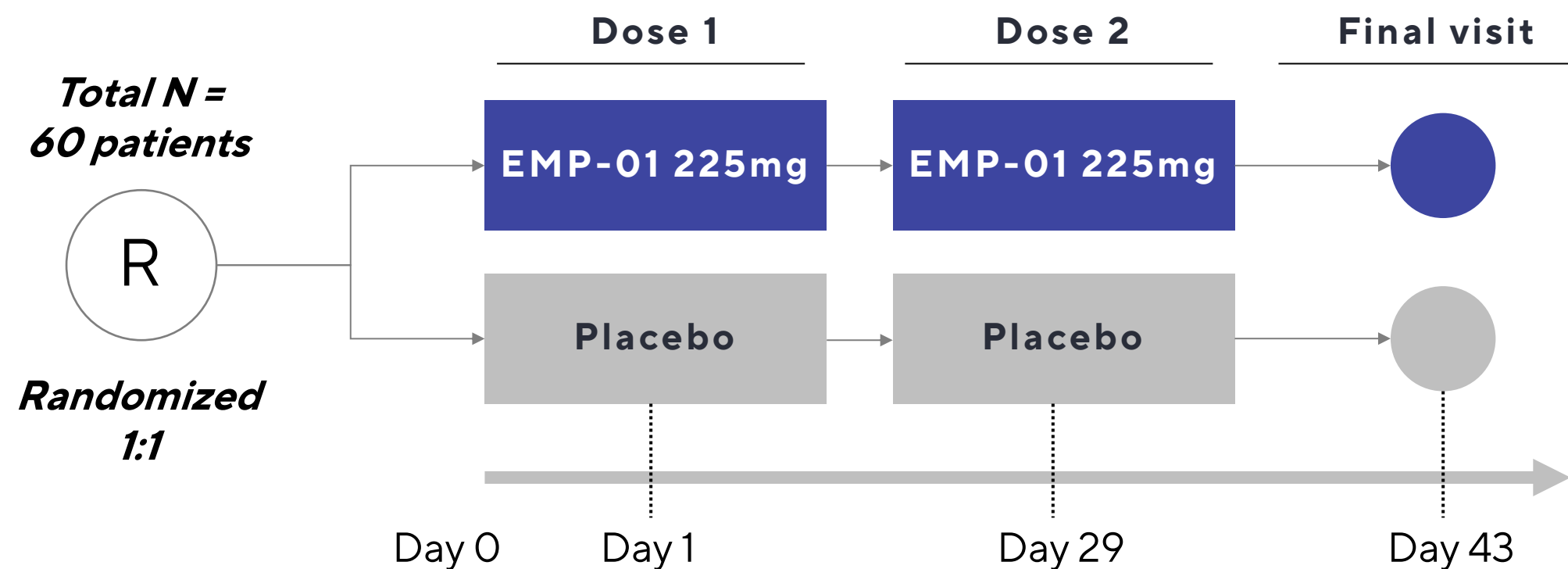
3. Vollenweider FX, Smallridge JW. Classic Psychedelic Drugs: Update on Biological Mechanisms. Pharmacopsychiatry. 2022

4. Danforth AL, Grob CS, Struble C, Feduccia AA, Walker N, Jerome L, Yazar-Klosinski B, Emerson A. Reduction in social anxiety after MDMA-assisted psychotherapy with autistic adults: a randomized, double-blind, placebo-controlled pilot study. Psychopharmacology (Berl). 2018

## EMP-01: Phase 2a Study Design

Exploratory Phase 2a, placebo-controlled study to assess the safety and efficacy of two 225 mg doses in adults with SAD

### EMP-01 PHASE 2A STUDY DESIGN (PRELIMINARY)



#### Study Design:

- Phase 2a, randomized, double-blind, placebo-controlled study
- Adult participants diagnosed with Social Anxiety Disorder (SAD)
- Liebowitz Social Anxiety Scale (LSAS) total score  $\geq 60$  at screening

#### Primary Endpoint:

- Safety and tolerability

#### Other Secondary Endpoints:

- LSAS total score (Baseline to Day 43 Visit)
- Change from Baseline in mean Clinical Global Impression (CGI) severity scores

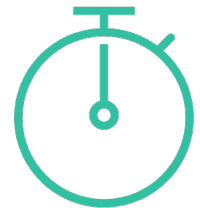
**Trial status:** Trial initiation expected in Q1'25  
Topline data anticipated in Q1'26

# BPL-003 (5-MeO-DMT) for TRD & AUD

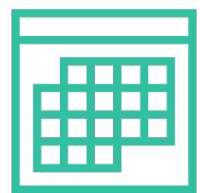
Strategic Investment into Beckley Psytech



# BPL-003 (5-MeO-DMT Nasal Spray) potential to become **first-in-class short-duration psychedelic** treatment with rapid acting and durable antidepressant effects



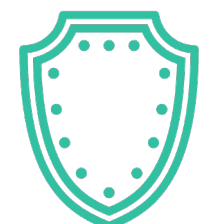
**Short duration of subjective effects:** BPL-003 is a short duration psychedelic, with acute effects resolving in ~2 hours, supporting greater commercial scalability



**Rapid & durable efficacy after a single dose:** In the Phase 2a open-label study in 11 patients, 55% achieved clinical response on Day 2 after a single dose, and this rate of response was maintained at Week 12



**First to market potential:** First short-duration psychedelic to receive FDA Investigational New Drug (IND) approval for a Phase 2 clinical trial



**Patent protected compound:** Issued and pending patents covering 5-MeO-DMT benzoate salt and polymorphs (2040/1 expiry<sup>1</sup>)

1. Exclusive of possible patent term adjustments or extensions or other forms of exclusivity. For additional detail please see the most recent 10-K filing

## BPL-003: Phase 1 Results

BPL-003 had a favorable safety profile and was well-tolerated, with no observed serious or severe adverse events

### BPL-003 PHASE 1 SAFETY DATA

	Placebo N=13	BPL-003 dose (N=31)							Total N=44
		1 mg N=4	2.5 mg N=4	4mg N=4	6 mg N=4	8 mg N=5	10mg N=5	12 mg N=5	
Any TEAEs <sup>1</sup>	2	1	1	4	3	4	2	4	21
Nasal discomfort			1	2	2	2		3	10
Nausea				2	1	2	1	1	7
Vomiting				2		1		2	5
Headache	1			1		2			4
Administration site pain						1	1		2
Chest discomfort						1			1
Dizziness							1		1
Pyrexia	1								1
Gastroenteritis		1							1
Back pain				1					1
Hypoesthesia					1				1
Limb discomfort					1				1
Tremor						1			1
Lacrimation Increased								1	1
Restlessness								1	1

<sup>1</sup> n = number of participants reporting at least one TEAE in that category, % - rounded proportion of cohort total  
Abbreviations: TEAE = Treatment Emergent Adverse Events, ECG = Electrocardiogram, C-SSRS = Columbia-suicide severity rating scale

### Key Takeaways

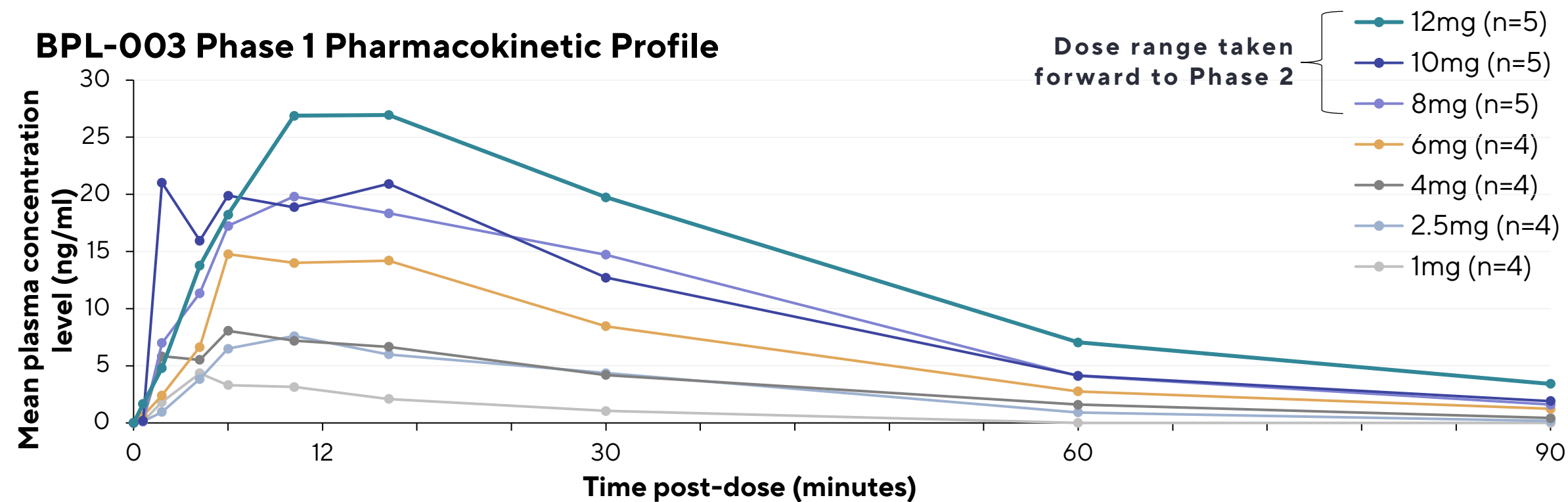
- 1 There were no severe or serious adverse events observed, and 89.5% TEAEs were mild and 10.5% were moderate in severity
- 2 Most common TEAEs (>10%) were nasal discomfort, nausea, vomiting, and headache. TEAEs did not appear to correlate with dose
- 3 There were no clinically significant findings for laboratory parameters, vital signs, ECGs or physical examinations
- 4 Blood pressure and heart rate increases were transient and resolved within 90 min without intervention. None were considered clinically significant.
- 5 Results from the C-SSRS showed participants experienced no increase in suicidal thoughts, intentions or behavior

## BPL-003: Phase 1 results

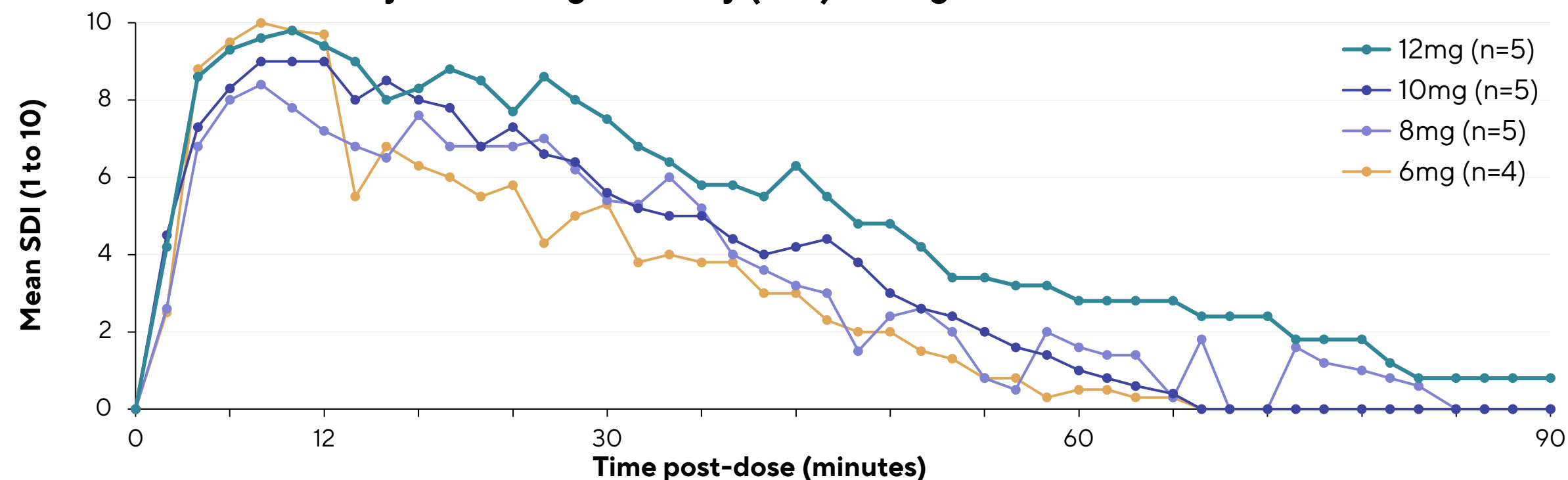
PK/PD results demonstrated a dose proportional profile with perceptual effects generally resolving within 60-90 min

### BPL-003 PHASE 1 RESULTS

#### BPL-003 Phase 1 Pharmacokinetic Profile



#### BPL-003 Phase 1 Subjective Drug Intensity (SDI) Rating



### Key Takeaways

#### Pharmacokinetics (PK)

- Exposure was dose-proportional
- Rapid onset with mean Tmax of 6-17 min
- Mean half life of 15-30 min

#### Pharmacodynamics (PD)

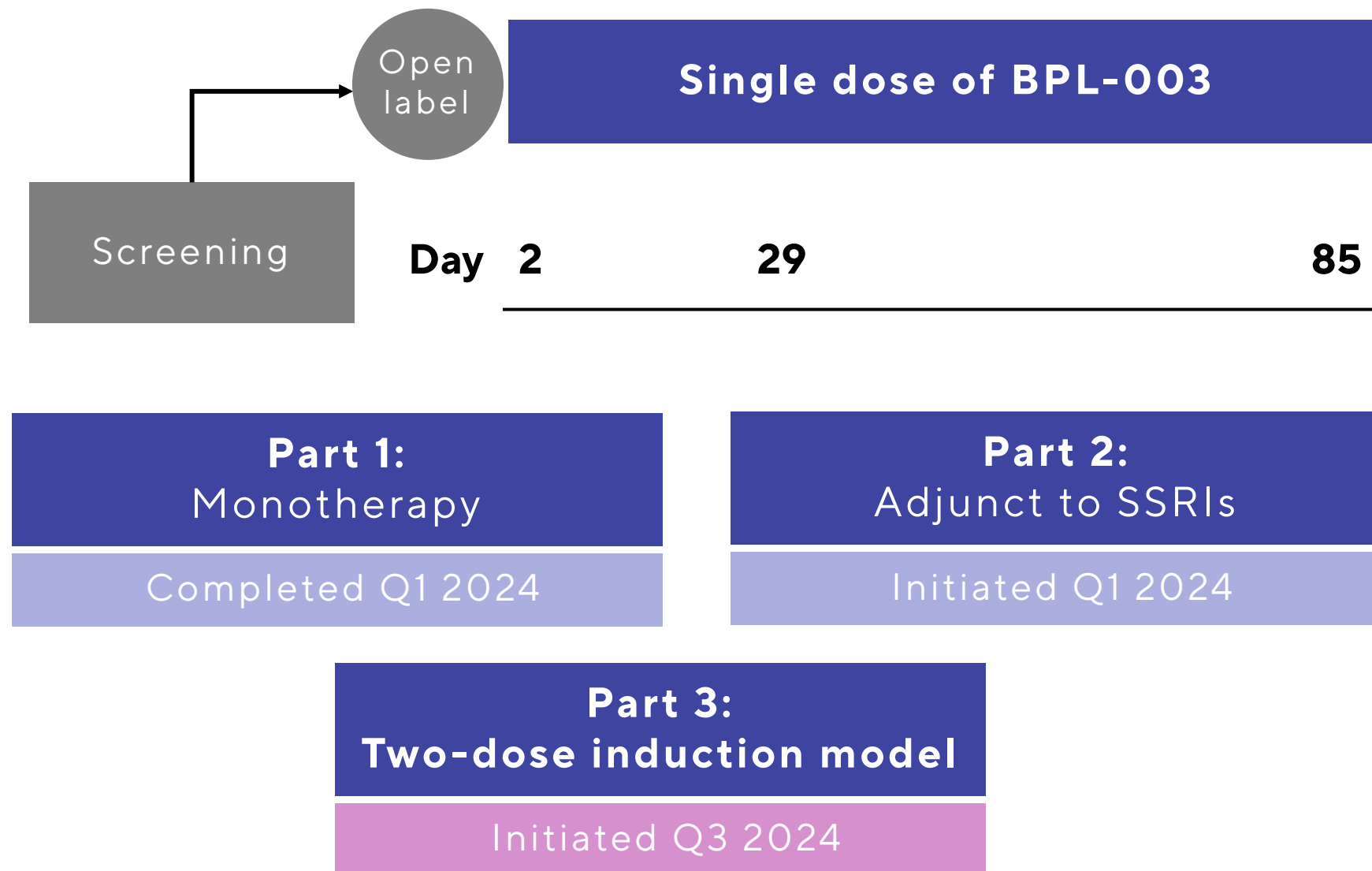
- Participants were psychedelic naive
- All participants on doses  $\geq 6$ mg achieved intensity scores  $\geq 7$
- Perceptual effects generally fully resolved within 60 - 90 mins



## BPL-003: Phase 2a Clinical Trial Design

# Completed Part 1 of an open-label Phase 2a study investigating BPL-003 as a therapy for patients with TRD

### BPL-003 PHASE 2A STUDY DESIGN



### STUDY DETAILS

- Open-label study evaluating a single dose of BPL-003 nasal spray, in patients with moderate-to-severe TRD
- Parts 1 & 3 are in patients not on anti-depressants, Part 2 is in patients who are also taking select SSRIs to explore effects of co-administration
- Psychological support during preparation, dosing and integration

### KEY INCLUSION CRITERIA

- Montgomery-Asberg Depression Rating Scale (MADRS) score  $\geq 24$
- **Part 1 & 3:** willing and able to discontinue current antidepressants
- **Part 2:** on current stable dose of antidepressant SSRI therapy

### KEY OBJECTIVES

#### Primary Endpoint:

- Safety and tolerability of BPL-003

#### Other Secondary Endpoints:

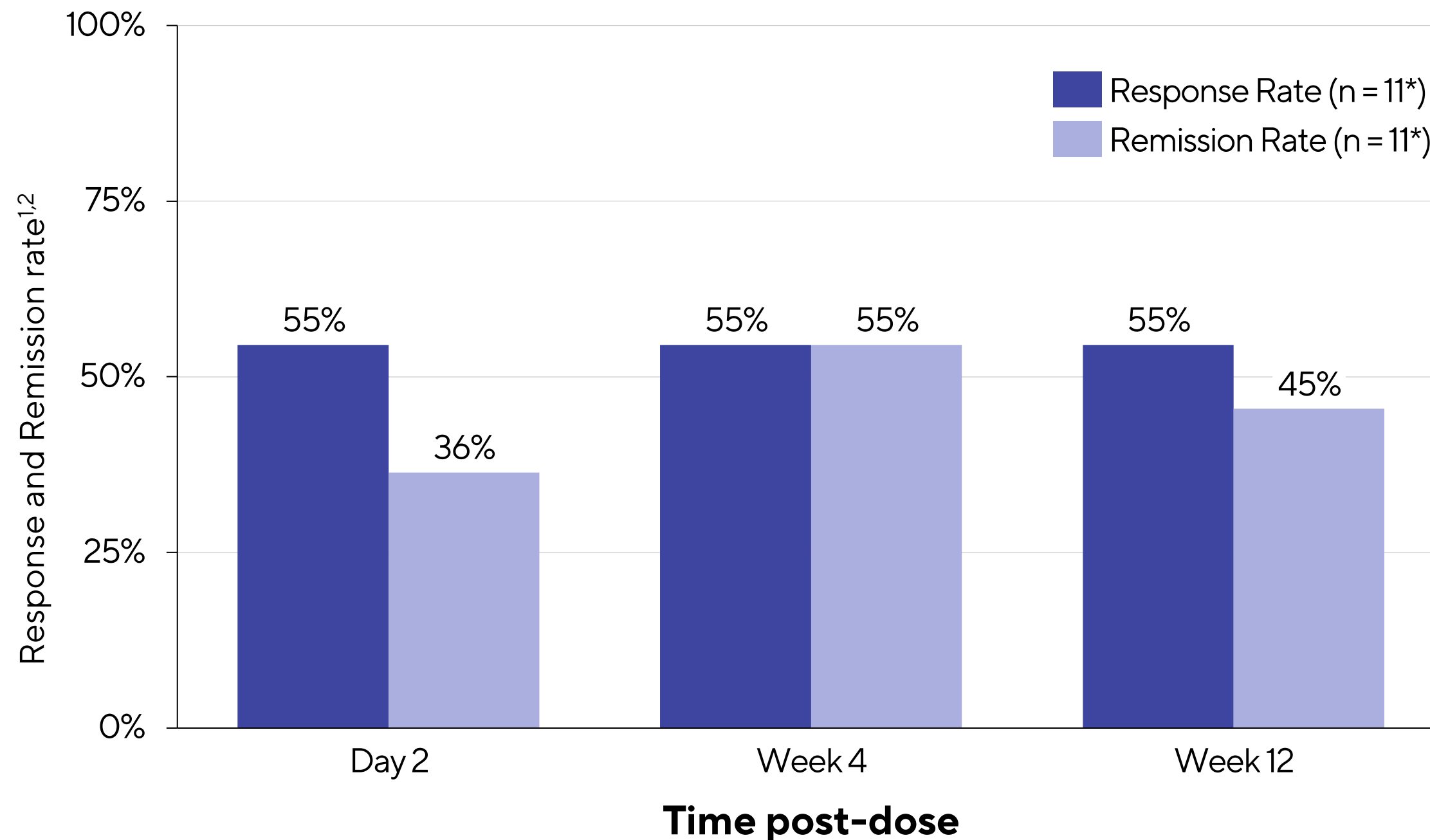
- MADRS change through Week 12
- Remission and response rates through Week 12

## BPL-003: Phase 2a TRD Results

BPL-003 produced meaningful clinical response and durable remission rates after just a single dose, and was generally well-tolerated with no serious adverse events

### BPL-003 PHASE 2A INITIAL RESULTS

Response and remission rate<sup>1</sup> in TRD patients after a single dose of BPL-003



Source: internal Beckley Psytech data

1. Response rate defined as  $\geq 50\%$  reduction in MADRS score and Remission rate defined as MADRS score  $\leq 10$

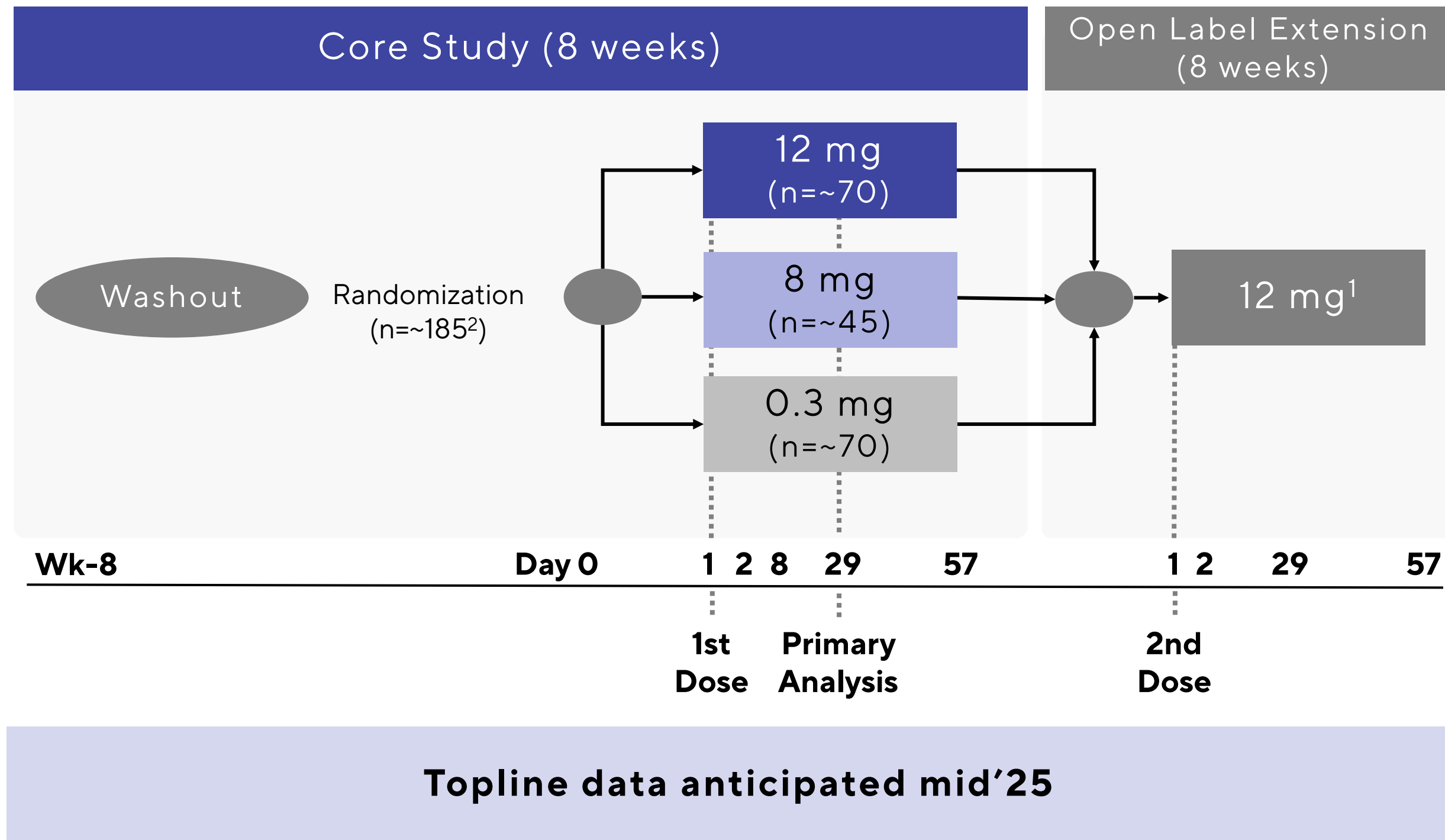
\* Prior to data analysis, one participant (from total of 12 patients) was determined not to meet multiple per protocol eligibility criteria and was excluded from the efficacy analysis.

### Key Takeaways

- 1 55% of patients achieved clinical response on Day 2 and this rate of response was maintained at Week 12
- 2 At Week 4, 55% of patients achieved both clinical remission and response
- 3 Acute effects resolved within an average time of less than 2 hours
- 4 Most common AEs ( $>10\%$ ) were nasal discomfort, headaches, nausea and vomiting, broadly consistent with Phase 1 findings

## BPL-003: Phase 2b clinical trial design

# BPL-003 randomized, quadruple-masked, monotherapy Phase 2 study in moderate to severe TRD patients



### KEY INCLUSION CRITERIA

- Patients with moderate to severe TRD
- Hamilton Depression Scale (HAM-D)  $\geq 19$
- Willing and able to discontinue current antidepressants

### KEY OBJECTIVES

#### Primary Endpoint:

- MADRS change from baseline at Week 4, 12mg vs. 0.3mg

#### Other Secondary Endpoints:

- MADRS change from baseline at Day 2, Wk 1 & Wk 8
- MADRS change from baseline for 8mg vs 0.3mg
- CGI-S, PGIC, EQ-5D

<sup>1</sup> Patients entering the open-label extension are randomized to receive either a single 12mg dose or a biphasic 4mg and 8mg dose approximately 10 minutes apart. <sup>2</sup>Total N changed due to an adjustment in the randomization ratio and lower than anticipated dropout rate  
Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; CGI-S = Clinical Global Impressions-Severity; PGIC = Patient's Global Impression of Change; EQ-5D = EuroQol-5D

# RL-007 for Cognitive Impairment



RL-007 is a potential **pro-cognitive neuromodulator**, investigated in >500 participants and demonstrating consistent cognitive effects and good tolerability



**Significant unmet need:** currently, no approved treatments for lead CIAS indication



**Reproducibility of effect:** Pro-cognitive effects demonstrated in two Phase 1 and two Phase 2 trials



**Tolerability:** No drug-related serious adverse events in over 500 study participant exposures and minimal potential for drug-drug interactions (DDIs)



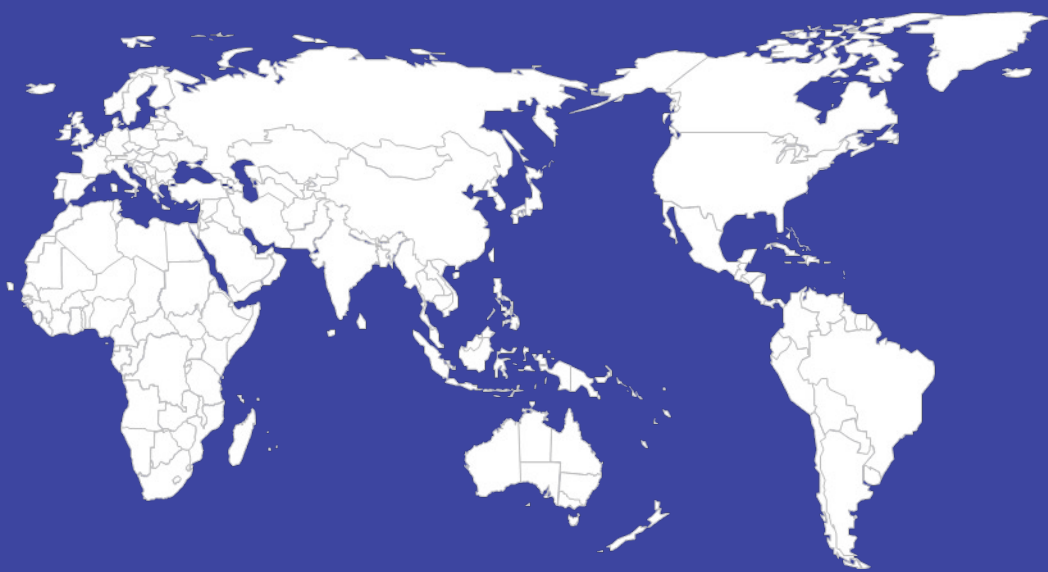
**Add-on therapy to standard of care:** clean DDI profile means it can likely be administered as an adjunctive to standard of care atypical antipsychotics

## RL-007: Disease Overview

# CIAS & Schizophrenia

Cognitive impairment associated with schizophrenia (CIAS) is a core feature of schizophrenia, accounts for much of the impaired functioning associated with the disorder and is not responsive to existing treatments

### CIAS & Schizophrenia in numbers



~24m

Global sufferers of Schizophrenia<sup>1</sup>

15th

Leading cause of disability worldwide (2016)<sup>2</sup>

~\$155bn

U.S. economic burden from adults with CIAS or Schizophrenia (direct + indirect costs)<sup>3</sup>

### URGENT NEED FOR INNOVATION

~80%

#### Cognitive impairment is very common<sup>4</sup>

Cognitive impairment is a common and major cause of disability in schizophrenia, with more than 80% of patients showing significant impairment

~10%

#### Schizophrenia patient employment rate

Five years following diagnosis, only 10% of schizophrenia patients have employment; being unemployed is primarily related to lower cognitive and social functioning<sup>5</sup>

0

#### FDA approvals for CIAS

As of November 2024, there are no FDA approved treatments for CIAS<sup>6</sup>

1. World Health Organization

2. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016

3. Cloutier et al, The economic burden of schizophrenia in the United States in 2013. J Clin Psychiatry 2016;77(6):764-771

4. Bora et al, Cognitive Impairment in Schizophrenia and Affective Psychoses: Implications for DSM-V Criteria and Beyond

5. Holm M et al, Employment among people with schizophrenia or bipolar disorder. 2021

6. GlobalData (as of 11/15/2022)

## RL-007: Phase 2a Results

# Demonstrated potential to improve cognitive signals on a subset of MCCB neurocognitive endpoints

### PHASE 2A TRIAL - EFFICACY DATA ON COMPONENTS MCCB COMPOSITE

T-Scores (Normalized for age, gender, and education level)



### Key Takeaways

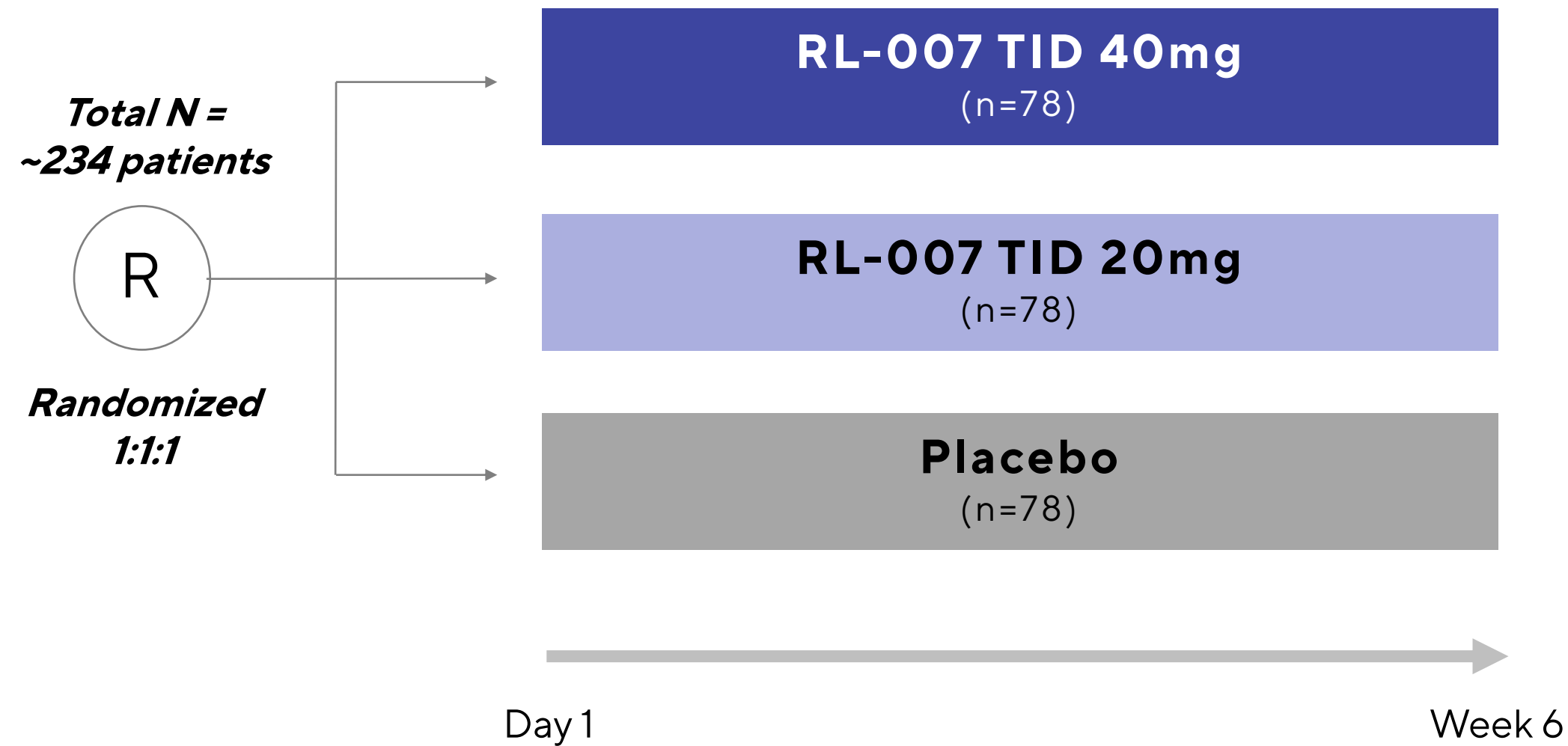
- 1 Cognitive function was assessed in 31 patients with CIAS across four cohorts (10, 20, 40 & 80mg). Patients received four doses of placebo followed by six doses of RL-007 over 4-days<sup>1</sup>
- 2 Study demonstrated dose-related trends for improvements on each MCCB sub-component neurocognitive test completed: Hopkins Verbal Learning Test, BACS Symbol Coding & Category Fluency
- 3 On the BACS Symbol Coding test, the best correlate of the MCCB total score, a Cohen's d effect size of 0.79 and 0.56 was seen at the 20mg and 40mg doses respectively versus placebo
- 4 qEEG data also demonstrated increases in amplitude in the alpha band and in the alpha-slow wave index, markers of alertness believed to correlate with aspects of cognition.

1. Day 2 "pre-RL-007" was compared to Day 4 "post-RL-007"  
 Abbreviations: MCCB = MATRICS™ Consensus Cognitive Battery

## RL-007: Phase 2b Study Design

A randomized, placebo-controlled study of RL-007 is currently underway in ~234 patients with CIAS with topline data anticipated in mid'2025

### PHASE 2B STUDY DESIGN



#### Primary Endpoint:

- MCCB neurocognitive composite score at Week 6

#### Other Secondary Endpoints:

- Select Individual Components of MCCB, including BACS Symbol Coding
- Clinical Global Impression Score

**Trial status:** First patient dosed in 1Q'23,  
Topline data anticipated mid'25





Nasdaq: ATAI

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