

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

Company Overview – April 2024



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Highlights

atai Life Sciences: Healing mental health disorders so that everyone everywhere can live a more fulfilled life



Mental health disorders are one of the largest global health burdens; in 2019, 1 in every 8 people, or approx. 1 billion people around the world, were living with a mental disorder.¹



atai's objective is to enable mental health patients to achieve clinically meaningful and sustained behavioral change through developing innovative, rapid-acting and durable therapeutics.



Eight clinical-stage psychedelic and non-psychedelic programs and strategic investments, each with a robust package of prior clinical evidence.



Validated operating model and ability to capture value: IPO of COMPASS Pathways in 2020 and licensing deal between Otsuka and atai subsidiary Perception Neuroscience in 2021.



Cash, marketable securities, and committed term loan funding expected to provide runway into 2026.²

¹ World Health Organization

² Committed term loan funding includes \$45M of additional capital that can be drawn not subject to milestones under the facility with Hercules Capital; marketable securities includes government agencies securities, and public equities



Drug Development Programs and Strategic Investments

Our strategy will be delivered through a robust portfolio of psychedelic and nonpsychedelic drug development programs and strategic investments

Programs / Investments

Primary Indication

PSYCHEDELIC PROGRAMS & STRATEGIC INVESTMENTS

COMP360¹ / Psilocybin

BPL-003² / 5-MEO-DMT

VLS-01/DMT

ELE-101² / Psilocin

IBX-210 / Ibogaine

EMP-01/R-MDMA

EGX-A & EGX-B / Novel 5-HT2A Receptor Agonists

Treatment-Resistant Depression

Treatment-Resistant Depression

Treatment-Resistant Depression

Major Depressive Disorder

Opioid Use Disorder

Undisclosed

Undisclosed

NON-PSYCHEDELIC PROGRAMS

RL-007 / Pro-cognitive neuromodulator³

GRX-917 / Deuterated etifoxine

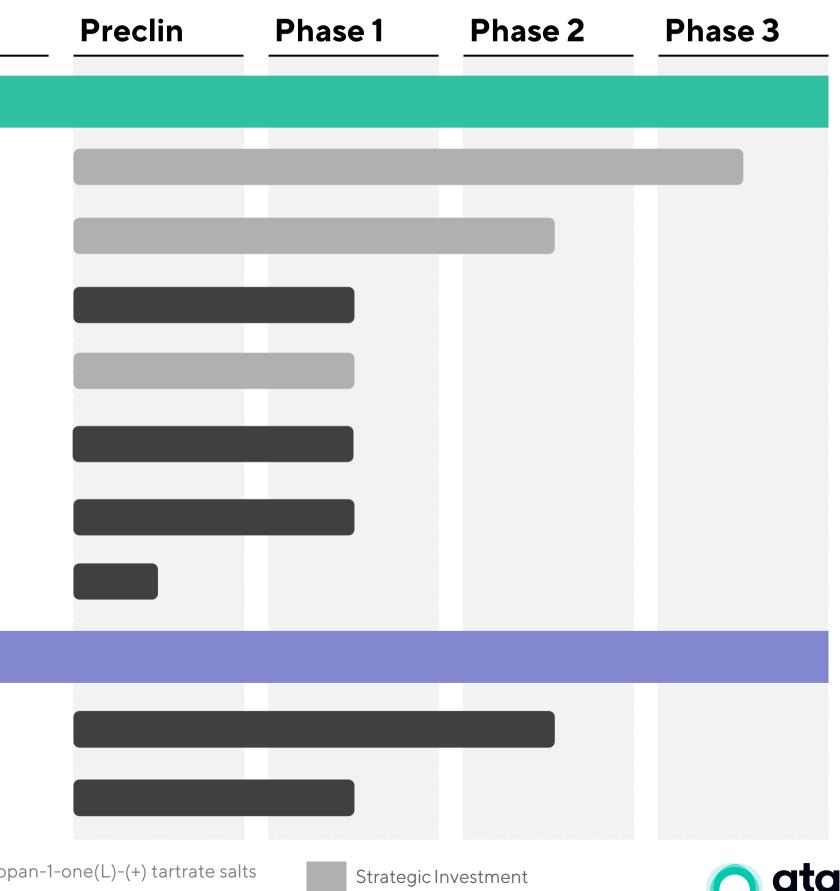
Cognitive Impairment Associated with Schizophrenia

Generalized Anxiety Disorder

¹ Strategic Investment in Compass Pathways

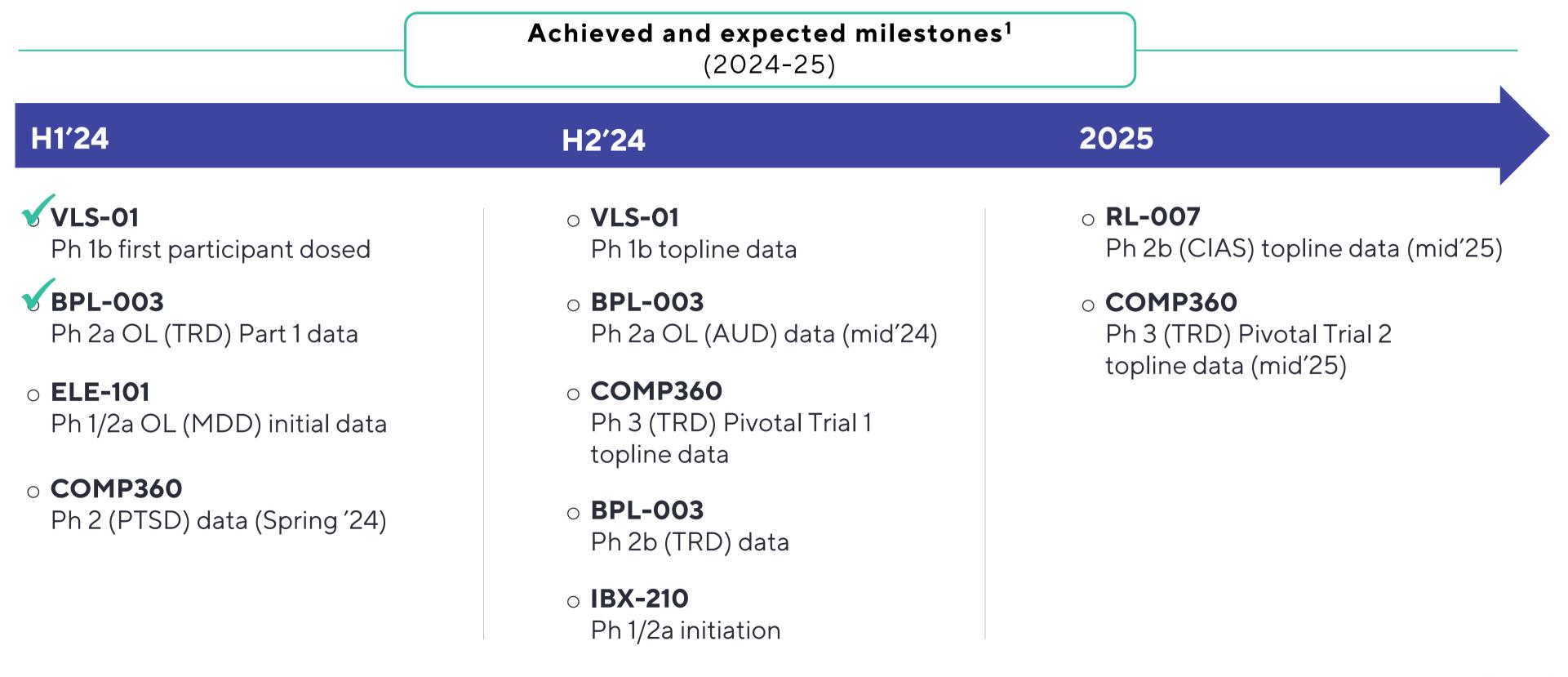
² Strategic Investment in Beckley PsyTech

³ RL-007 compound is (2R, 3S)-2-amino-3-hydroxy-3-pyridin-4-yl 1-pyrrolidin-1-yl-propan-1-one(L)-(+) tartrate salts



Upcoming Catalysts

We expect to deliver several meaningful R&D milestones anticipated across our key programs and strategic investments through 2024 and 2025¹





Programs in Depression BPL-003, VLS-01, COMP360, ELE-101



atai's Depression Portfolio Comparison

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

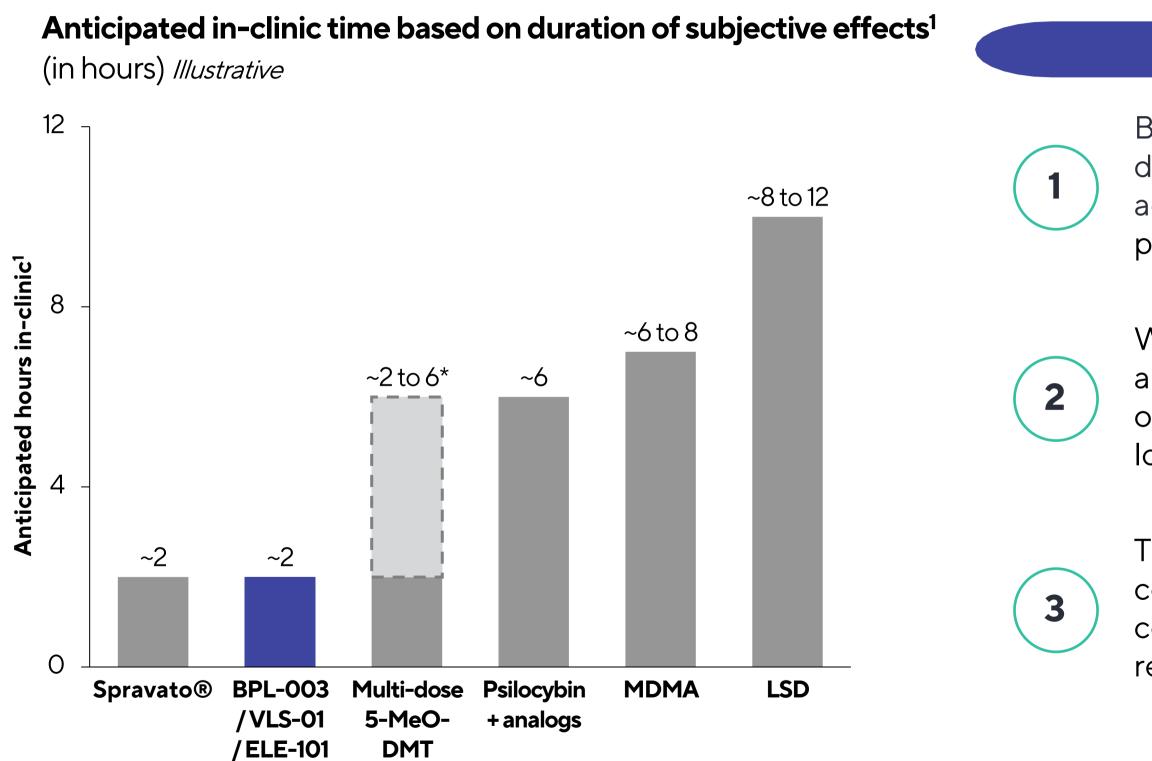
Associated Program	Compound	Primary Indication	Route of Administration	Receptor binding affinity (5-HT2A : 5-HT1A) ¹	Rapid Onset of Treatment Effect	Appr. Duration in clinic
BPL-003	5-MeO-DMT	TRD	Intranasal	0.01		~2h
VLS-01	DMT	TRD	Oral transmucosal film	3.4		~2h
COMP360	Psilocybin ²	TRD	Oral	2.0		~6h
ELE-101	Psilocin	MDD	Intravenous	2.0		~2h

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



Commercial Positioning

atai's focus is on psychedelics with the potential to leverage the 2-hour interventional psychiatry treatment paradigm successfully established by Spravato^{\mathbb{R}}



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

2. <u>https://www.spravatohcp.com/#find-a-center</u>

* If multi-dose required

Key Takeaways

BPL-003, VLS-01 and ELE-101 have the potential in depression to offer a predictable, single-dose model administered within the 2-hour in-clinic treatment paradigm established by Spravato®

We anticipate this facilitates more scalable adoption and allows clinics to accommodate a greater number of patients daily, compared to psychedelics with longer duration subjective effects

This may ultimately drive improved patient convenience and treatment access in the >4,000 certified delivery clinics² for Spravato® with proven reimbursement and logistics pathways



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

Strategic Investment into Beckley Psytech



BPL-003: Phase 1 Results

Beckley Psytech's BPL-003 had a favorable safety profile and was well tolerated in the Phase 1 SAD study, with no observed serious or severe adverse events

BPL-003 Phase 1 Treatment-Emergent Adverse Events (TEAEs)¹

			BPL-003 dose (N=31)				Total		
	Placebo N=13	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	Total N=44
Any TEAEs	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

¹ n = number of subjects reporting at least one TEAE in that category, % - rounded proportion of cohort total

Key Takeaways

There were no severe or serious adverse events observed, and 89.5% TEAEs were mild and 10.5% were moderate in severity.

Most common TEAEs (>10%) were nasal discomfort, nausea, vomiting, and headache. TEAEs did not appear to correlate with dose.



2

There were no clinically significant findings for laboratory parameters, vital signs, ECGs or physical examinations.



Blood pressure and heart rate increases were transient and resolved within 90 min without intervention. None were considered clinically significant.

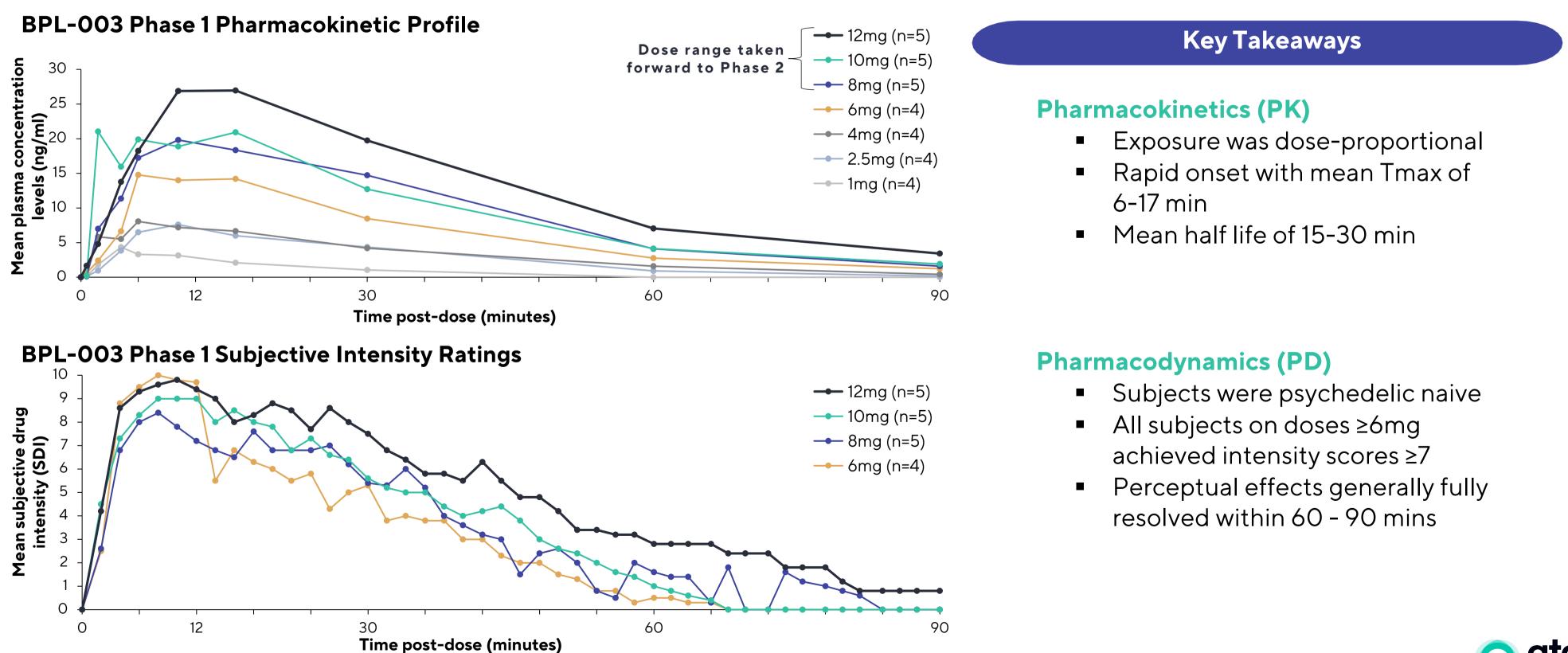


Results from the C-SSRS showed participants experienced no increase in suicidal thoughts, intentions or behavior.



BPL-003: Phase 1 Results

Results from the completed BPL-003 Phase 1 study demonstrated a dose proportional PK/PD profile with perceptual effects generally resolving within 90 min

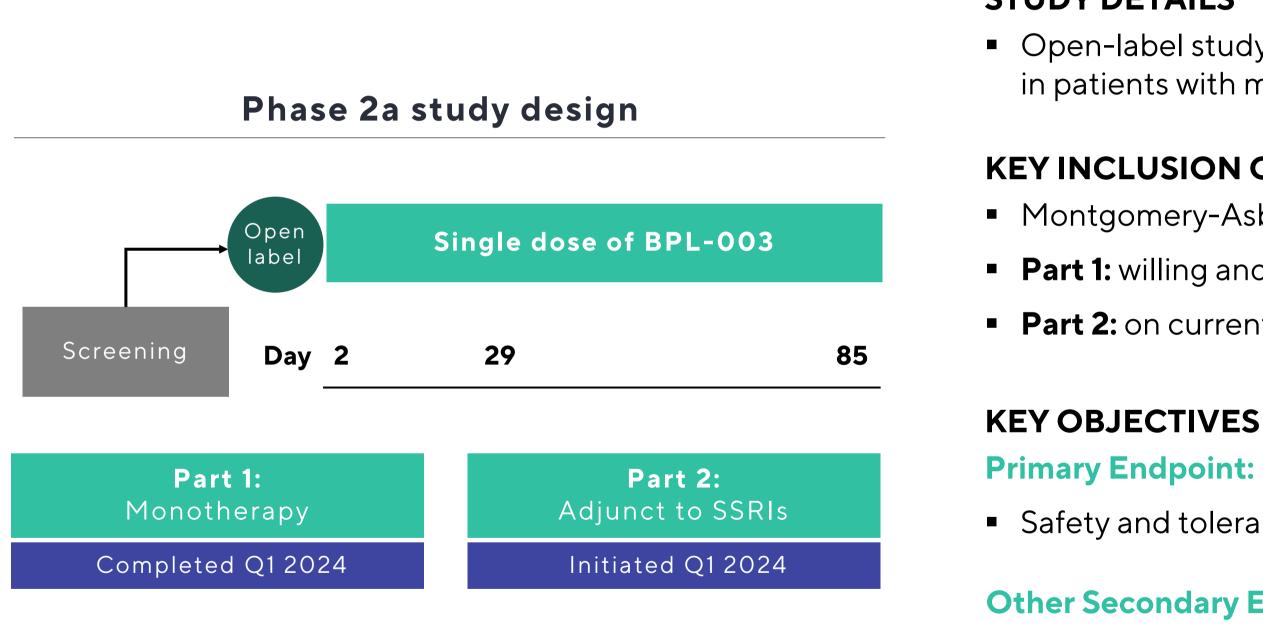


Source: internal Beckley Psytech data Abbreviations: SAD = Single Ascending Dose; PK = Pharmacokinetic; PD = Pharmacodynamic



BPL-003: Phase 2a Clinical Trial Design

Completed Part 1 of an open-label Phase 2a study investigating 10mg of BPL-003 as a monotherapy for TRD patients



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

STUDY DETAILS

 Open-label study evaluating a single dose of BPL-003 nasal spray, in patients with moderate-to-severe TRD

KEY INCLUSION CRITERIA

■ Montgomery-Asberg Depression Rating Scale (MADRS) score ≥24

• **Part 1:** willing and able to discontinue current antidepressants

Part 2: on current stable dose of antidepressant SSRI therapy

Safety and tolerability of BPL-003

Other Secondary Endpoints:

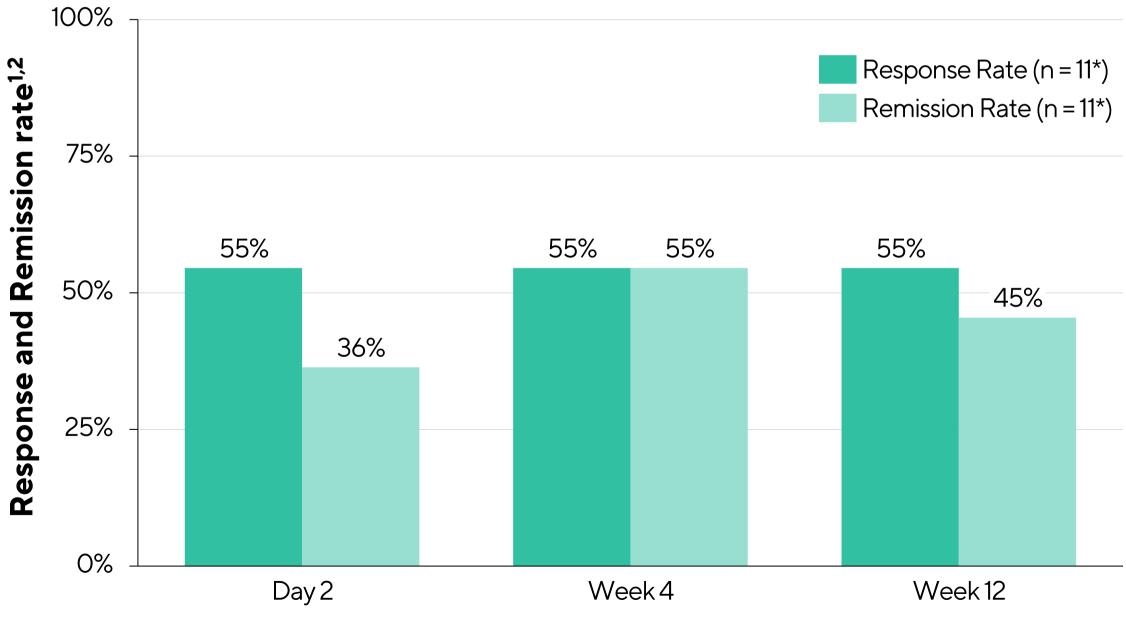


BPL-003: Phase 2a Results

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 rate¹ in TRD patients after a single dose of BPL-003



Time post-dose

Source: internal Beckley Psytech data

l. Response rate defined as ≥50% reduction in MADRS score and Remission rate defined as MADRS score ≤10

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

Key Takeaways



55% of patients achieved clinical response on Day 2 and this rate of response was maintained at Week 12



At Week 4, 55% of patients achieved both clinical remission and response



Acute effects resolved within an average time of less than 2 hours

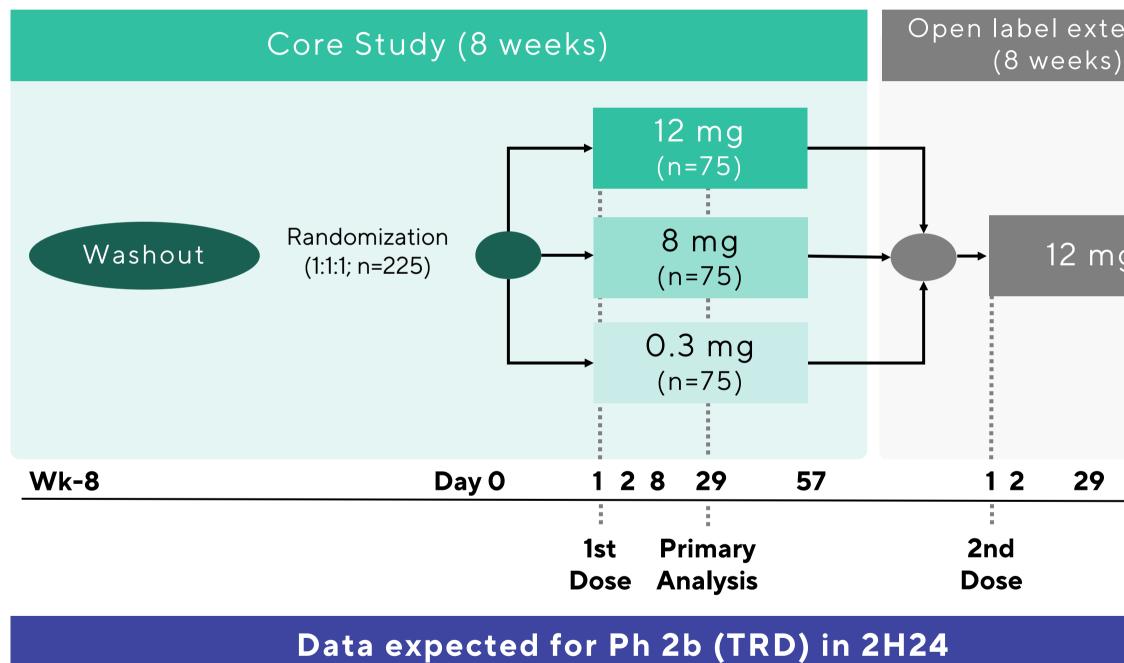


Most common AEs (>10%) were nasal discomfort, headaches, nausea and vomiting, broadly consistent with Phase 1 findings



BPL-003: Phase 2b Clinical Trial Design

BPL-003 is actively recruiting for its ongoing Phase 2b study, a randomized, quadruple-masked, monotherapy study in 225 moderate to severe TRD patients



(first patient dosed Oct 2023)

¹ 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 = EuroQoI-5D

nsic	on
- 1	
9 ¹	
	57

KEY INCLUSION CRITERIA

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

KEY OBJECTIVES

Primary Endpoint:

- MADRS change from baseline at Week 4
- **Other Secondary Endpoints:**
- MADRS change from baseline at Day 2, Week 1 and Week 8
- CGI-S, PGIC, EQ-5D



VLS-01 (DMT) for TRD



VLS-01: Product Overview

Potential for rapid onset, durable efficacy, and designed to fit within 2-hour in-clinic treatment paradigm

PRODUCT	DMT (N,N-Dimethyltryptamine) in an oral transmucosal film (OTF)	Le
INDICATIONS	<i>Lead:</i> Treatment Resistant Depression <i>Potential expansions:</i> Eating Disorders, Substance Use Disorders	
INTELLECTUAL PROPERTY	Granted U.S. patent covering OTF administration of DMT, supported by several pending U.S. and PCT patent applications	
CURRENT STATUS	Phase 1b first participant dosed in 1Q 24 Phase 1b trial results anticipated in 2H 24	

VLS-01 Key Product Features

- Short duration of psychedelic effect with improved tolerability and convenience from OTF delivery relative to other psychedelics in development for depression
- Designed for rapid onset, sustained efficacy, and to fit within a two-hour inclinic treatment paradigm
- Optimized OTF formulation is designed to improve the PK profile and the patient and provider experience

ead indication overview

Depression is a mood disorder that affects the thoughts and behavior of an individual, leading to psychological, physical, and social problems

Treatment resistant depression (TRD) is diagnosed after two failed courses of antidepressants

FDA approved depression treatments can be characterized by a slow onset, long-term side effects and inadequate response rate

Global disease burden



~300m

Global sufferers of depression in 2019¹

33%

Patients who have inadequate response or relapse after current treatments²



^{1.} World Health Organization

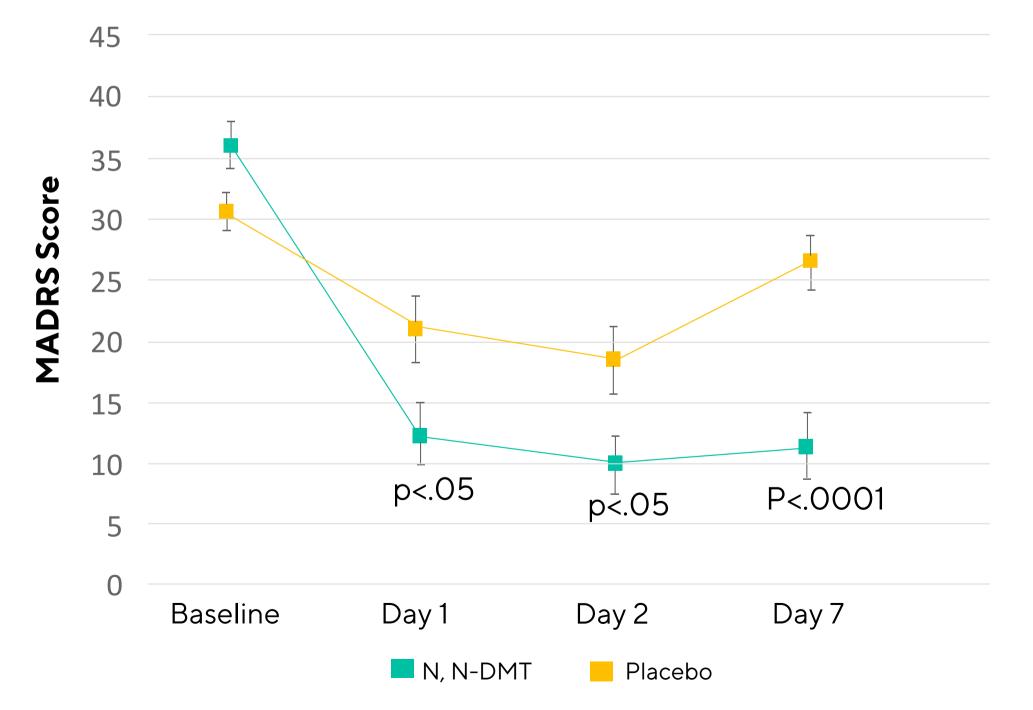
^{2.} Salzer, "National Estimates of Recovery-Remission From Serious Mental Illness", Psychiatry Online (2018)

Abbreviations: OTF = Oral transmucosal film; PK = Pharmacokinetic; PCT = Patent Cooperation Treaty

VLS-01: Efficacy in Randomized Control Trial of DMT in TRD Double-blind, randomized placebo-controlled trial with DMT in 29 patients with TRD demonstrated rapid & statistically significant changes on HAM-D & MADRS

PRIOR CLINICAL EVIDENCE (THIRD PARTY STUDY¹)

Double-blind, randomized placebo-controlled trial of Ayahuasca (DMT is major active ingredient) in 29 patients with TRD



Note: TRD = Treatment Resistant Depression; DMT = N,N-Dimethyltryptamine

1. Palhano-Fontes et al. "Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression", Psychol Med (2019)

Key Takeaways



2

3

Summary: A single administration of .36 mg/kg met both primary and key secondary efficacy endpoints by demonstrating rapid and statistically significant changes on depression severity measures of HAM-D & MADRS

Primary endpoint (HAM-D - not shown): N,N-DMT arm achieved the primary endpoint of a statistically significant difference in depression severity relative to placebo (p<.05).

Key secondary endpoint (MADRS – see left): rapid and statistically significant differences were observed at all timepoints assessed, including as early as Day 1 and through Day 7. MADRS is a potential registrational endpoint.

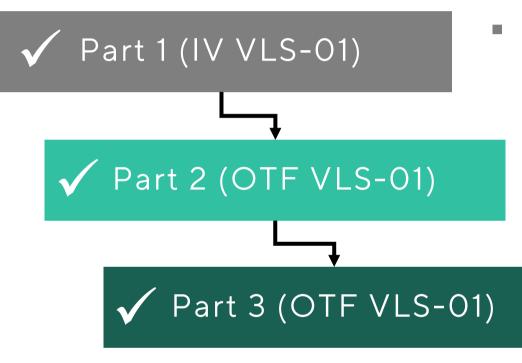
There were no serious adverse events reported.



VLS-01: Phase 1 Clinical Trial Design & Results

Phase 1 results of VLS-01 showed it was safe and well-tolerated with dose-dependent increases in exposure

STUDY DESIGN:



Phase 1 PK / PD RESULTS:

Program status: Phase 1b first participant dosed in Q124. Topline results expected 2H 24

IV VLS-01: PK / PD results were consistent with the known pharmacological profile of DMT, producing robust exposure-dependent increases in the subject intensity of psychedelic experience.

OTF VLS-01: Produced generally dose-dependent increases in exposure, approaching that seen with IV administration, alongside subjective psychedelic experiences in most patients.

• **OTF VLS-01:** 160mg with a backing layer via buccal administration experienced the most robust and consistent increases in exposure and subjective effects compared to the other OTF cohorts, with results comparable to the 30 mg IV cohort of DMT.



COMP 360 (Psilocybin) for TRD, PTSD and Anorexia

Strategic Investment into Compass Pathways

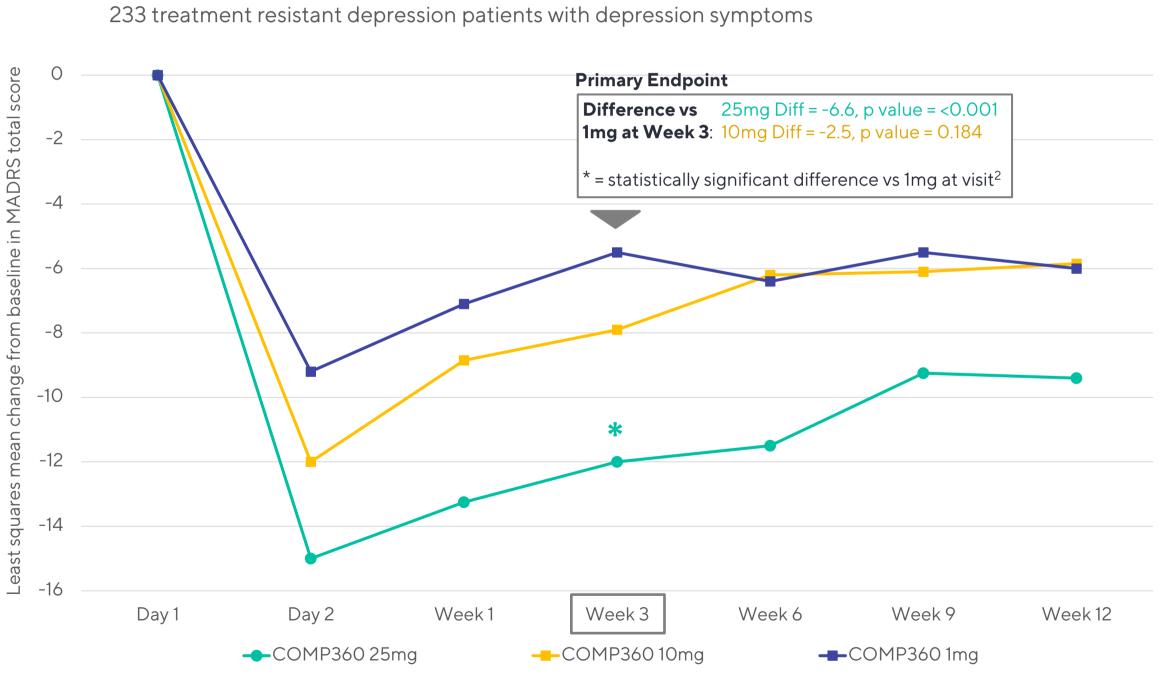


SUMMARY: COMP360

OWNERSHIP 9,565,774 shares¹ Oral Psilocybin (COMP360) PRODUCT PHARMA-5-HT2A-R agonist COLOGY Rapid onset, potential for sustained efficacy PRODUCT **FEATURES** after single dose Primary: Treatment Resistant Depression, Anorexia Nervosa, PTSD INDICATIONS Potential: Major Depressive Disorder, Autism, Bipolar Disorder, Chronic Cluster Headache CURRENT Phase 3 pivotal trial 1 data expected summer-24 Phase 3 pivotal trial 2 data expected mid-25 STATUS INTELLECTUAL Proprietary formulation of synthetic psilocybin, PROPERTY COMP360 COMP360 demonstrated efficacy in reducing depressive symptom severity with rapid and HIGHLIGHT durable response in Phase 2b study

COMP360 Phase 2b trial showed a rapid, sustained reduction in depressive symptoms

PRIOR EVIDENCE IN HUMANS (COMP360 PHASE 2b)



Note: MADRS = Montgomery-Åsberg Depression Rating Scale; COMP360 = a proprietary high-purity, polymorphic crystalline formulation of psilocybin; In COMPASS's model of psilocybin therapy, COMP360 is administered in conjunction with psychological support from specially trained therapists.

- Ownership as of March 27th, 2024
- end points.

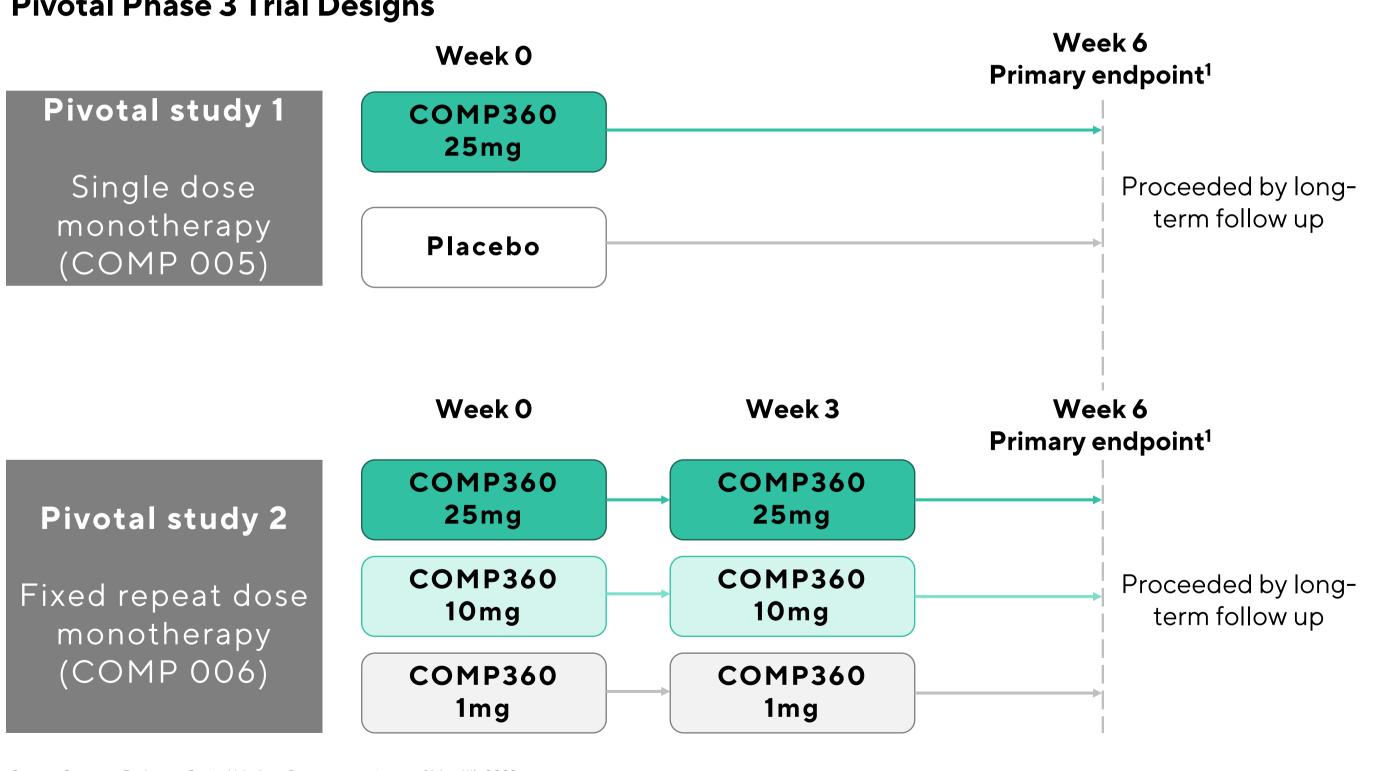
2. Post-hoc analysis showed results were also positive at the other time points listed for 25mg dose, however, the nonsignificant finding for the comparison between the 10mg group and the 1mg group terminated significance testing based on the prespecified hierarchical test procedure for all subsequent key secondary efficacy



COMP360: Phase 3 Trial Designs

COMPASS Pathways is currently conducting a Phase 3 pivotal program, with topline data expected in 4Q 2024 and mid 2025

Pivotal Phase 3 Trial Designs Week O **Pivotal study 1 COMP360** 25mg Single dose monotherapy Placebo (COMP 005)



Source: Compass Pathways Capital Markets Day presentation as of May 11th, 2023

1. Primary endpoint = Change from baseline in MADRS total score at week 6

2. The participant population (TRD definition and core inclusion / exclusion criteria) remains unchanged compared to Phase 2b

Randomization = 2:1Target $N^2 = 255$

Topline data expected: 4Q 2024

Randomization = 2:1:1Target $N^2 = 568$

Topline data expected: Mid 2025



ELE-101 (Psilocin) for MDD

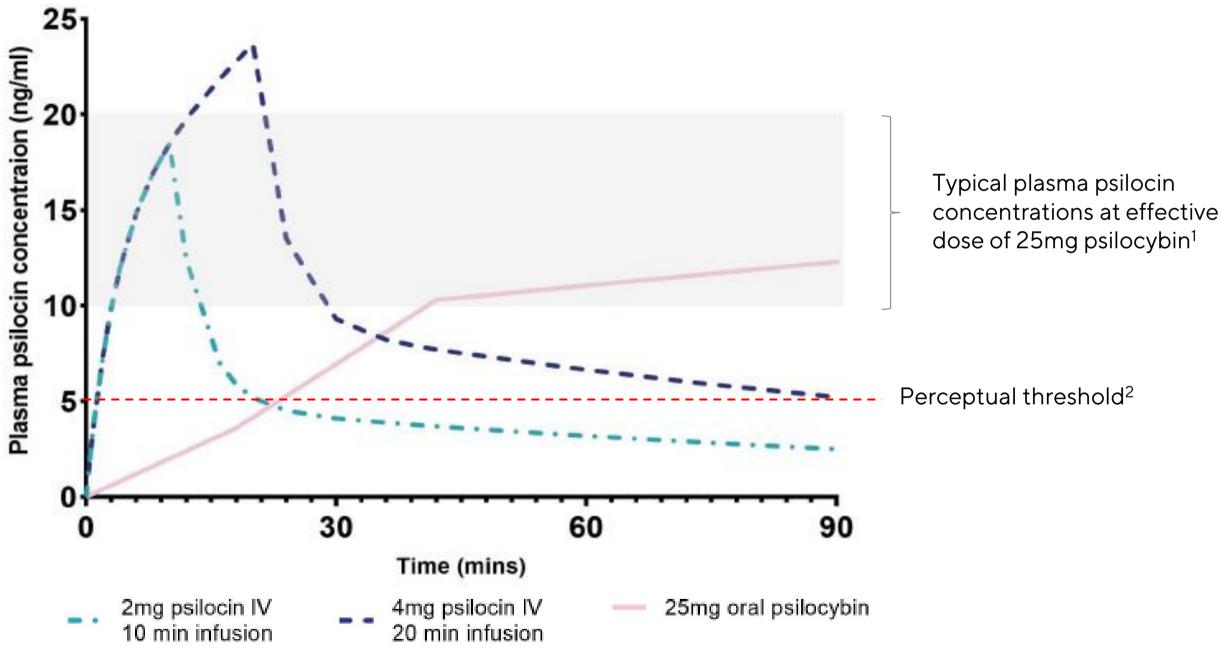
Strategic Investment into Beckley Psytech



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 psilocybin¹



¹ 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

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

Expected benefits of IV psilocin vs oral psilocybin:

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

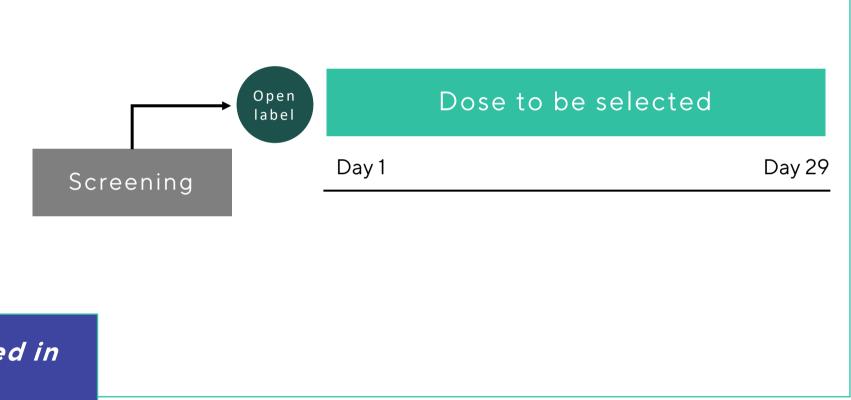


ELE-101: Phase 1/2a Clinical Trial Design

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

ELE-101 Phase 1/2a – Part B ELE-101 Phase 1/2a – Part A **Open-label MDD cohort** Single Ascending Dose Dose 4 Placebo Dose_3 Open label Placebo Day 1 Screening Dose 2 Placebo Dose 1 Placebo Initial results anticipated in Day 7 Day 1 H1 2024

Key Objectives:	Key C
» Safety and tolerability	» Sat
 » Safety and tolerability » Assessment of PK & PD » Target concentration of psilocin in <2 minutes 	sev
» Target concentration of psilocin in <2 minutes	» Ke
» Consistency of subjective intensity	>>



Objectives:

afety and tolerability of ELE-101 in patients with moderate to evere MDD

ey Secondary Endpoints:

Assessment of MADRS change (Day 2, 4, 6, 15, 29)

» CGI-S, PGIC



IBX-210 (IV-Ibogaine) for Substance Use Disorder



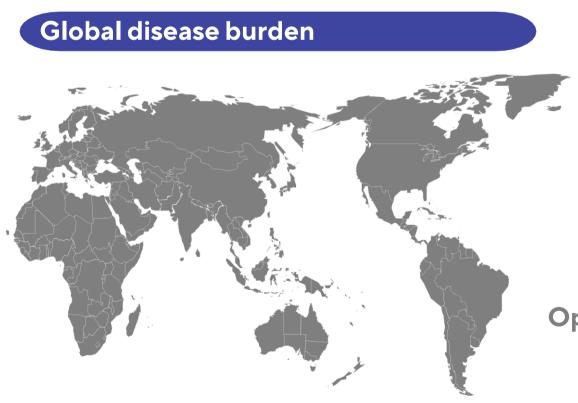
Product Overview: IBX-210 for Opioid Use Disorder A single dose of ibogaine may support withdrawal and long-term relapse prevention in OUD patients

PRODUCT	IBX-210 is a novel IV formulation of ibogaine, which is an indole alkaloid with potential for clinical benefit through oneirophrenic effects	Le
INDICATIONS	<i>Lead:</i> Opioid Use Disorder ("OUD") <i>Potential expansions:</i> Add'I Substance Use Disorders, PTSD, TBI ¹	i (
INTELLECTUAL PROPERTY	Issued and pending method of treatment claims for OUD) (5 (
CURRENT STATUS	Phase 1 oral ibogaine study completed in 3Q 23 IBX-210 Phase 1/2a study anticipated to initiate in H2 2024	2 2 (

IBX-210 Key Product Features

- A single dose of ibogaine delivered in a monitored setting may support withdrawal and long-term relapse prevention in Opioid Use Disorder patients
- Prior clinical evidence:
 - \succ In third-party open label studies, ibogaine was associated with significantly reduced opioid cravings, both at discharge and at one month post treatment, as well as improved mood in patients with OUD
 - \succ In addition, a double-blind, placebo-controlled study in subjects with cocaine use disorder demonstrated a statistically significant benefit on urine confirmed relapse of a single administration of ibogaine compared to placebo

- World Health Organization
- 3. Salzer, "National Estimates of Recovery-Remission From Serious Mental Illness", Psychiatry Online (2018)



d indication overview

ubstance use disorders are highly prevalent and characterized by an ability to control the use of a legal or illegal drugs, such as opioids ncluding prescription opioids) or alcohol.

urrent standard of care for OUD primarily consists of psychosocial upport and synthetic full and partial opioid receptor agonists nethadone & buprenorphine), where approximately 30% of patients chieve treatment success (defined as >80% illicit opioid free weeks). In ddition, long-acting opioid antagonists (naltrexone) lead to a proportion patients achieving treatment success.

~3m

US OUD Incidence in 2020²

>100k

Opioid-related deaths in US in 2022

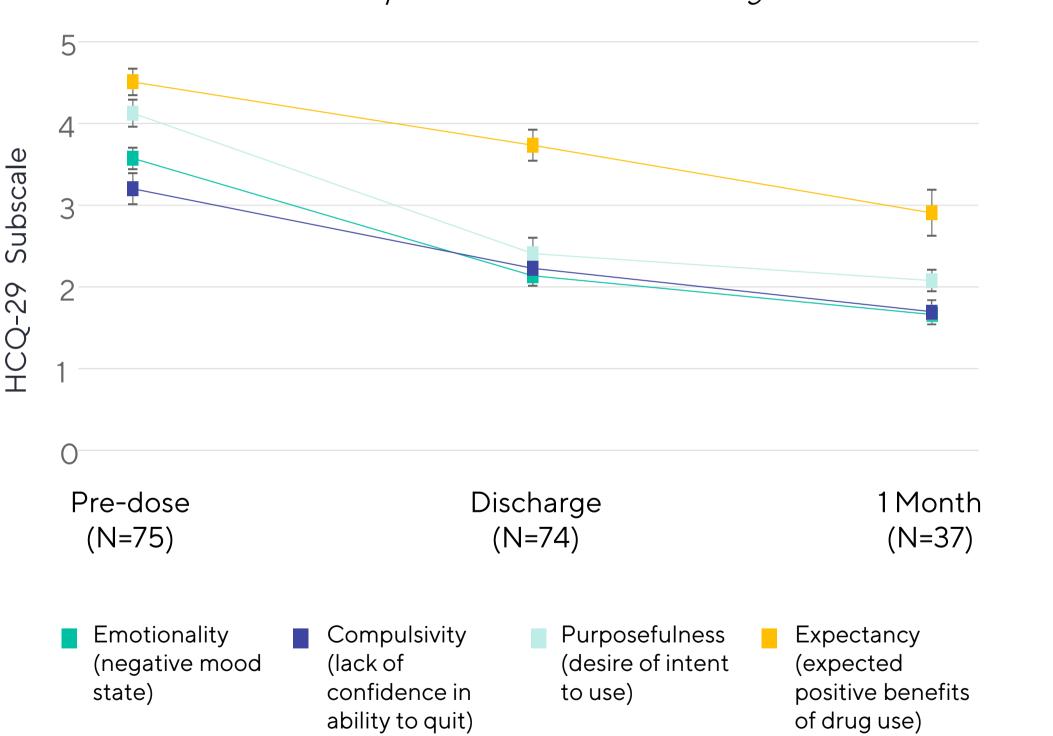


Post traumatic stress disorder and traumatic brain injury, respectively

Clinical Evidence: Efficacy of ibogaine in Open-Label Safety & Efficacy Study

Results from an open-label study of 8-12 mg/kg of ibogaine in patients seeking detoxification from opioids and cocaine

PRIOR CLINICAL EVIDENCE (THIRD PARTY STUDY¹)



Self-reported dimensions of craving

Note: TRD = Treatment Resistant Depression; DMT = N,N-Dimethyltryptamine; HCQ = Heroin Craving Questionnaire 1 Mash et al., "Ibogaine Detoxification Transitions Opioid and Cocaine Abusers Between Dependence and Abstinence: Clinical Observations and Treatment Outcomes" (2018)

Key Takeaways

Summary: A single-dose of ibogaine showed reductions in self-reported opioid cravings in 74 opioid dependent patients.



Efficacy – Relapse Prevention (shown left): Opioid dependent patients had significant reductions in the mean scores of four HCQ-29 domains of craving measured at program discharge and out to 1 month for patients continuing through study completion. Cravings are an important mediator of relapse.



Efficacy – Post-Acute Withdrawal Syndrome: signs and symptoms at post dose assessments were reduced compared to pre-dose baseline withdrawal severity measures. Objective signs of opioid withdrawal were mild and none were exacerbated at later time points.

Safety: Ibogaine was reported to be well tolerated with no serious adverse events.



SUMMARY

IBX-210 could potentially become a paradigmshifting therapy for **Opioid Use Disorder (OUD)**

Current standard of care for OUD is medication therapy, requiring opioid substitutes that carry significant side effects

Current strategies for withdrawal support have high rates of relapse

IBX-210 has the potential to become the first & best in-class treatment for OUD, minimizing risk of relapse

	Therapy	Mechanism of Action	Single Therapeutic Episode	No Opioid Side Effects	Minimal Abuse Potential	High Adherence / Low Risk of Relapse
Sustained relapse prevention Single dose administered in monitored setting, providing both withdrawal support and oneiric experience driving sustained remission	Ibogaine (IBX-210) DemeRx	Cholinergic, glutamatergic and monoaminergic receptor modulator	0		0	0
Medication	Methadone	Mu-agonist				
Assisted Therapy ¹ Daily therapy given in substitution of opioid in outpatient setting in attempt	Buprenorphine	Partial Mu-agonist				
to wean off from opioid	Naltrexone	Mu-antagonist				
Withdrawal Support² Therapies given for symptomatic	Clonidine	Alpha-2 agonist				
management during supervised withdrawal (detoxification)	Lofexidine	Alpha-2 agonist	\bigcirc	\bigcirc	\bigcirc	

Note: OUD = Opioid Use Disorder

Source: Publicly available information, including company websites and clinicaltrials.gov, GlobalData, Evaluate Pharma (both as of 2022) 1. Current Standard of Care

2. Rarely used given high rates of relapse. Used primarily in institutional or penitentiary settings



RL-007 for Cognitive Impairment



Product Overview: RL-007 for Cognitive Impairment Demonstrated consistent pro-cognitive effects in prior clinical trials, with a favorable safety profile in >500 subjects

PRODUCT	Oral, pro-cognitive neuromodulator	Lead in
		> Cog
INDICATIONS	<i>Lead:</i> Cognitive impairment associated with schizophrenia (CIAS) <i>Potential expansions:</i> Cognitive disorders including Alzheimer's	char
	dementia and/or Autism	Sucl
INTELLECTUAL PROPERTY	Issued composition of matter, formulation and method of use IP	belc
		> CIA
CURRENT	Phase 2a CIAS trial completed in H2′21 Phase 2b first patient dosed in 1Q′23	mor
STATUS	Phase 2b data expected in mid'25	> No

RL-007 Key Potential Product Features

Pro-cognitive effects demonstrated across four prior clinical studies, including two Phase 1 and two Phase 2 trials

- Consistent "inverted-U" dose response across clinical & preclinical studies
- Demonstrated safety & tolerability with no evidence of sedative side effects across the 10 clinical studies in >500 subjects



- 3. Bora et al, Cognitive Impairment in Schizophrenia and Affective Psychoses: Implications for DSM-V Criteria and Beyond
- 4. GlobalData (as of 31/12/2023)

indication overview

gnitive impairment associated with schizophrenia (CIAS) is aracterized by attention, learning, memory, and exec function deficits

ch deficits result in cognitive function around 2.5 standard deviations low the mean of the general population²

AS is a common and major cause of disability in schizophrenia, with bre than 80% of patients showing significant impairment³

FDA approved treatments⁴

Global disease burden

~24m

Global sufferers of Schizophrenia¹

>80%

Patients with Schizophrenia experiencing significant cognitive impairment³



^{1.} World Health Organization

Schaffer et al., 2013

Clinical Evidence: Efficacy on Cognitive Endpoints in a Phase 2 Study

Third-Party Phase 2 study in DPNP showed statistically significant positive cognitive signals (exploratory endpoints)

Background

- Phase II, randomized, placebo-controlled, crossover clinical study in subjects with diabetic peripheral neuropathic pain (DPNP) that assessed improvements in verbal learning and memory as an exploratory endpoint
- 4-week placebo periods were compared to 4-week RL-007 periods
 - "Intermediate-dose escalation" RL-007 40mg (first week) to 80mg (n=60)
 - "High-dose escalation" RL-007 150mg (first week) to 300mg (n=60)

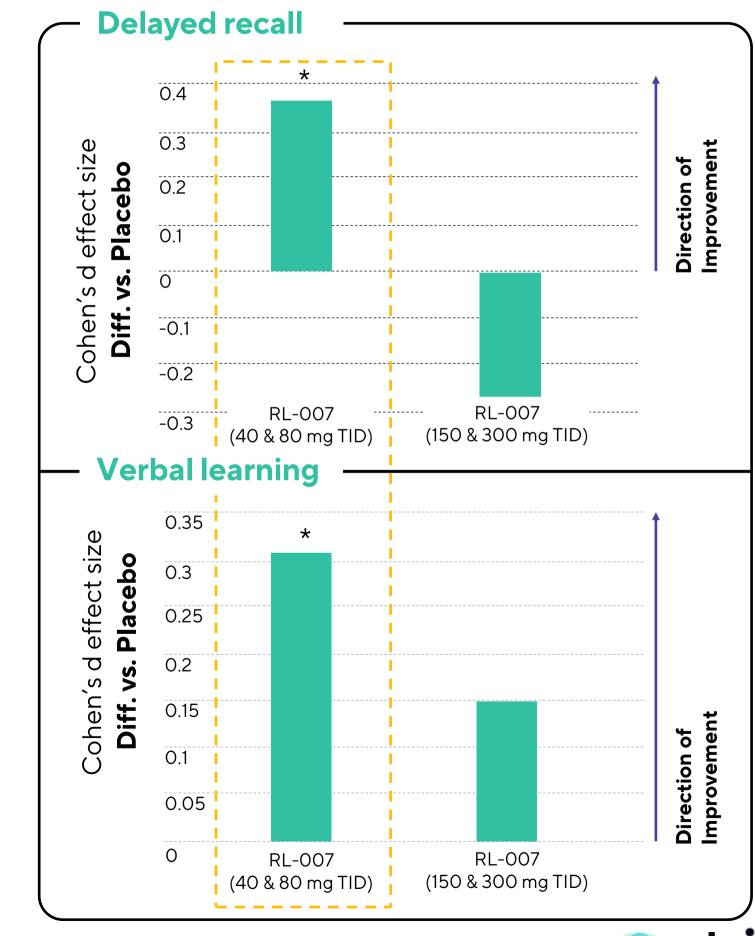
Key Takeaways

RL-007 showed statistically significant pro-cognitive effects on learning and memory within the "Intermediate-Dose escalation" 40mg to 80mg arm.

The 40 to 80mg arm patients also reported a statistically significant improvement on the Cognitive and Physical Function Questionnaire (p = 0.021)

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Inverted U-shaped dose response whereby intermediate doses yield greater clinical activity is replicated and consistent with from prior clinical and preclinical studies





Clinical Evidence: Efficacy Signals Reproduced in Phase 2a Study in CIAS atai's Phase 2a study in CIAS demonstrated positive cognitive signals on a subset of MCCB neurocognitive endpoints

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Background

- Cognitive function was assessed in 31 patients with CIAS across four RL-007 cohorts (10, 20, 40 & 80mg). Patients received four doses of placebo followed by six doses of RL-007 over 4-days. Day 2 "pre-RL-007" was compared to Day 4 "post-RL-007".
- The primary objectives of the single-blinded study was to confirm safety on-top of SOC and to identify signals of cognitive benefit in patients with CIAS, including on three MCCB sub-component neurocognitive tests, HVLT¹, BACS Symbol Coding & Category Fluency

Key Takeaways

Study demonstrated dose-related trends for improvements on each MCCB neurocognitive endpoints, including a Cohen's d effect size of 0.79, 0.56 and 0.38 at the 20mg, 40mg, and 80mg, respectively, on the BACS Symbol Coding test.

Importantly, Symbol Coding is the most sensitive subcomponent and correlates with overall performance on the MCCB neurocognitive composite, the latter being a registrational endpoint and the primary endpoint for the on-going Phase 2b study of RL-007.

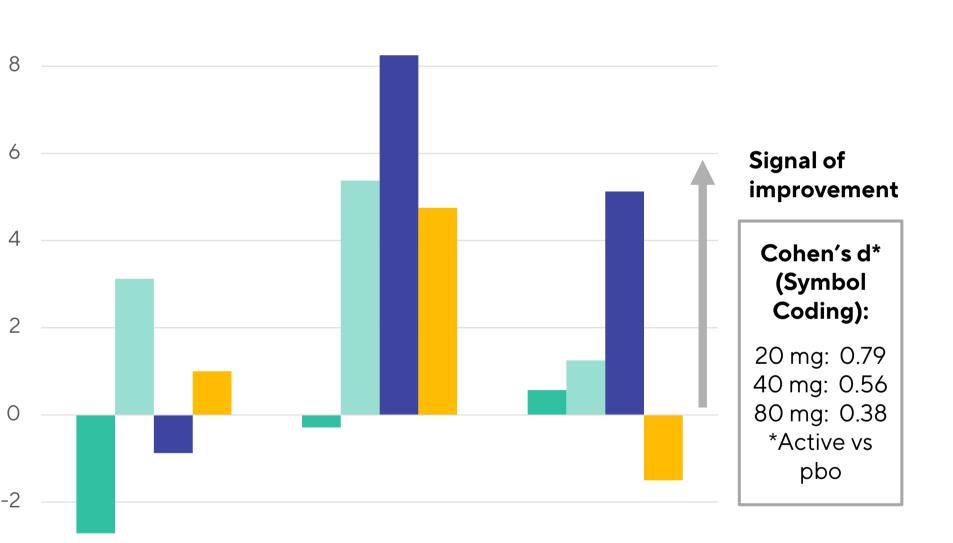
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2

In addition, gEEG data was consistent with the prior clinical evidence and 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.

PHASE 2a TRIAL - EFFICACY DATA ON COMPONENTS MCCB COMPOSITE

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

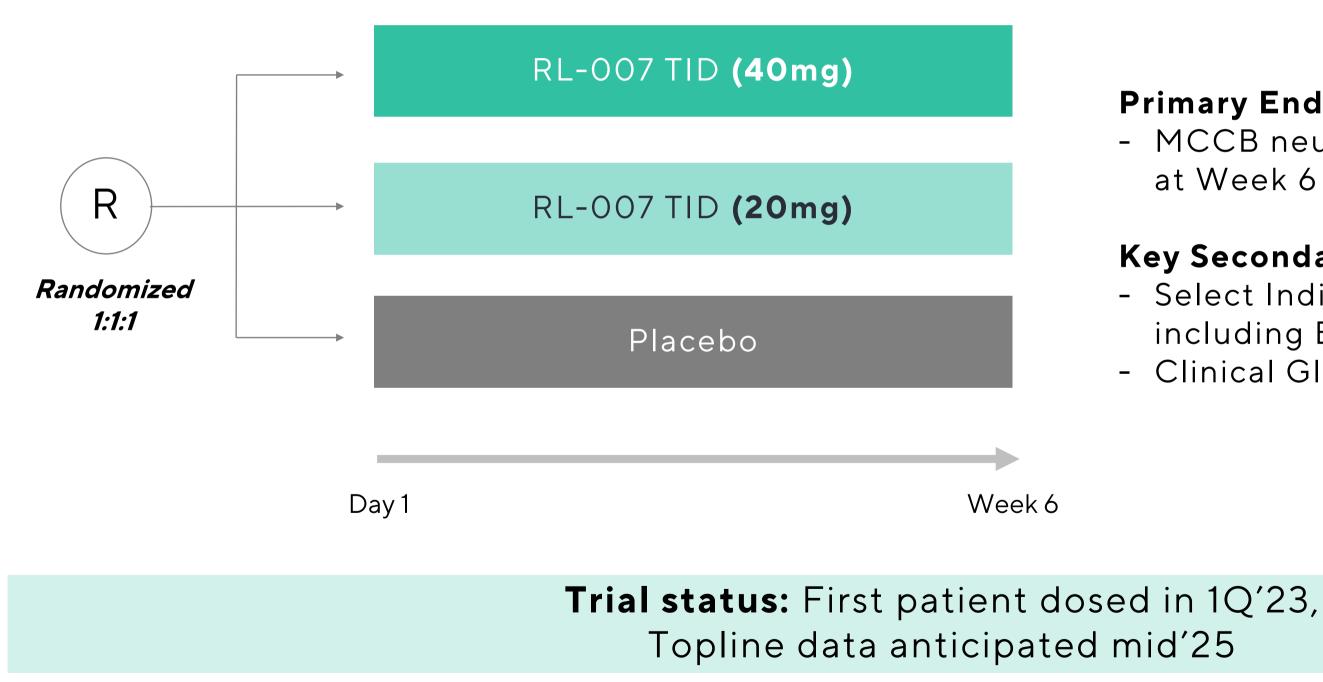






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Clinical Trial Design: RL-007 Phase 2b Study Randomized, placebo-controlled study of RL-007 in ~234 patients with CIAS



Note: MCCB = MATRICS Consensus Cognitive Battery; BACS = Brief Assessment of Cognition in Schizophrenia; CIAS = Cognitive Impairment Associated with Schizophrenia; TID = 3x/day dosing

Primary Endpoint:

- MCCB neurocognitive composite score at Week 6

Key Secondary Endpoints:

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



GRX-917 for Anxiety Disorders



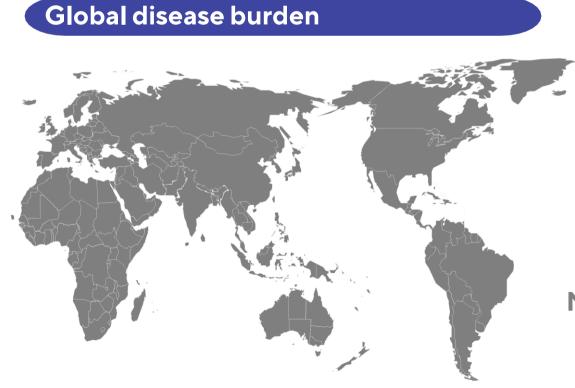
Product Overview: GRX-917 for Anxiety Disorders Designed to have rapid onset of anxiolytic activity but without the negative side effects seen with benzodiazepines

PRODUCT	Deuterated etifoxine HCI oral dosage form (GRX-917)	Lead in
INDICATIONS	Lead: Anxiety Disorders (e.g., GAD, SAD, PTSD, etc.)	Anxi pers
INTELLECTUAL PROPERTY	Issued composition of matter on deuterated etifoxine (GRX-917) and corresponding methods of use	> 50% optie
CURRENT STATUS	Phase 1 trial completed in H2′22 Exploring partnership and external funding opportunities	> No F

GRX-917 Key Product Features

- Demonstrated rapid onset activity of anxiolytic activity (non-deuterated etifoxine approved in France)
- Review of ~14m prescriptions in France underscores the strong safety track record for etifoxine
- Differentiated tolerability profile, with limited sedative, addictive and/or cognitive impairing properties, unlike benzodiazepines

Anxiety and Depression Association of America (2021)



indication overview

xiety disorders develop when feelings of apprehension and unease rsist over an extended period and potentially worsen over time

% of US patients go untreated as a result of sub-optimal treatment tions²

FDA approved novel treatments over the past decade³

~3()()m

Anxiety disorder sufferers in 2019¹

#1

Most common mental health disorder¹



^{1.} World Health Organization

^{3.} GlobalData (as of 6/1/2023) - All recent approvals by the FDA have been reformulations of long-standing antidepressant and benzodiazepine options

Nasdaq: ATAI

