



**EMP-01 (R-MDMA)  
Phase 2a Top Line Results in  
Social Anxiety Disorder  
(SAD)**

**February 26, 2026**

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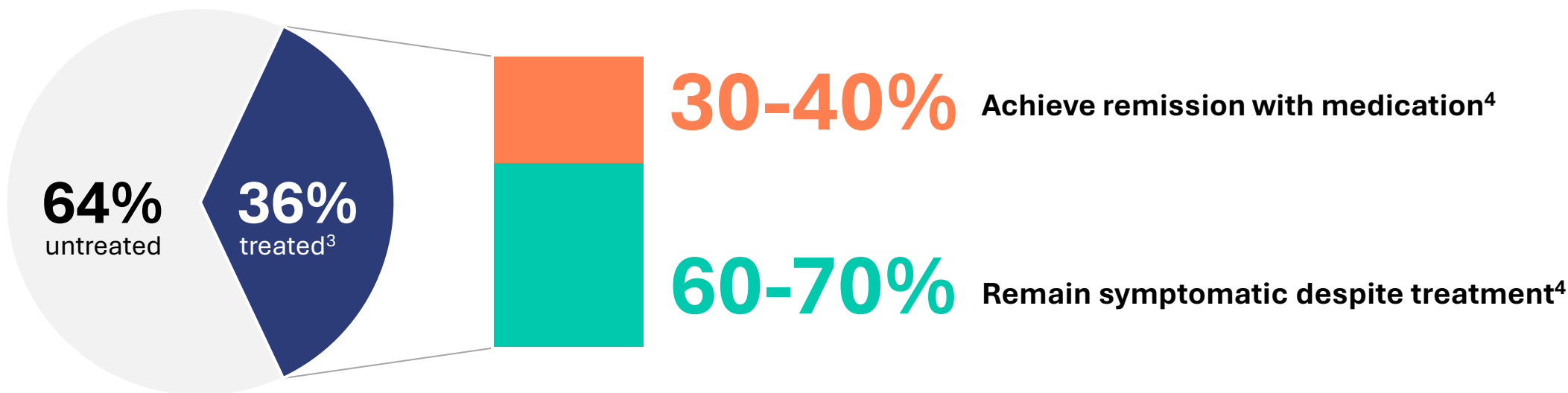
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# Social anxiety disorder (SAD) is one of the most common psychiatric disorders, affecting an estimated ~32M adults in the US<sup>1</sup>

**12%** Lifetime prevalence in the US<sup>2</sup>  
(affects 5-6x more people than TRD)

**0** Novel molecules for SAD in 20+ years

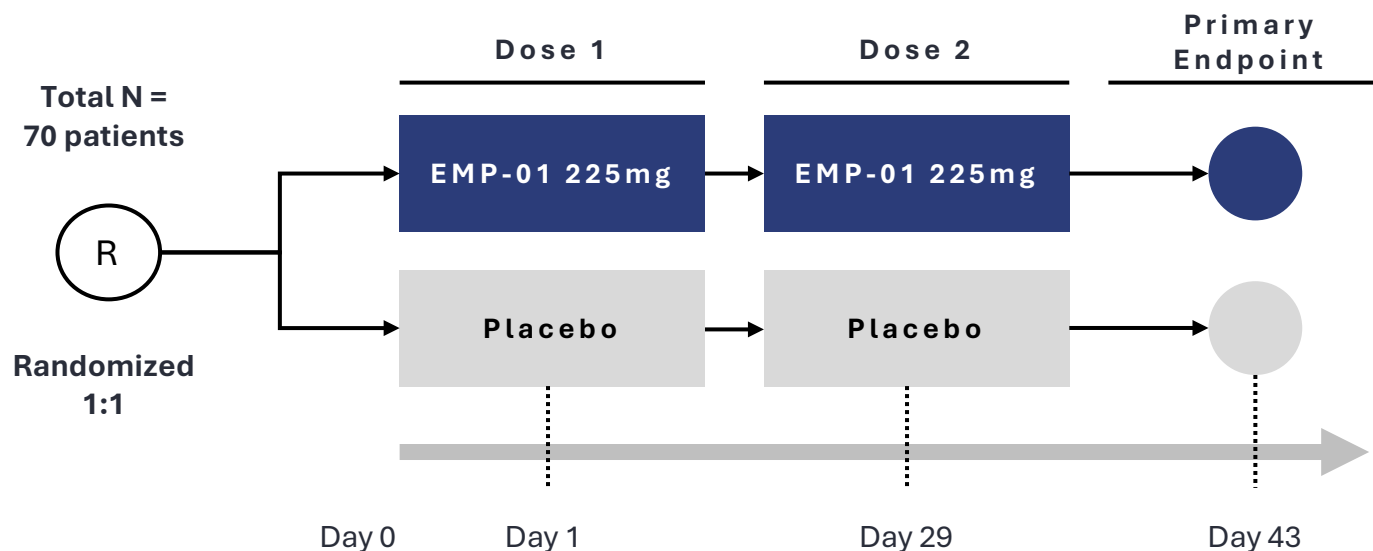


**Less than half of patients receive any type of treatment for SAD, with limited relief as current treatments provide only moderate efficacy and slow-onset improvement with most patients failing to achieve full remission**

# Exploratory Phase 2a, randomized, placebo-controlled study assessing safety, tolerability, and efficacy of 2 doses of EMP-01 in 70 adults with SAD

## Study Endpoints

### EMP-01 Phase 2a Study Design



#### 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  $\geq 70$  at screening

#### Primary Endpoint:

- Safety and tolerability (baseline to Day 43)

#### Secondary Endpoint:

- Change in LSAS total score (baseline to Day 43)

#### Exploratory Endpoints:

- Subjective drug effects scales
- Change from baseline in clinician and patient rated anxiety, depression, and health status scales and proportion of treatment responders
- PK of EMP-01 and its metabolites

# Baseline characteristics were well balanced across arms

Population: ITT

Characteristic	Placebo (N=36)	EMP-01 225mg (N=35)	Overall (N=71)
<b>Age</b> mean (SD)	33.7 (9.1)	34.0 (11.2)	33.9 (10.1)
Age range	20-54	20-59	20-59
<b>Sex</b>			
Female n (%)	16 (44.4)	18 (51.4)	34 (47.9)
Male n (%)	20 (55.6)	17 (48.6)	37 (52.1)
<b>Ethnicity</b>			
Hispanic or Latino n (%)	2 (5.6)	0	2 (2.8)
Not Hispanic or Latino n (%)	34 (94.4)	34 (97.1)	68 (95.8)
Not Reported n (%)	0	1 (2.9)	1 (1.4)
<b>BMI</b> Mean (SD)	25.3 (3.6)	26.3 (3.5)	25.8 (3.5)
<b>Baseline LSAS Total Score (0-144)</b> Mean (SD)	108.3 (16.72)	108.4 (16.71)	108.4 (16.60)
Baseline LSAS range	77-139	72-134	72-139
<b>Prior medications</b> total n (%)	16 (44.4)	13 (37.1)	29 (40.8)
SSRI n (%)	13 (36.1)	8 (22.9)	21 (29.6)
SNRI n (%)	2 (5.6)	1 (2.9)	3 (4.2)
Beta Blockers n (%)	6 (16.7)	7 (20.0)	13 (18.3)

Source: Table 14.1.1.6 Demographics and Baseline Characteristics (Intent-to-Treat Population). Abbreviations: BMI=Body Mass Index; CGI-S = Clinical Global Impression-Severity; LSAS = Liebowitz Social Anxiety Scale; SD = Standard Deviation; SNRI = Serotonin-Norepinephrine Reuptake Inhibitor; SSRI = Selective Serotonin Reuptake Inhibitor; ITT: Intent to treat population

# Generally favorable and manageable safety and tolerability profile

Characteristic	Placebo (N=35)	EMP-01 225mg (N=35)	Overall (N=70)
Any TEAE n (%)	27 (77.1)	35 (100.0)	62 (88.6)
<b>Any Serious TEAE n (%)</b>	<b>0</b>	<b>0</b>	<b>0</b>
Any <b>Drug-Related TEAE</b> n (%)	17 (48.6)	35 (100.0)	52 (74.3)
<b>Maximum Severity</b>			
Mild	23 (65.7)	14 (40.0)	37 (52.9)
Moderate	4 (11.4)	21 (60.0)	25 (35.7)
<b>Severe</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Related TEAEs Leading to Discontinuation</b>			
≥1 related-TEAE leading to treatment discontinuation	0	3 (9%)**	3
≥1 related-TEAE leading to study discontinuation	<b>0</b>	<b>0</b>	<b>0</b>

## Takeaways

- Well-tolerated safety profile
- No severe or serious TEAEs
- All TEAEs were mild to moderate
- No suicidal intent or behavior reported during the study
- Low mean CEQ scores confirm that participants did not report meaningfully challenging or unpleasant subjective experiences

Source: 14.3.1.1 Summary of All TEAEs with Risk Differences (Safety Population), Source: Table 14.3.1.7 Incidence of TEAEs by Maximum Severity, System Organ Class and Preferred Term (Safety Population). <sup>1</sup> 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. \*\* N=3: n=2 Elevated blood pressure, n=1 Suicidal ideation. Abbreviations: TEAE = Treatment-Emergent Adverse Event; AESI = Adverse Event of Special Interest; CEQ = Challenging Experience and Questionnaire

## Drug-related TEAEs were in line with expected psychedelic profile

Drug-related TEAEs excluding AESIs (>15%), n (%)	Placebo (N=35)	EMP-01 225mg (N=35)
Nausea	1 (2.9)	21 (60.0)
Headache	8 (22.9)	17 (48.6)
Fatigue	4 (11.4)	15 (42.9)
Dizziness	1 (2.9)	13 (37.1)
Decreased Appetite	0	10 (28.6)
Palpitations	0	9 (25.7)
Vomiting	0	8 (22.9)
Paraesthesia	0	8 (22.9)
Hyperhidrosis	0	7 (20.0)
Bruxism	0	6 (17.1)
Vision Blurred	0	6 (17.1)

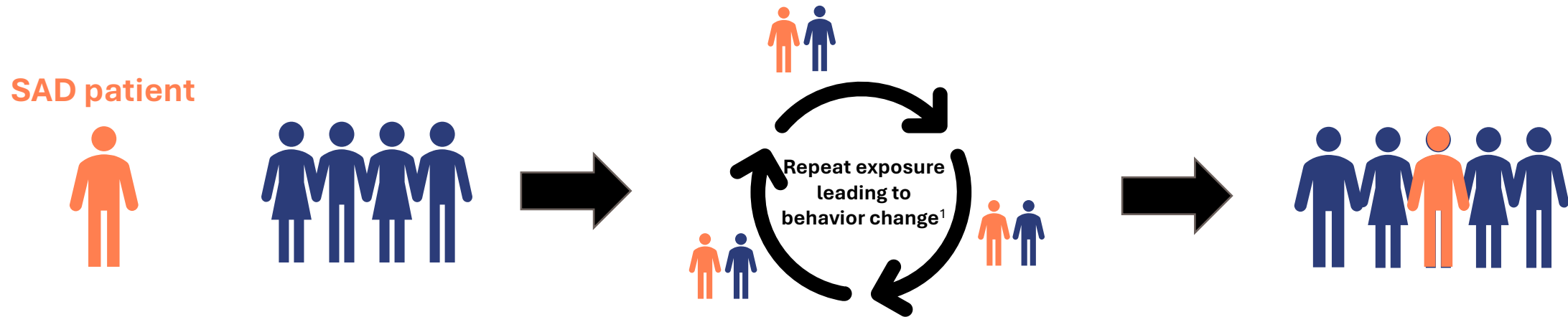
**AESIs reflected expected psychedelic-related experiences, were transient, and all mild/moderate**

**Common psychedelic drug-related AESIs (>15%):**

- Feeling of relaxation
- Sensory disturbance
- Hallucination, visual
- Illusion
- Euphoric mood
- Anxiety
- Somnolence
- Disinhibition

Source: Safety: Table 2. Incidence of Common (≥15%) Non-Serious TEAEs by System Organ Class and Preferred Term (Population: Safety), Source: Safety: 14.3.1.8 Incidence of TEAEs by Strongest Relationship, System Organ Class and Preferred Term (Population: Safety). <sup>1</sup> 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. Common=≥10% incidence. Drug-related=probable and/or related. Abbreviations: TEAE = Treatment-Emergent Adverse Event; AESI = Adverse Event of Special Interest

# Treatment is difficult for SAD patients to engage with as it requires repeat exposure to social situations



Unique opportunity for EMP-01 to support mindset shift to engage in disease modifying treatment

# Efficacy: EMP-01 showed clinically meaningful improvement across the LSAS

Population: mITT (n=70)

MMRM (Baseline to Day 43)	Placebo (N=35)	EMP-01 225mg (N=35)
<b>LS Mean (Standard Error)</b>	-16.67 (4.54)	-28.53 (4.64)
95% CI	-25.7, -7.6	-37.8, -19.3
<b>LS Mean Treatment Difference (LSMD)</b>		<b>-11.85</b>
<b>p-value (one-tailed)</b>		<b>0.036</b>
<b>Standardized Effect Size</b>		<b>-0.45</b>

## Meaningful improvements observed across both fear and avoidance domains

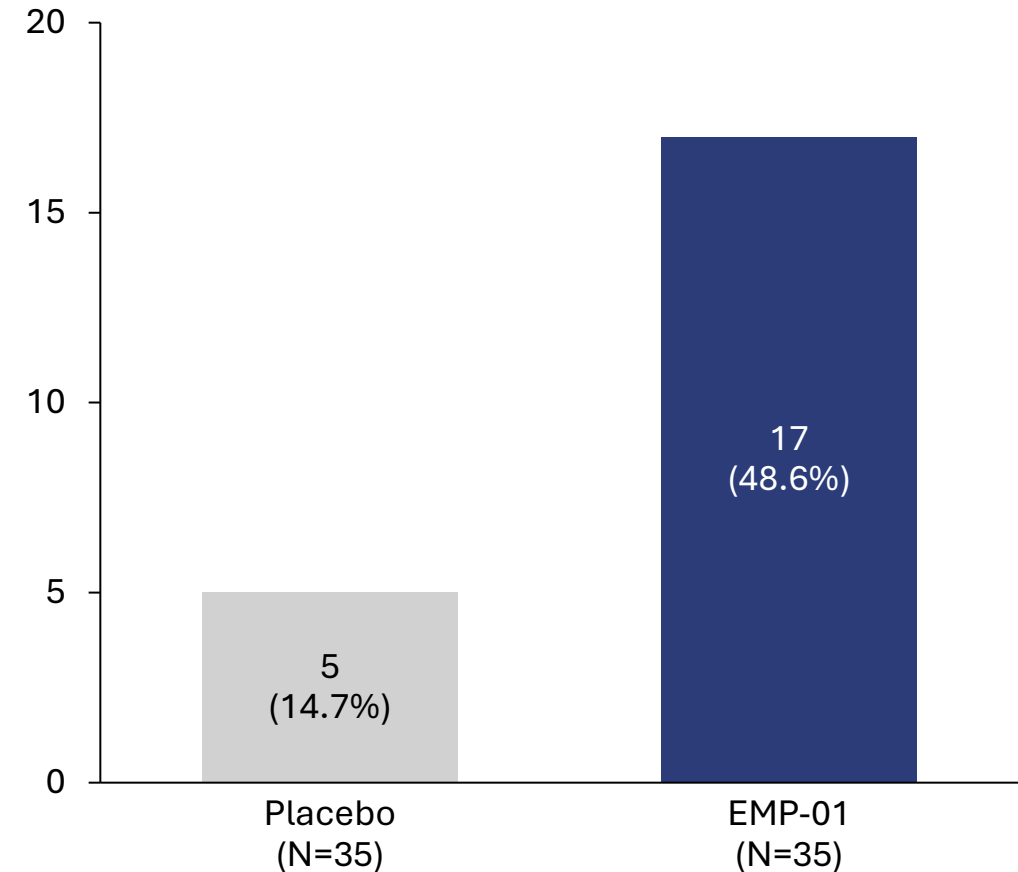
LSAS Sub-Scale Scores Mean (SD) %	Placebo (N=35)	EMP-01 225mg (N=35)
<b>Change From Baseline To Day 43</b>		
Fear Total	-8.1 (11.87) -15.45%	-13.7 (13.63) -25.39%
Avoidance Total	-8.5 (12.04) -17.1%	-15.1 (14.91) -28.6%
Fear Social Interactions	3.8 (5.28) -15.8%	-7.0 (6.97) -26.9%
Avoidance Social Interactions	-4.6 (5.65) -18.32%	-8.14 (7.23) -31.85%
Fear Performance	-4.3 (6.85) -15.1%	-6.69 (7.12) -23.6%
Avoidance Performance	-3.9 (6.75) -15.7%	-7.0 (8.18) -24.9%

# CGI-I responder analysis supported LSAS findings

## Treatment Response (CGI-I = 1 or 2)

CGI-I Responder	Placebo (N=35 <sup>1</sup> )	EMP-01 225mg (N=35)
Yes n (%)	5 (14.7)	<b>17 (48.6)</b>
No n (%)	29 (85.3)	18 (51.4)
Risk Difference (95% CI)		33.87% (13.47, 54.26)
<b>Number Needed to Treat (95% CI)</b>		<b>2.95 (1.84, 7.42)</b>

## CGI Responders (Score ≤ 2) at Day 43



1. One patient in the placebo arm had a missing value at Day 43 on the CGI-I Responder Assessment. Abbreviations: CGI-I = Clinical Global Impression-Improvement; CI = Confidence Interval; LSAS = Liebowitz Social Anxiety Scale

# EMP-01-201: Clinical activity benchmarking vs. approved SAD therapies

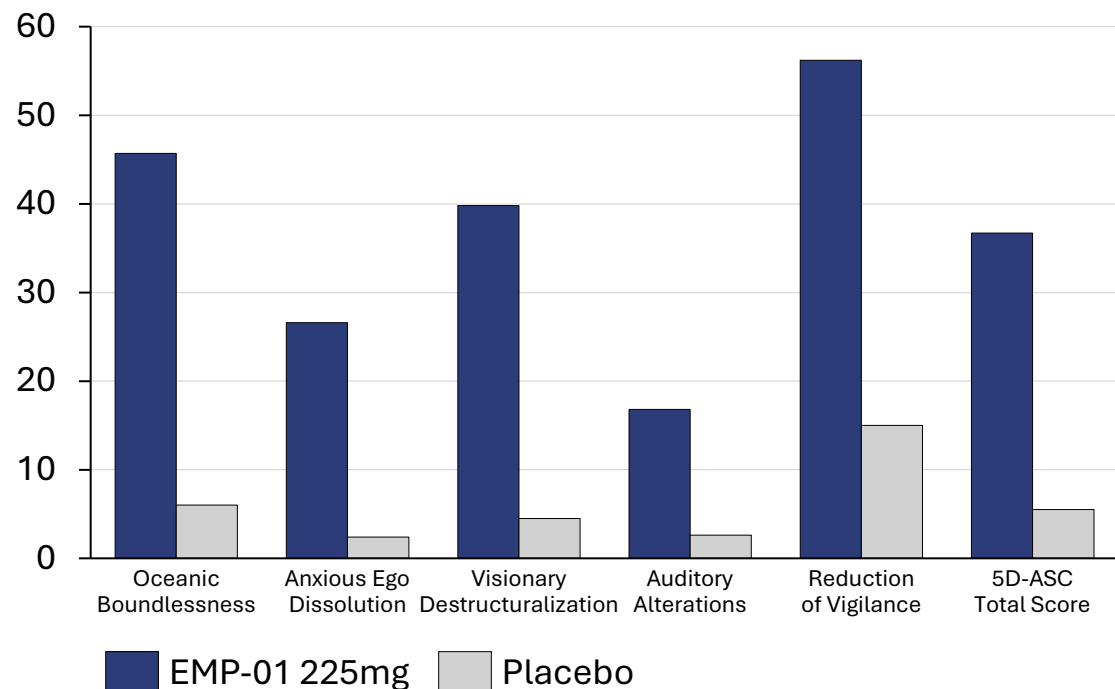
Drug / Trial	Baseline LSAS	LSAS LS Mean Difference vs. Placebo	CGI-I Responders (RR)	Effect Size (Hedges' g)	NNT
<b>EMP-01</b>	<b>108.4</b> <b>N=71</b>	<b>-11.85</b> <b>(CI: -24.8, 1.1)</b>	<b>RR: 3.31</b>	<b>0.45</b>	<b>2.95</b>
<b>SSRIs for SAD</b>	74-96 24 studies <sup>1</sup>	-10.14 <sup>1</sup>	RR: 1.65 <sup>1</sup>	0.39 <sup>2</sup>	3.7 <sup>3</sup>
<b>SNRIs for SAD</b>	86-89 4 studies <sup>1</sup>	-11.91 <sup>1</sup>	RR: 1.30 <sup>1</sup>	0.45 <sup>2</sup>	4.6 <sup>4</sup>
<b>Psychotherapy/ CBT</b>				0.48 <sup>5</sup>	3.8 <sup>6</sup>

\*FOR ILLUSTRATIVE PURPOSES ONLY - no head-to-head study has been conducted comparing EMP-01 against any other candidates or products, and differences exist between study designs, patient populations and other factors. Caution should be exercised when comparing results across unrelated studies or trials.

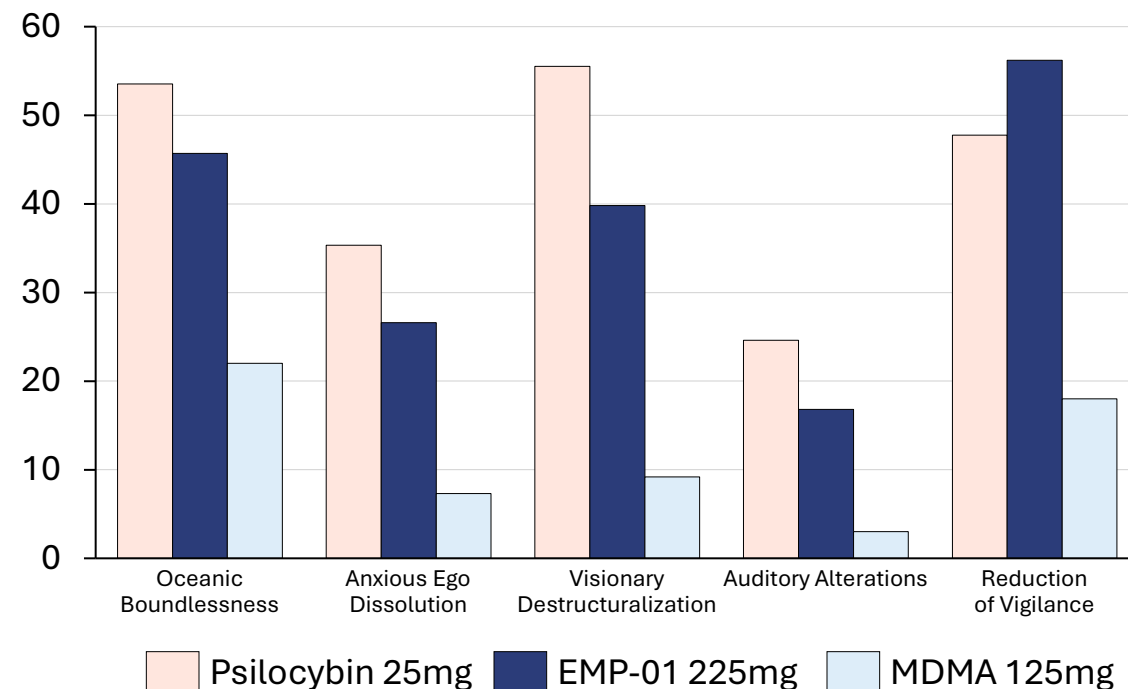
Sources: 1. Williams et al., *Pharmacotherapy for social anxiety disorder (SAD) (Review)*. (2017). 2. Davis et al., *Update on the efficacy of pharmacotherapy for social anxiety disorder: a meta-analysis*. (2014). 3. van der Linden et al., *The efficacy of the selective serotonin reuptake inhibitors for social anxiety disorder (social phobia): A meta-analysis of randomized controlled trials*. (2000). 4. Liebowitz, M. et al. (2007). Efficacy of venlafaxine XR and placebo in social anxiety disorder: Effects of gender and physical symptoms. 5. Carpenter et al., *Cognitive behavioral therapy for anxiety and related disorders: A meta-analysis of randomized placebo-controlled trials*. (2018). 6. de Ponti et al., *The efficacy of psychotherapy for social anxiety disorder, a systematic review and meta-analysis*. (2024). Abbreviations: CBT = Cognitive Behavioral Therapy; CGI-I = Clinical Global Impression-Improvement; CI = Confidence Interval; LS = Least Square; LSAS = Liebowitz Social Anxiety Scale; NNT = Number Needed to Treat; SAD = Social Anxiety Disorder; RR = Relative Risk

# Subjective-effect profile reflects the unique pharmacology of the R-enantiomer of MDMA

**5D-ASC Raing Scale Total and Subscale Score (0-100)**  
Day 1 and Day 29 Observed Score Mean<sup>1</sup>



**5D-ASC Comparison\*: EMP-01<sup>1</sup> / Psilocybin<sup>2</sup> / Racemic MDMA<sup>3</sup>**



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***EMP-01 produced a robust psychedelic experience, with a distinct profile that differs from racemic MDMA, and its subjective effects fully resolved on average in <6 hours***

# EMP-01: Strong feasibility, favorable safety profile, and encouraging early signals of efficacy



## FEASIBILITY & EXECUTION

- An **exploratory Phase 2a study** demonstrated **feasibility, generally well tolerated safety profile, and patient acceptability**
- Successfully evaluated EMP-01 in **70 adults** with marked-severe SAD across 7 UK sites in 7 months
- Strong **adherence and retention** through the primary endpoint



## SAFETY & TOLERABILITY

- Generally **well-tolerated** with favorable and manageable safety profile; **comparable to racemic MDMA**
- **No SAEs, no severe TEAEs**, no suicidal intent or behaviors
- 225mg of EMP-01 was **robustly psychedelic**
- **Subjective effects** fully resolved on average <6 hours



## EFFICACY

- Placebo-adjusted **improvement in LSAS at Day 43** (LSMD -11.85;  $g = 0.45$ ,  $p\text{-value} = 0.036$ , one-tailed)
- Observed marked **improvement in clinician-rated global response** (CGI-I Responder: EMP-01: 49% vs PBO: 15%); lower NNT vs SoC
- **Improved Fear and Avoidance** on LSAS subdomains after two doses over six weeks, including social-avoidance behaviors, without psychotherapy

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Abbreviations: CGI-I = Clinical Global Impression – Improvement; LSAS = Liebowitz Social Anxiety Scale; LSMD = Least Squares Mean Difference; PBO = Placebo; SAD = Social Anxiety Disorder; SAE = Serious Adverse Event; TEAE = Treatment-Emergent Adverse Event

# Thank You