



# Strategic Investment in Beckley Psytech

BPL-003 | ELE-101

**Conference Call | Thursday January 4, 2024**



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# Strategic Investment in Beckley Psytech

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# Strategic Investment in Beckley Psytech underscores our conviction in psychedelic-based treatments

1

Reinforces atai's position as the biopharma company with the largest and most diverse portfolio of clinical-stage psychedelic candidates

2

Two patent-protected, clinical-stage compounds BPL-003 (intranasal 5-MeO-DMT) and ELE-101 (intravenous psilocin) complement atai's existing programs

3

Transaction adds multiple clinical readouts within next 12 months to atai's catalyst map, including a Phase 2b readout of BPL-003 in TRD anticipated for 2H24

4

BPL-003 has potential to become a first-in-class short-duration psychedelic treatment with rapid acting and durable antidepressant effects

5

Anticipated synergies through collaboration on digital therapeutics and pre-commercial activities

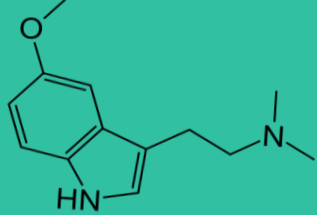
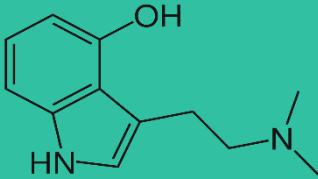


# Transaction Terms

- atai will own 35.5% of Beckley Psytech
- \$50m total investment:
  - \$40m direct investment into the company
  - \$10m in secondary share purchases
- 1:1 warrant coverage with 30% premium on primary issuances
- Right to appoint and hold 3 of 9 seats on Beckley Psytech's Board of Directors
- Time-limited right of first refusal on a future sale of the company, asset sales or other transfer of commercial rights
- Indefinite right of first negotiation for BPL-003 and ELE-101

## Compound Comparison

BPL-003 and ELE-101 are two novel, patent-protected, short-duration psychedelic candidates, aimed at optimizing for patient access

	 <b>BPL-003</b> (5-MeO-DMT)	 <b>ELE-101</b> (Psilocin)
<b>Target position &amp; primary indication</b>	First-in-class with 5-MeO-DMT for TRD	Short-duration active metabolite of psilocybin for MDD
<b>Formulation</b>	Intranasal in dry powder nasal spray device	Intravenous infusion in ready to use vial
<b>Treatment duration</b>	<2 hours in clinic	<2 hours in clinic
<b>US regulatory status</b>	IND accepted Feb 2023	IND planned for H2 2024
<b>Intellectual property</b>	Granted US / EU / UK patents <sup>1</sup>	Granted US patents <sup>1</sup>

<sup>1</sup> Other regions pending // Abbreviations: TRD = Treatment Resistant Depression; MDD = Major Depressive Disorder; IND = Investigational New Drug Application





## Beckley Pipeline

BPL-003 (5-MeO-DMT) and ELE-101 (Psilocin) have multiple anticipated clinical value inflection points in 2024

Programs	Indication	Phase 1	Phase 2a	Phase 2b	Key Milestone
BPL-003	Treatment-Resistant Depression				Phase 2b readout in 2H'24
BPL-003	Treatment-Resistant Depression				Phase 2a (open-label) readout in 1H'24
BPL-003	Alcohol Use Disorder				Phase 2a (open-label) readout mid-'24
ELE-101	Major Depressive Disorder				Phase 1/2a (open-label) readout in 1H'24

## atai's Depression Portfolio Comparison

A diverse portfolio of differentiated psychedelic assets to address the heterogeneity of patients who suffer from depression

Associated Program	Compound	Primary Indication	Route of Administration	Receptor binding affinity (5-HT <sub>2A</sub> : 5-HT <sub>1A</sub> ) <sup>1</sup>	Rapid Onset of Treatment Effect	Appr. Duration in clinic
VLS-01	DMT	TRD	Oral transmucosal film	3.4		<2h
BPL-003	5-MeO-DMT	TRD	Intranasal	0.01		<2h
ELE-101	Psilocin	MDD	Intravenous	2.0		<2h
COMP360	Psilocybin <sup>2</sup>	TRD	Oral	2.0		~6 h

<sup>1</sup> Besnard et al. 2012 // <sup>2</sup> Psilocybin is not present in the body in meaningful concentrations after oral consumption // Abbreviations: TRD = Treatment Resistant Depression; MDD = Major Depressive Disorder



# BPL-003

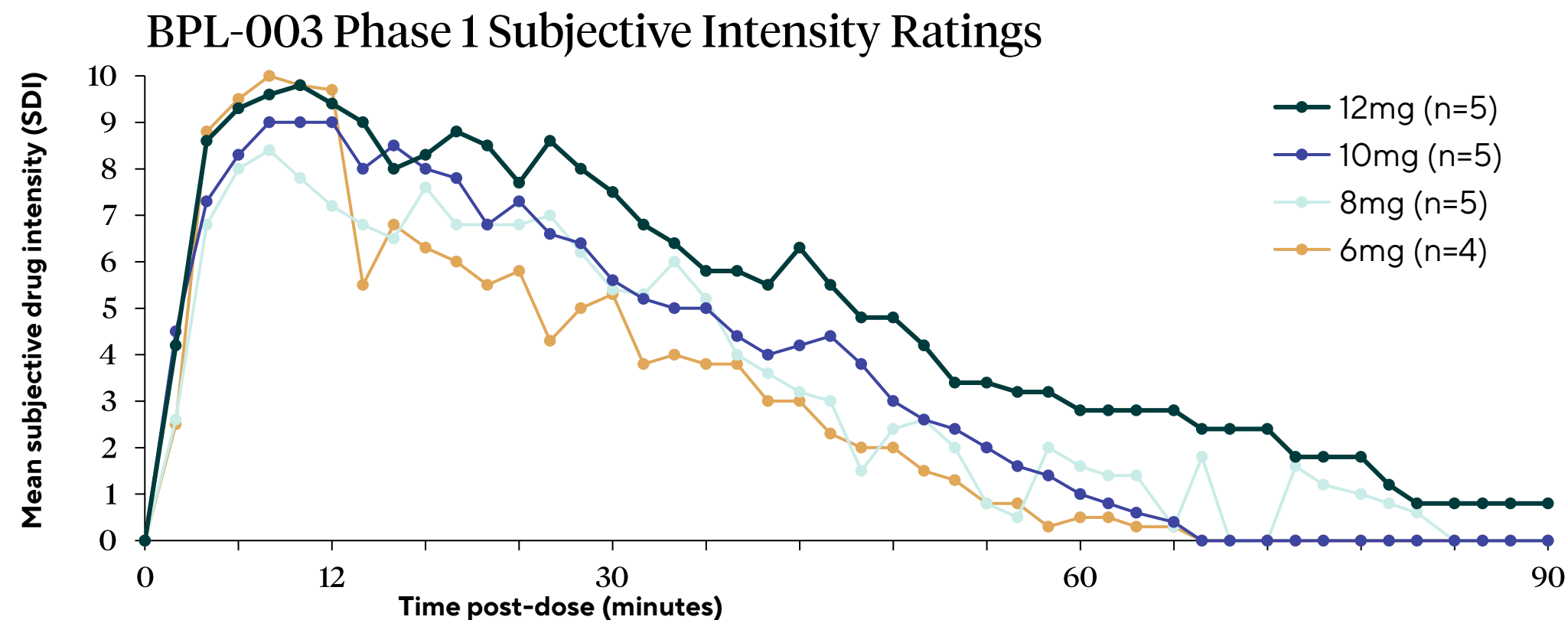
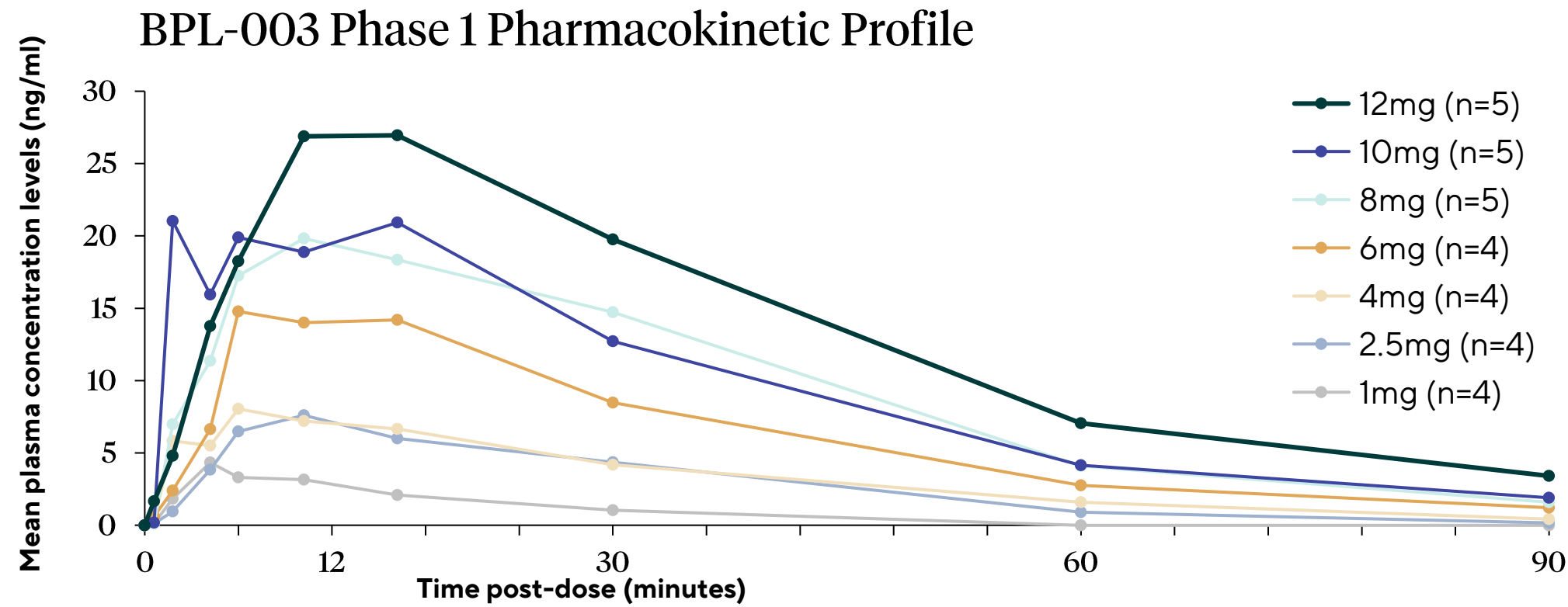
(intranasal  
5-MeO-DMT)  
for TRD & Alcohol  
Use Disorder

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## BPL-003: Intranasal 5-MeO-DMT

Results from completed Phase 1 SAD study showed BPL-003 had a favorable safety profile and was well tolerated whilst demonstrating dose proportionate PK/PD profile



### Key Findings

#### Safety

- » All adverse events (AEs) were mild (89.5%) or moderate (10.5%); no Serious AEs occurred
- » Most common AEs (>10%) : nasal discomfort, nausea, vomiting, and headache

#### Pharmacokinetics (PK)

- » Exposure was dose-proportionate
- » Rapid onset: mean Tmax of 6-17 min
- » Short duration: mean t1/2 of 15-30 min

#### Pharmacodynamics (PD)

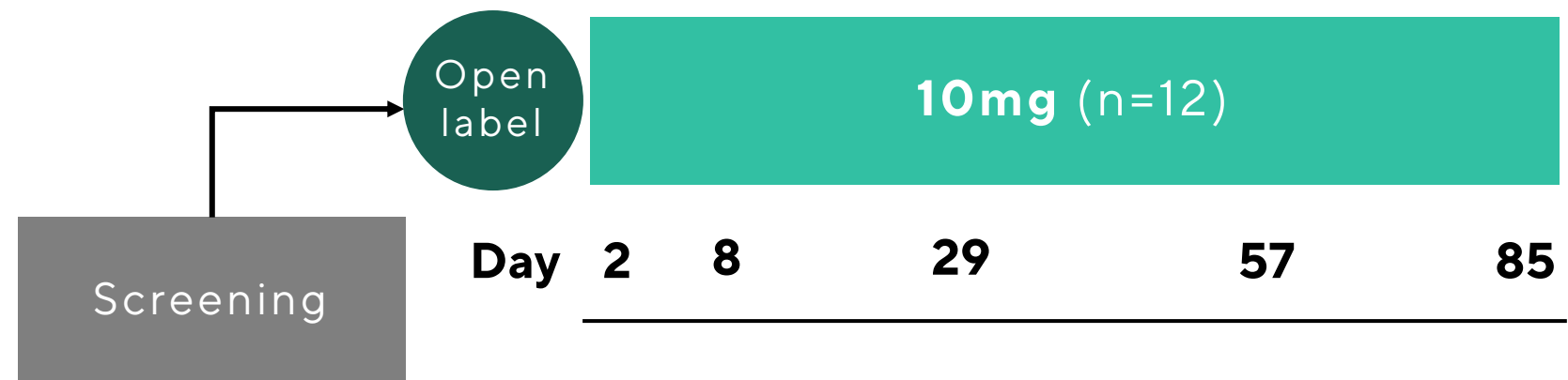
- » Subjects were psychedelic naive
- » All subjects on doses  $\geq 6$ mg achieved intensity scores  $\geq 7$
- » Perceptual effects generally fully resolved within 60 - 90 mins

Abbreviations: SAD = Single Ascending Dose; PK = Pharmacokinetic; PD = Pharmacodynamic

## BPL-003 Phase 2a Clinical Trial Design

# BPL-003 Phase 2a is an open-label monotherapy study in TRD patients

Core Study (12 weeks)



Data expected for Ph 2a (TRD) in 1H24

### Key Inclusion Criteria

- » Patients with moderate-severe treatment resistant depression
- » Montgomery-Asberg Depression Rating Scale (MADRS) score  $\geq 24$
- » Willing and able to discontinue current antidepressants

### Key Objectives:

#### Primary Endpoint:

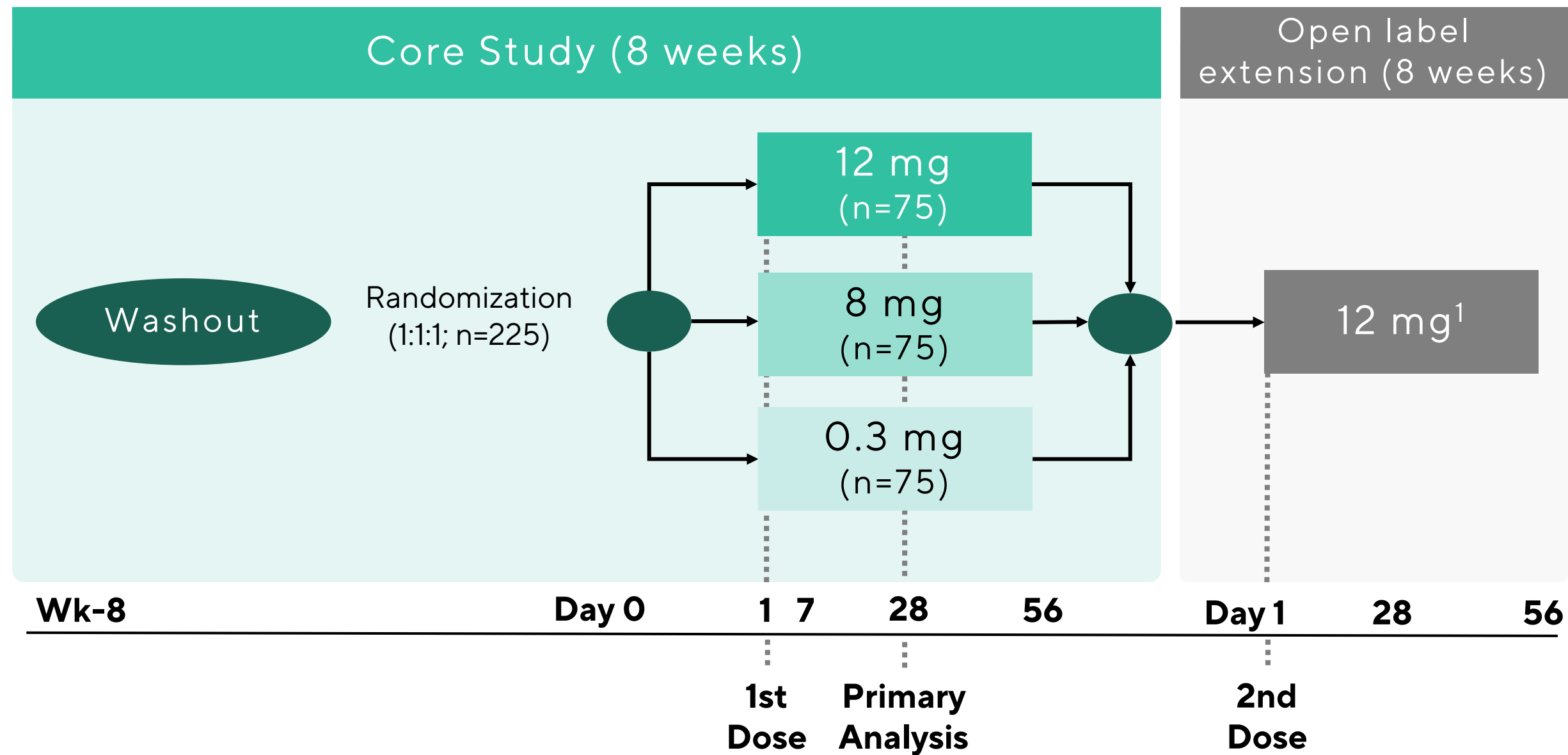
- » Safety and tolerability of BPL-003 monotherapy

#### Key Secondary Endpoints:

- » MADRS change at Day 2, 8, 29, 57 and 85
- » CGI-S, PGIC, EQ-5D

## BPL-003 Phase 2b Clinical Trial Design

BPL-003 Phase 2b is a randomized, double-blind, single-dose monotherapy study in moderate to severe TRD patients



**Data expected for Ph 2b (TRD) in 2H24**  
*(first patient dosed Oct 2023)*

### Key Inclusion Criteria

- » Patients with treatment-resistant depression
- » Hamilton Depression Scale (HAM-D)  $\geq 19$
- » Willing and able to discontinue current antidepressants

### Key Objectives:

#### Primary Endpoint:

- » MADRS change from baseline at day 28

#### Key Secondary Endpoints:

- » MADRS change at Day 1, 7 and 56
- » CGI-S, PGIC, EQ-5D

<sup>1</sup> Patients entering the open-label extension are randomized 1:1 to receive either a single 12mg dose or a biphasic 4mg and 8mg dose approximately 10 minutes apart  
Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; CGI-S = Clinical Global Impressions-Severity; PGIC = Patient's Global Impression of Change; EQ-5D = EuroQoL-5D

# ELE-101

(IV psilocin)  
for MDD

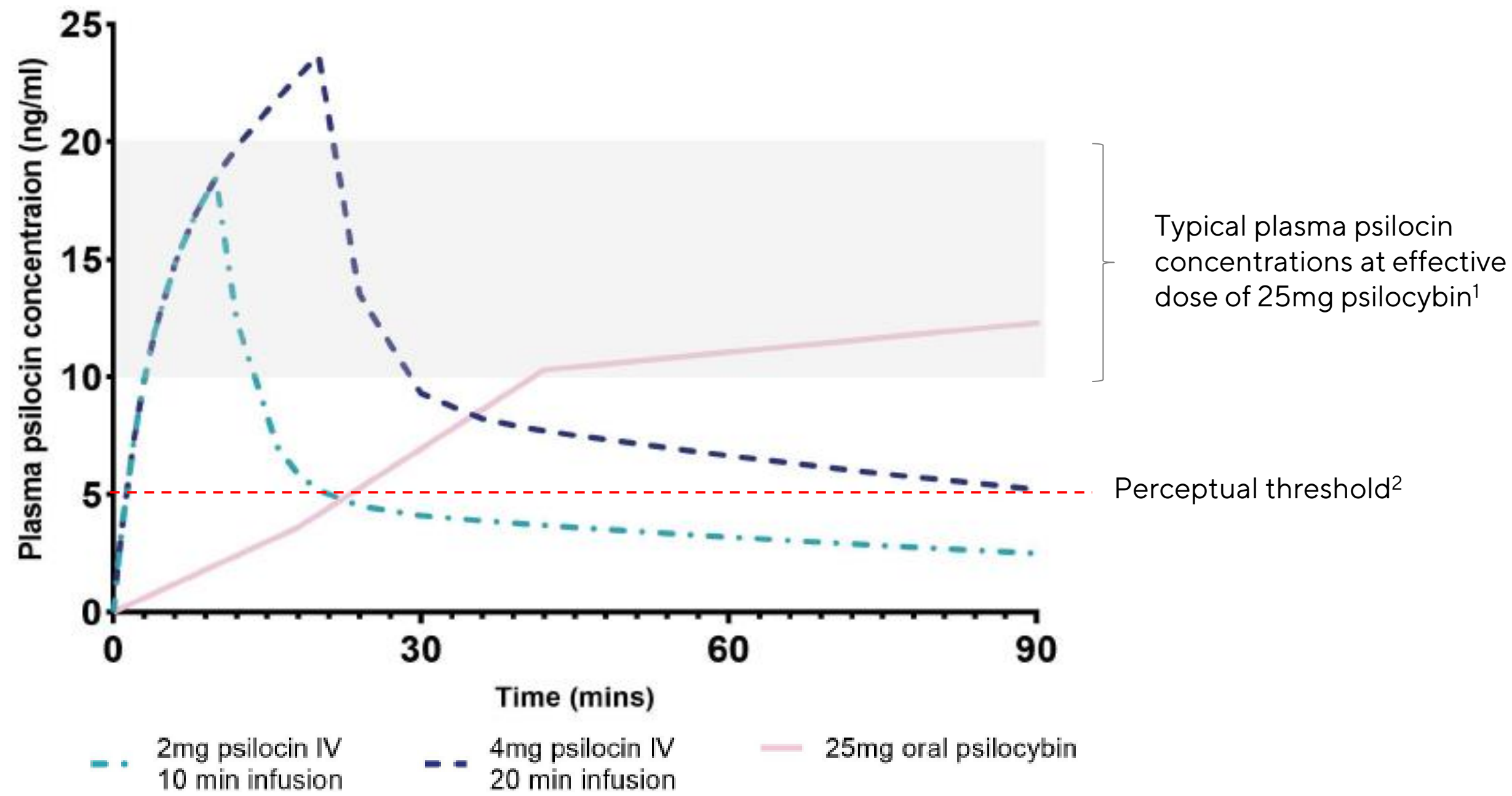
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## ELE-01: IV Psilocin

# Potential benefits of psilocybin's active moiety in an optimized delivery and treatment model

Psilocin pharmacokinetics for IV psilocin (simulated) vs. oral psilocybin<sup>1</sup>



### Expected benefits of IV psilocin vs oral psilocybin:

- » Reduced variability
- » Shorter half life = shorter duration of psychedelic effect, anticipated to be <2 hours

<sup>1</sup> Psilocin simulations based on primary data from Brown et al. 2017, Madsen et al. 2019, Hasler et al. 1997, and Carhart-Harris et al. 2011.

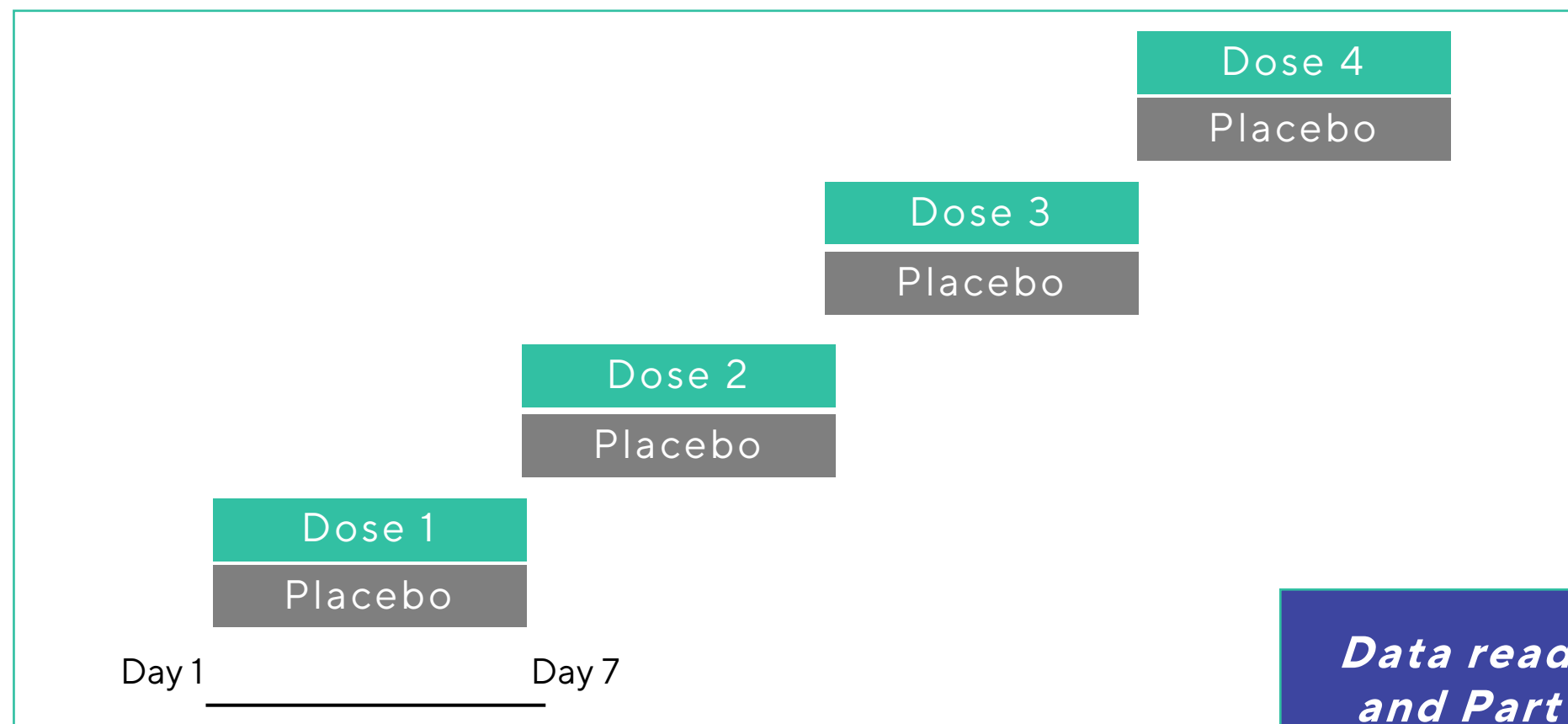
<sup>2</sup> Holze F. et al (2023). Pharmacokinetics and Pharmacodynamics of Oral Psilocybin Administration in Healthy Participants. Clin Pharmacol Ther.

## ELE-101 Phase 1/2a Clinical Trial Design

# Randomized, Phase 1 dose-escalation study in healthy volunteers followed by Phase 2a open-label study in MDD

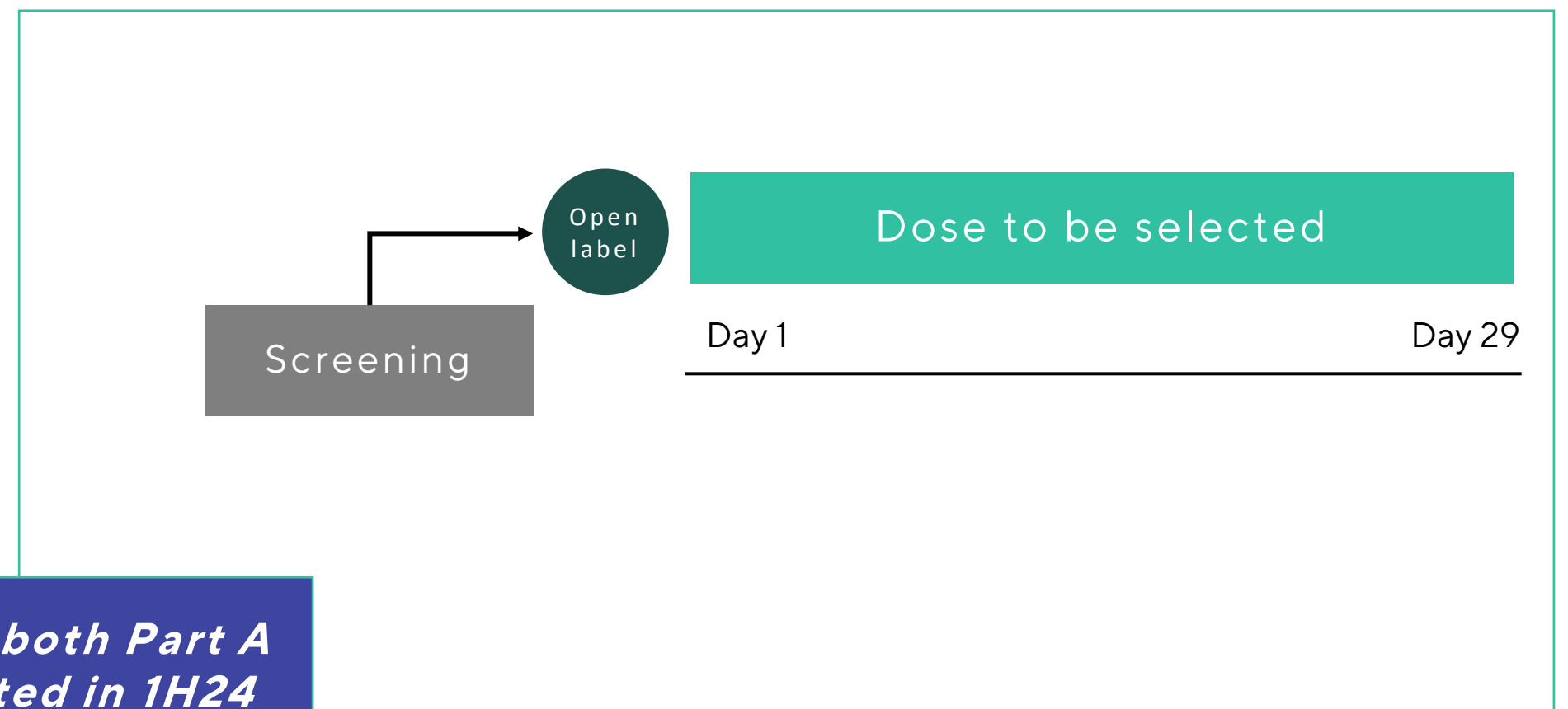
### ELE-101 Phase 1/2a – Part A

Single Ascending Dose



### ELE-101 Phase 1/2a – Part B

Open-label MDD cohort



*Data readouts for both Part A and Part B expected in 1H24*

#### Key Objectives:

- » Safety and tolerability
- » Assessment of PK & PD
  - » Target concentration of psilocin in <2 minutes
  - » Consistency of subjective intensity

#### Key Objectives:

- » Safety and tolerability of ELE-101 in patients with moderate to severe MDD
- » Key Secondary Endpoints:
  - » Assessment of MADRS change (Day 2, 4, 6, 15, 29)
  - » CGI-S, PGIC

Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; PK = Pharmacokinetics; PD = Pharmacodynamics; CGI-S = Clinical Global Impressions-Severity; PGIC = Patient's Global Impression of Change; MDD = Major Depressive Disorder

# Summary

1. Conviction that **short-duration psychedelics** could drive broader patient access
2. **Multiple additional catalysts** in next 12 months with addition of two patent-protected, clinical-stage programs
3. Reinforces atai as the biopharma company with **largest, most diverse** portfolio of clinical psychedelic candidates
4. BPL-003 has potential to become **first-in-class** short-duration psychedelic treatment
5. **Synergies** through collaboration in preparation for commercialization





Nasdaq: ATAI

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