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Daily Low-Dose Psilocin Mucate and First-in-Human Pharmacokinetics

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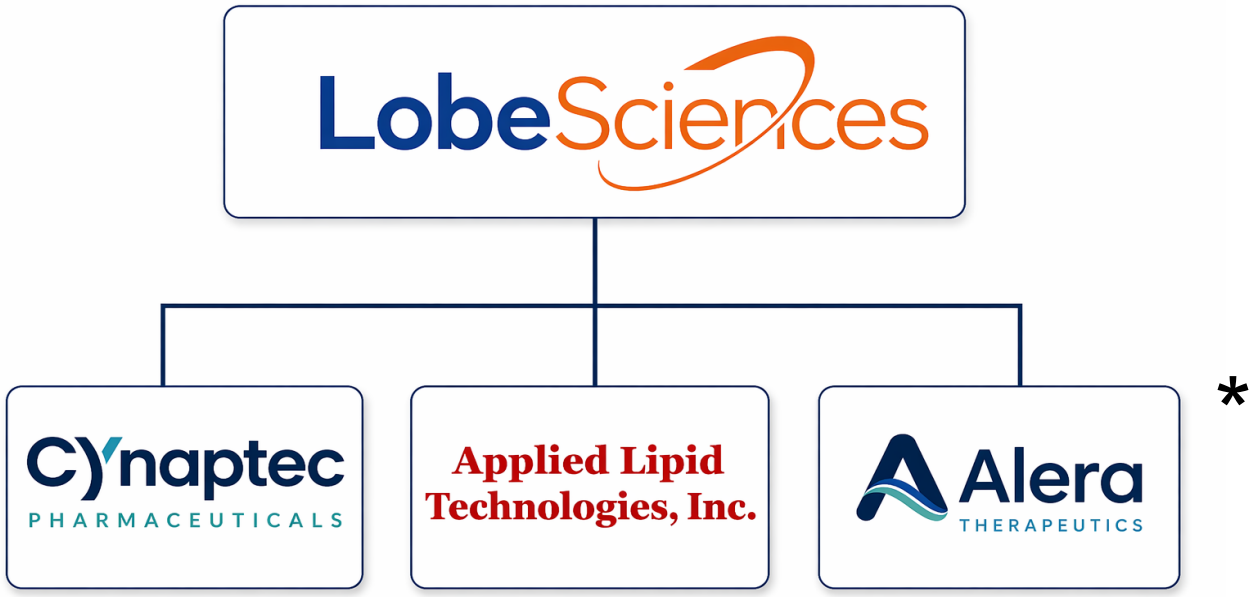
Lobe Operates Three Therapeutically focused Subsidiaries

This presentation will focus on Cynaptec's L-130 (psilocin mucate)



*Alera is currently evaluating several new development opportunities

Psilocybin Development Landscape

Dosing across the class is episodic and medically monitored, with follow-up over weeks or months

Treatment-session model
One or two high-dose sessions, followed by weeks or months of follow-up.

Monitoring burden
Controlled clinical setting, trained facilitators and monitors, preparation and integration support.

L-130 differentiation point
Designed to explore controlled exposure, lower-dose repeatability and non-hallucinogenic development.

Representative psilocybin / psilocin-class programmes outside Lobe

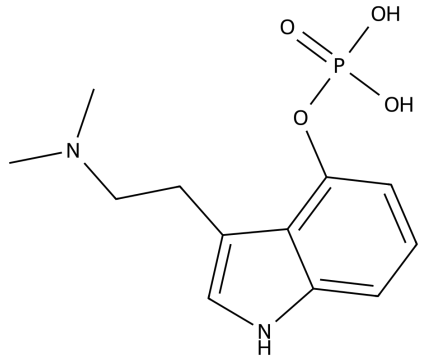
Clinical stage and dose / session model

Company / sponsor	Candidate	Lead indication	Stage	Dose level / schedule	Monitoring model
COMPASS Pathways	COMP360 synthetic psilocybin	Treatment-resistant depression	Phase 3 positive; rolling NDA	**25 mg x2 in COMP006 (vs 1 mg control); ~3 wks apart**	High-dose monitored sessions plus psychological support
Usona Institute	Synthetic psilocybin	Major depressive disorder	Phase 3 active / not recruiting	**Single 25 mg oral dose; 5 mg and placebo arms; optional 25 mg re-dose follow-up**	7–10 h dosing session with two facilitators plus integration
Cybin	CYB003 deuterated psilocin analog	Major depressive disorder	Phase 3 recruiting	**8 mg or 16 mg x2, ~3 wks apart**	Manualized psychological support and monitored sessions
Incannex	PSX-001 synthetic psilocybin	Generalized anxiety disorder	Phase 2 positive; late-stage prep	**25 mg x2 dosing sessions**	Controlled clinical setting plus psychotherapy protocol
Psyence BioMed	NPX-5 nature-derived psilocybin	Adjustment disorder in palliative cancer	Phase IIb dosing initiated	**25 mg nature-derived psilocybin**	Structured therapy-supported treatment model
Sunstone / Filament	Psilocybin / PEX010-related supply	Cancer-related depression / anxiety	Phase 2 investigator studies	**Single 25 mg oral group-dosing session**	Preparation, group dosing and integration support
Tryptamine Therapeutics	TRP-8802 oral psilocybin; TRP-8803 IV psilocin	BED, IBS, fibromyalgia	Phase 2a oral studies; IV early-stage	**25 mg x1 (BED); 25 mg x2 (IBS); 15→25 mg (fibromyalgia); IV dose not public**	Psychotherapy and carefully monitored dosing sessions
atai / Beckley Psytech	ELE-101 IV psilocin benzoate	Major depressive disorder	Phase 2a proof-of-concept	**Single IV psilocin benzoate, 10-min infusion; mg not publicly disclosed**	Shorter IV monitored session; discharge readiness ~2 h

Implication: the field validates psilocybin biology, though most competitor programmes still require clinic-based psychedelic sessions. L-130 is positioned around controlled exposure, lower-dose repeatability and non-hallucinogenic development.

Psilocybin is an Inactive Prodrug

And must be Enzymatically Dephosphorylated to become Psilocin; the Active Metabolite



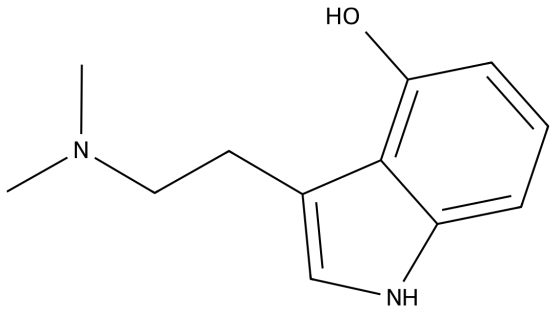
Psilocybin

Alkaline phosphatase

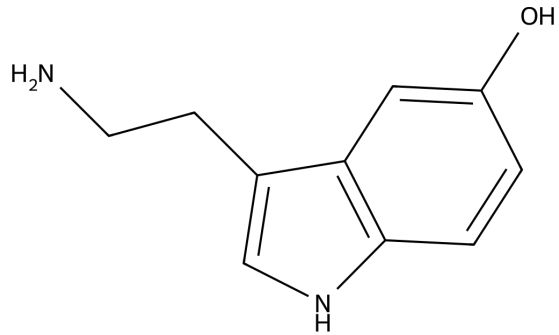
Dephosphorylation

52%

*(20–80%)** bioavailability



Psilocin



Serotonin

Activates serotonin receptors

5-HT2A

*Hasler F, et al. Pharm Acta Helv. 1997;72(3):175–184

Current Challenges Facing the Development of Psilocybin as a Therapeutic

Psilocybin is a Prodrug which must be metabolized to Psilocin to be active

Psilocybin itself has essentially no pharmacological activity unless converted

Psilocybin is poorly bioavailable (50%) and inconsistent

Published studies report a range of bioavailability from 20% to 80% with no consistent pattern

To provide consistent therapeutic effect, dose levels must be higher than needed causing severe side effects requiring monitoring

Hallucinations are the primary side effect

The Problem and the Solution: Psilocybin ⟶ Psilocin

Problem: Dosing psilocybin at levels that will be consistently efficacious requires doses that cause hallucinations.

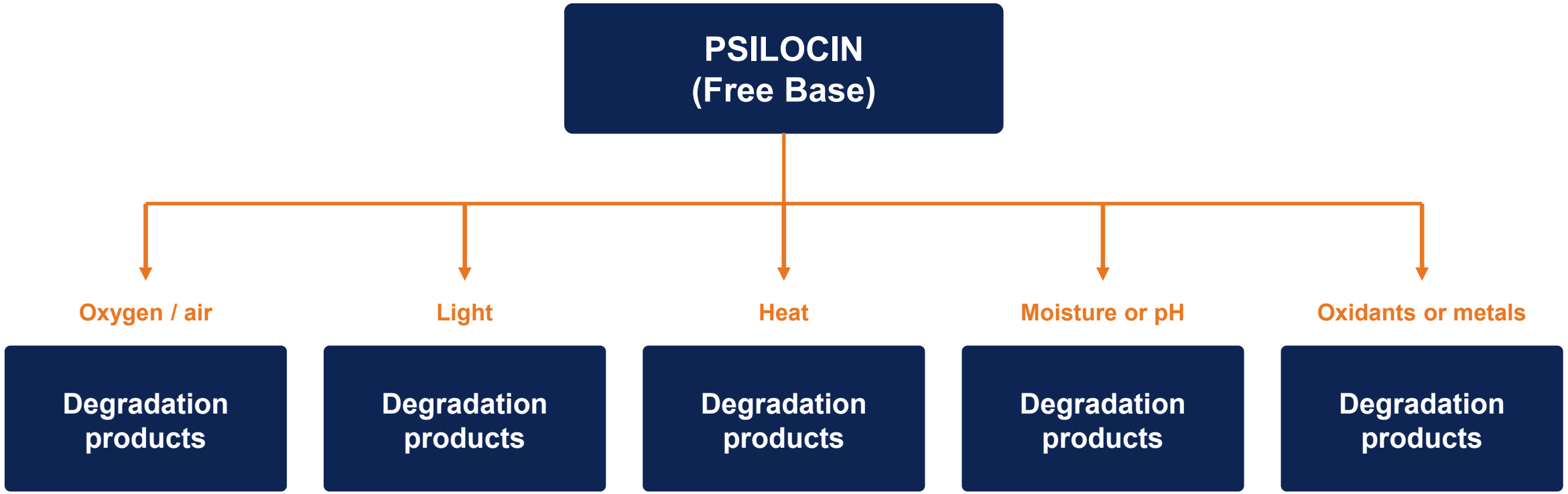
- The hallucinations force the use of the therapeutic to be infrequent (weekly or less frequent dosing interval)
- Patients have to be observed for hours post-dose often with counseling
- Cost per session becomes limiting for broad usage thereby limiting commercial opportunity and potentially insurance reimbursement

Solution: Synthesize the active metabolite, Psilocin, in a stable bioavailable form and dose directly.

- Psilocin could be dosed at therapeutic levels far below those that produce significant side effects (hallucinations)
- Psilocin, as a therapeutic, could be given daily, increasing commercial viability
- However, psilocin is unstable and unsuitable as an API. A stable version is needed

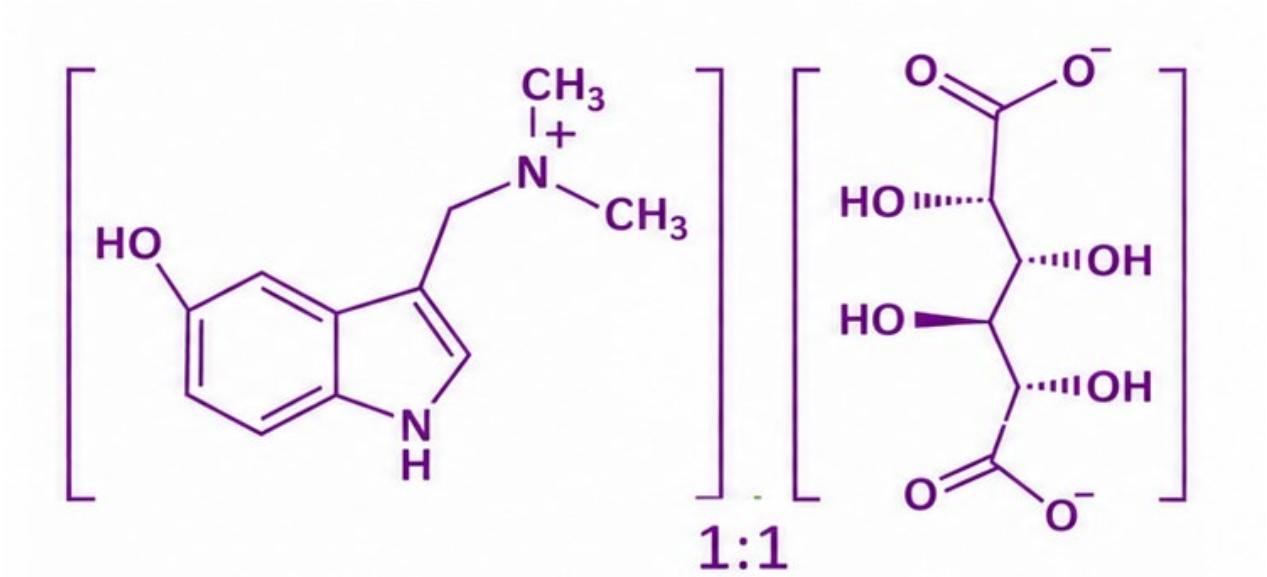
Psilocin (as the free base) is Unstable

Multiple Degradation Pathways Create a Stability Nightmare for Formulators



The Solution to Psilocybin's Challenges: L-130 (Psilocin Mucate)

Delivers psilocin the active metabolite as a stable API



L-130* (Psilocin Mucate)

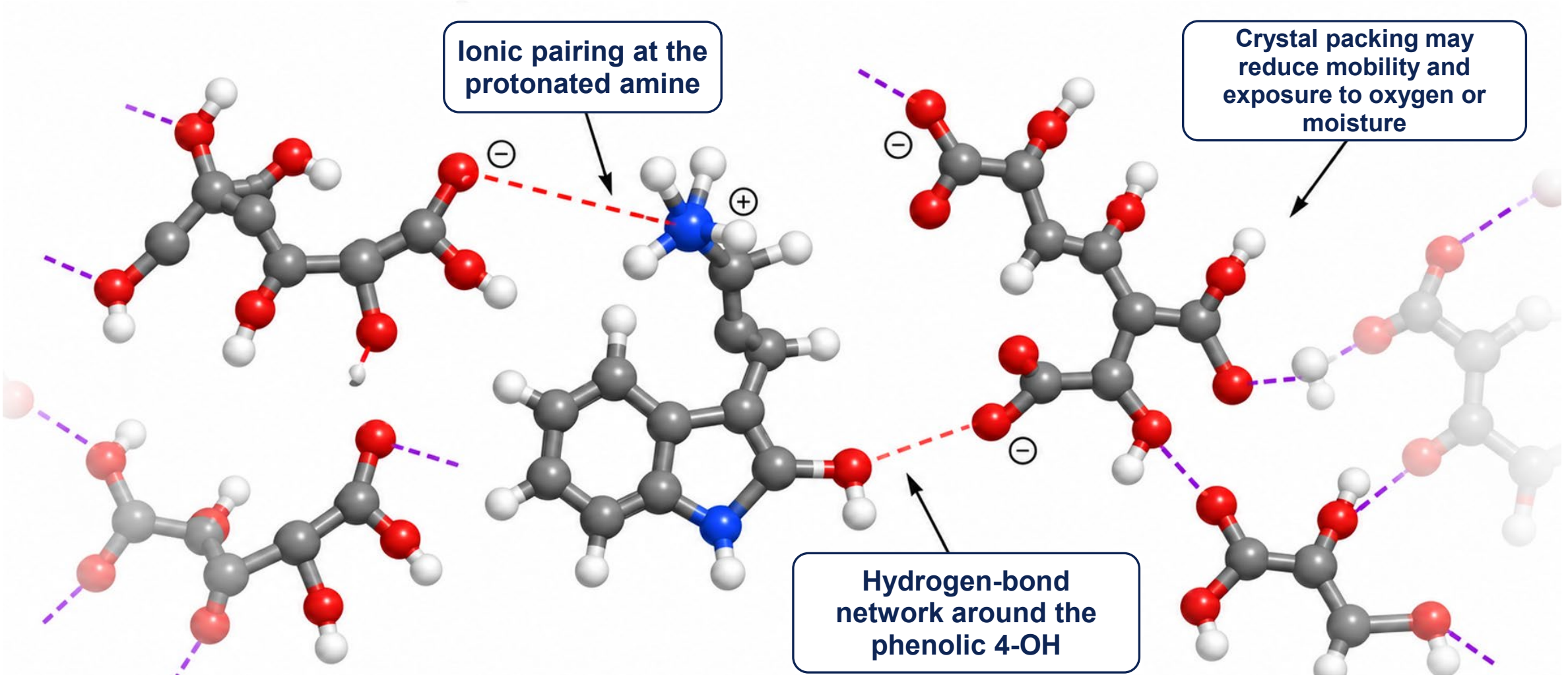
$C_{18}H_{26}N_2O_9$

MW: 414.41 g/mol

Following 129 attempts to stabilize psilocin, the mucate (L-130) was synthesized

L-130 (Psilocin Mucate Salt)

Proposed Solid-State Stabilization Model



Conceptual hypothesis; exact proton positions and intermolecular contacts require solid-state structural confirmation.

Can Psilocin be given daily, at sub-hallucinogenic levels and still be effective?

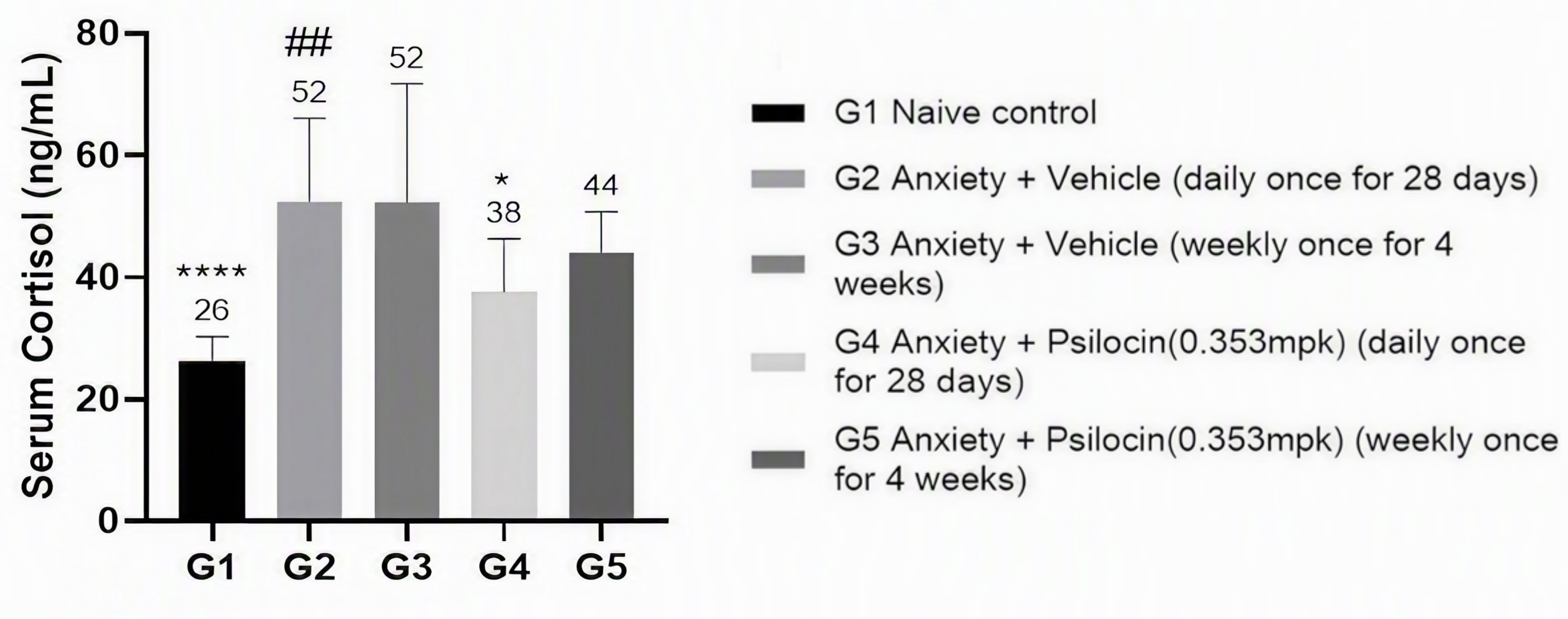
Four endpoints (n=12/group) were evaluated comparing daily versus weekly dosing. Animals were subjected to stress (CUMS*) then the impact of a human equivalent dose of ~2mg was measured as follows:

- **Cortisol Levels**
- **Elevated Plus Maze**
- **Open Field-Internal Zone**
- **Novel Object Recognition**

*CUMS paradigm consisted of a rotating series of mild stressors applied over a 28-day period, including: Food deprivation, Day-night reversal with soiled bedding, Cage tilting, Crowded housing, Exposure to a novel odor, Restraint stress, Cold and heat stress and Intermittent white noise. These stressors were applied sequentially, one per day, in a cyclical pattern to create a chronic anxiety/stress state

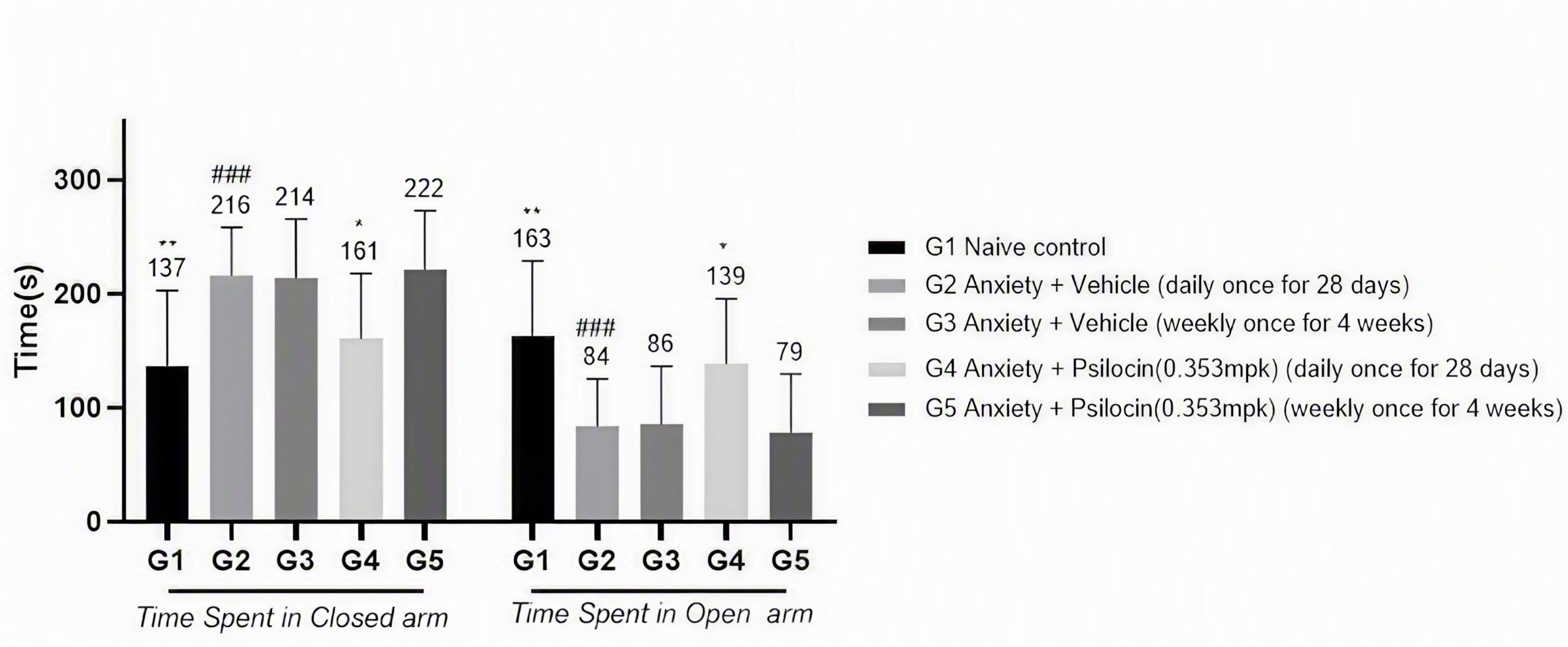
Cortisol Levels Following CUMS (n=12/group)

Only Daily Dosing Results are Statistically Significant



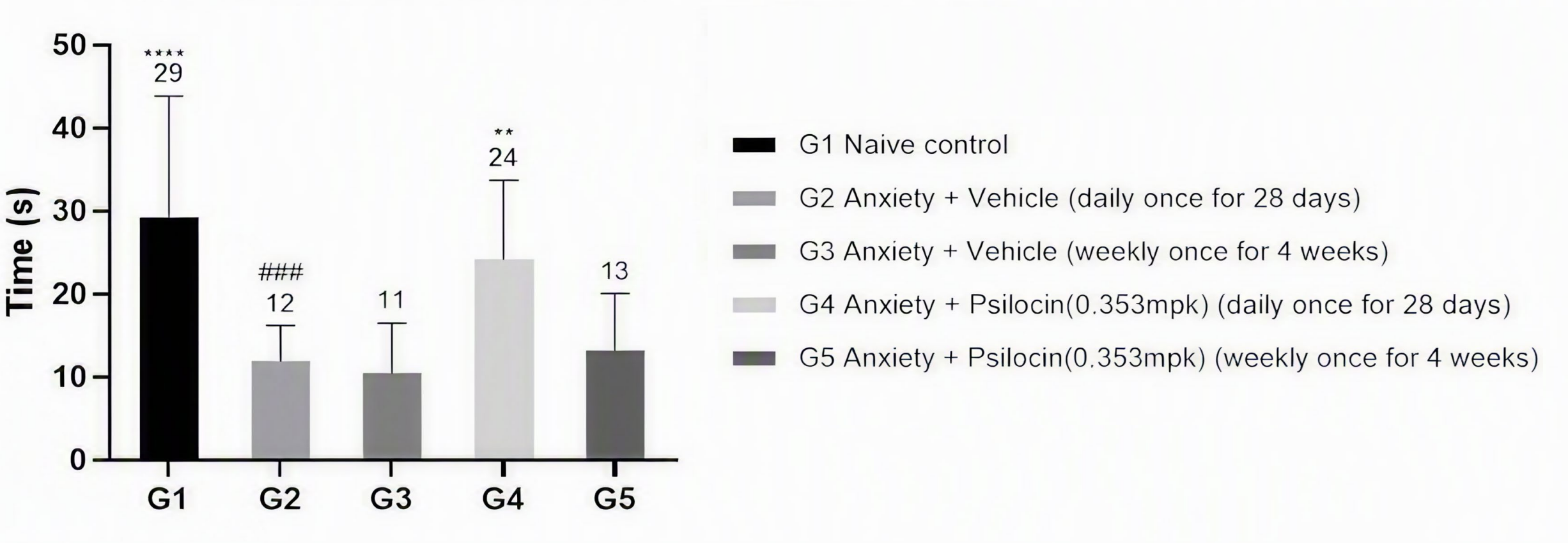
Elevated Plus Maze

Only Daily Dosing Results were Statistically Significant

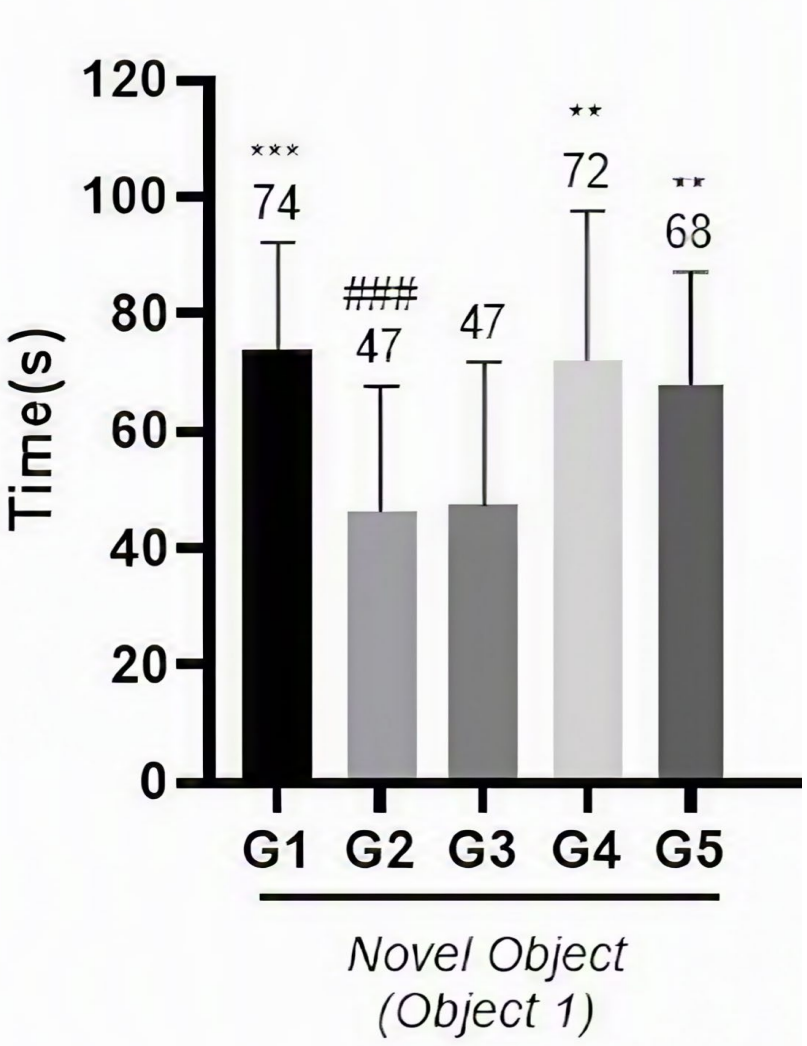


Open Field-Internal Zone

Only Daily Dosing Resulted in Statistical Significance



Novel Object Recognition



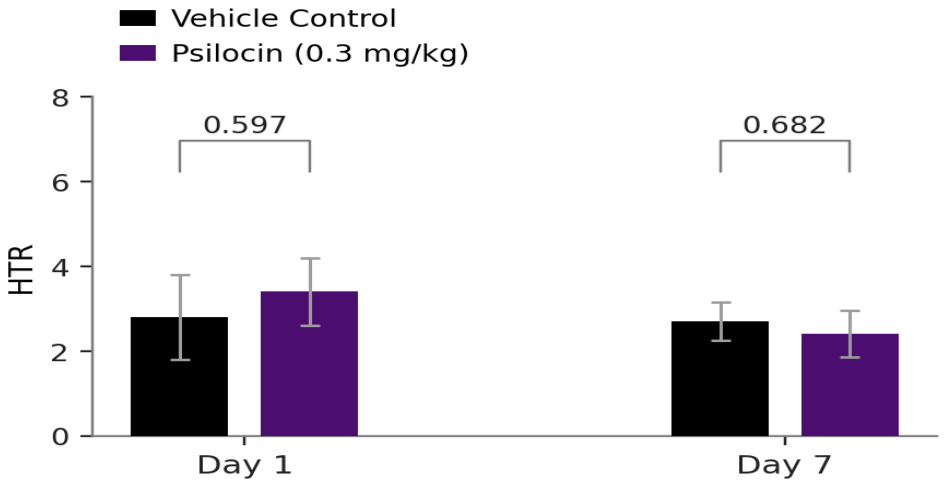
- **Both Daily (G4) and Weekly(G5) achieved significant results**
- **However, daily dosing results were nearly identical to those observed for the naïve group**

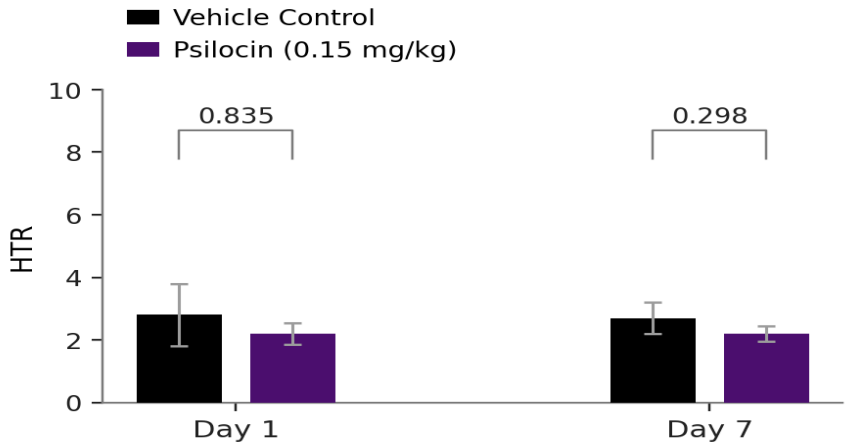
A Repeat Dose Study Assessing Potential Hallucinations at 3 Dose Levels

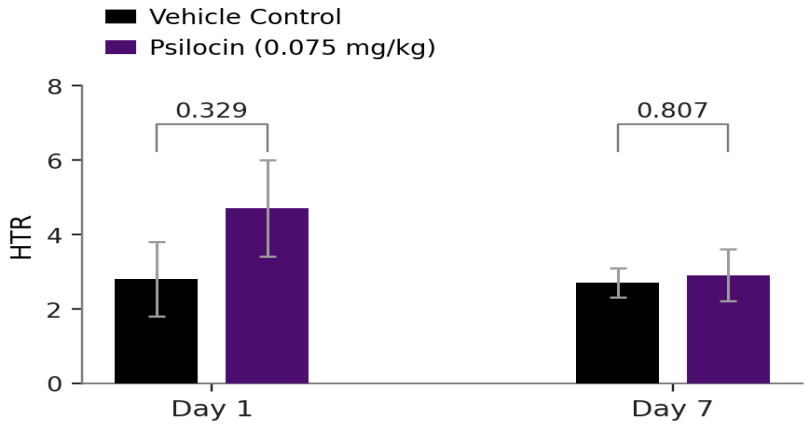
Head-twitch response (HTR) across repeat dosing, highlighting Day 1 and Day 7.

Key observations (p-values appear in charts):

- At doses test, 0.075, 0.15 and 0.3 mg/kg, HTR did not differ from control over 7 days.
- At these doses, no increased HTR was seen vs. control, however, anxiolytic effect was significant for daily dosing only.







L-130 Psilocin Mucate's "First-In-Human" Study

Published: Sancilio et al., 2024

Study Design

- Single-dose Phase 1a safety study (4 mg psilocin mucate)

Safety

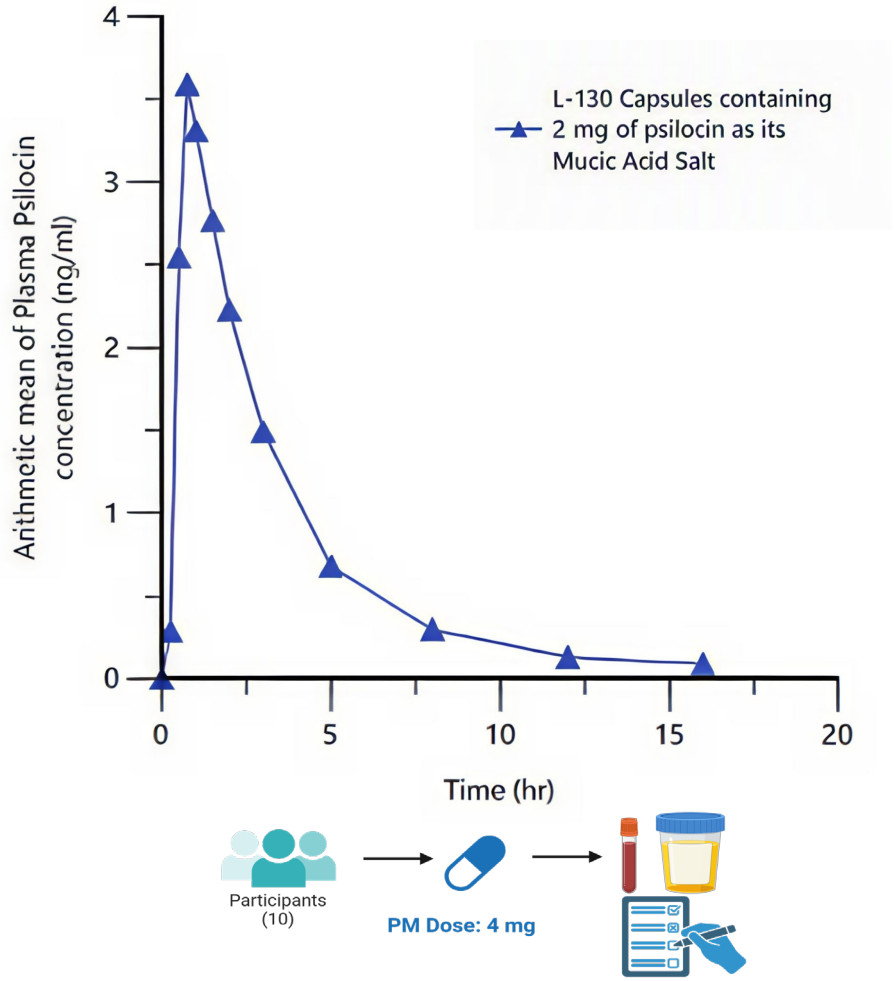
- No serious adverse events and no hallucinogenic effects at this dose

Pharmacokinetics

- Psilocin was rapidly absorbed after oral administration
- **Tmax at <45 mins** (vs 2-4 hours psilocybin)

Additional Finding

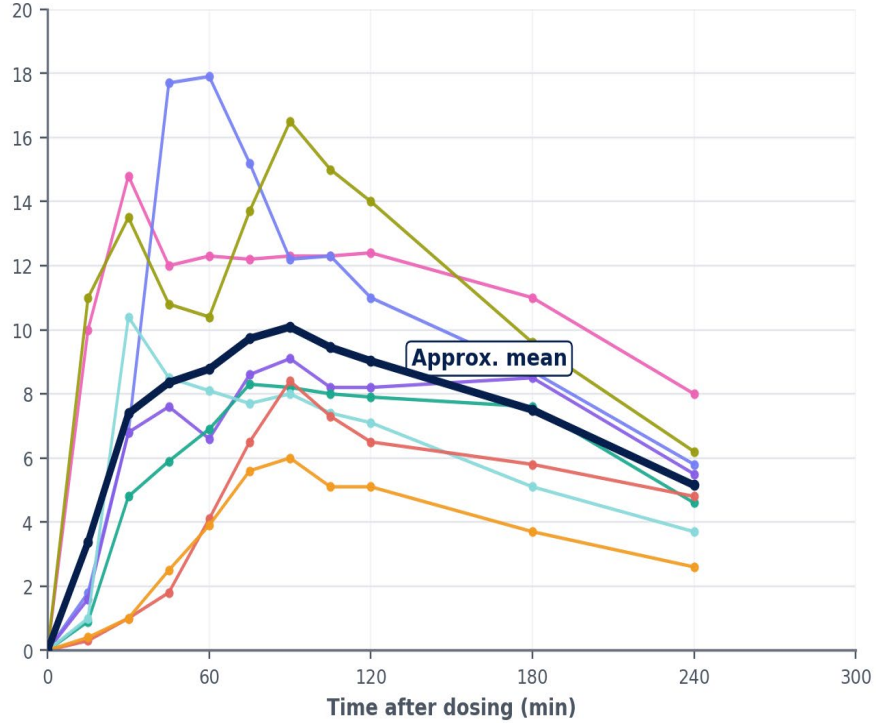
- Self reported anxiolytic effect on day of dosing, after 1 week (62.5%) and 4 weeks (42.9%)



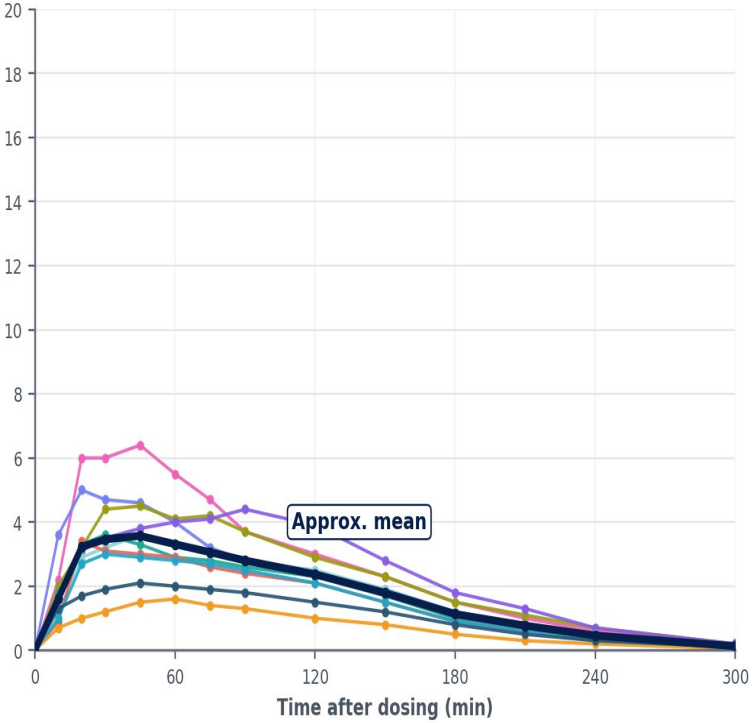
Human Psilocin Exposure (Psilocybin vs Psilocin)

Psilocin derived from psilocybin shows broad variability; L-130 psilocin mucate shows a tighter exposure range.

Psilocin After Psilocybin (10mg)* = (7mg psilocin after MW correction)



Psilocin After L-130 Psilocin Mucate (4mg) = (2mg psilocin after MW correction)**



L-130 appears to deliver psilocin more efficiently and far more reproducibly than psilocybin, potentially enabling predictable therapeutic blood concentrations at substantially lower doses.

*Madsen et al **Sancilio et al

L-130 Appears Active in Anxiolytic Models and Shows Similar Signs in Humans with no Hallucinations

- Any application utilizing psilocybin can be easily reformulated with psilocin (L-130)
- Psilocin (L-130) has demonstrated superior anxiolytic activity (preclinical) given daily compared to weekly dosing
- L-130 is highly bioavailable, stable, and reproducible with no apparent accumulation or receptor saturation with repeated daily dosing

Current Applications of L-130 (psilocin mucate)

A Patented and New Chemical Entity and some Applications

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Cluster Headache (CH):

Targeting one of the most severe pain conditions known, affecting 200,000+ in the U.S. and over one million globally. An unmet need.

Substance Use Disorder (Addiction):

Preclinical data suggests L-130 may reduce relapse rates post-treatment for substance use disorders. Nearly one in six Americans live with substance use disorder.

Generalized Anxiety Disorder (GAD):

GAD impacts 2.7% of U.S. adults, making it one of the most common and persistent mental health conditions, and a significant therapeutic opportunity.

L-130 (psilocin mucate): Development Progress and Next Steps

A patented, stabilized psilocin-based therapeutic platform advancing to address significant unmet needs

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Completed for L-130

- API Scale-Up Completed
- Long-Term Stability (API) Completed
- 28-Day Toxicology Completed
- Daily vs Weekly Dosing Evaluated
- Pre-IND Guidance Completed
- CTA Filed (ex-U.S.)
- First-in-Human Study Completed (10 healthy volunteers)
- Patents Issued and Pending
- IND-Enabling Studies Nearing Completion

Cluster Headache (CH)

A severe and debilitating pain condition with significant unmet need.

Next Steps

Phase 2a Proof of Concept → **Further Development (Phase 2b/3) (Subject to commercial factors)**

- Leverage existing nonclinical **and clinical** data.
- Plan to proceed directly into a Phase 2a proof-of-concept study.
- Timing and advancement dependent on commercial factors.

Substance Use Disorder (SUD)

A major public health challenge with high relapse rates and limited effective treatments.

Next Steps

Continue Preclinical Studies → **Phase 1b/2a Proof of Concept** → **Phase 2**

- Continue preclinical studies to confirm efficacy and further characterize dose, safety and mechanism of action.
- Upon completion, initiate a proof-of-concept Phase 1b/2a trial, followed by a Phase 2 study.

Generalized Anxiety Disorder (GAD)

A common and persistent mental health condition with significant therapeutic opportunity.

Next Steps

Phase 2a Dose-Finding Study (under existing CTA) → **Further Development (Phase 2b/3)**

- Plan to conduct a fairly large Phase 2a study under our existing CTA.
- Objective is to identify the minimum effective dose for GAD without hallucinations.

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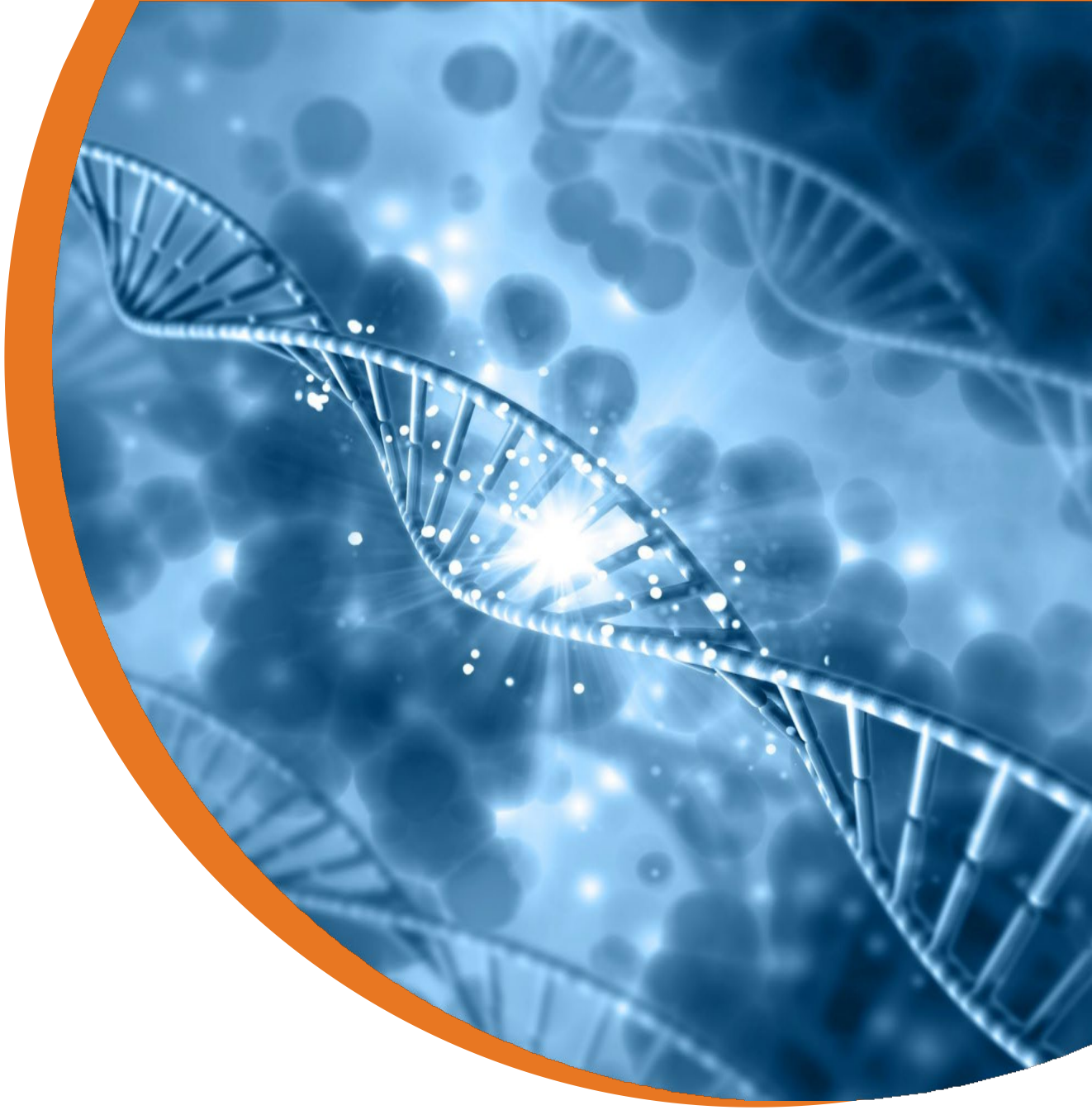

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