

### Transforming Mental Health Care

Investor Presentation

November 2025



#### Disclaimer

#### Cautionary Note Regarding Forward-Looking Statements

This presentation includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, you can identify forward-looking statements by terms such as "believe," "continue," "could," "estimate," "expect," "may," "might," "plan," "potential," "project," "target," "would," or the negative of these terms, and similar expressions intended to identify forward-looking statements. However, not all forward-looking statements contain these identifying words. These forward-looking statements include express or implied statements relating to our strategic plans or objectives; our expectations and projections about our future cash needs and financial results; our plans and expectations regarding our phase 3 trials in TRD, including our expectations regarding the time periods for the release of data from the COMP005 and COMP006 Phase 3 trials for TRD; our expectations regarding discussions with the FDA, including discussions regarding potential NDA acceleration strategies, including potential for rolling NDA submission for COMP360 psilocybin treatment in TRD; our expectations regarding potential commercial launch timelines and our plans regarding commercial readiness; the potential for the pivotal phase 3 program in TRD to support regulatory filings and approvals on an accelerated basis or at all; our expectations regarding the safety or efficacy of our investigational COMP360 psilocybin treatment, including as a treatment for treatment of TRD or PTSD; our ability to obtain regulatory approval and adequate coverage and reimbursement; our ability to transition from a clinical-stage to a commercial-stage organization and effectively launch a commercial product, if regulatory approval is obtained or on an accelerated timeline or at all; and our expectations regarding the benefits of our investigational COMP360 psilocybin treatment. By their nature, these statements are subject to numerous risk and uncertainties, including the uncertainties associated with risks related to clinical development which is a lengthy and expensive process with uncertain outcomes, and therefore our clinical trials may be delayed or terminated and may be more costly than expected; the results of early-stage clinical trials of our investigational COMP360 psilocybin treatment may not be predictive of the results of later stage clinical trials; our need for substantial additional funding to achieve our business goals and if we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our clinical trials; our acceleration strategies for our NDA submission may not be successful; FDA may ultimately disagree with our proposal for a rolling NDA submission and may not permit us to utilize the rolling review process; our efforts to obtain marketing approval from FDA or regulatory authorities in any other jurisdiction for our investigational COMP360 psilocybin treatment may be unsuccessful; our efforts to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment. if approved, may be unsuccessful; the risk that our strategic collaborations will not continue or will not be successful; and our ability to retain key personnel; and other factors beyond our control, that could cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied in our statements. For additional disclosure regarding these and other risks we may face, see the disclosure contained under the heading "Risk Factors" and elsewhere in the Company's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and subsequent public filings with the US Securities and Exchange Commission (the "SEC"). You should not rely upon forward-looking statements as predictions of future events. Although our management believes that the expectations reflected in our statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Moreover, neither we, nor any other person, assumes responsibility for the accuracy and completeness of these statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date such statements are made and should not be construed as statements of fact. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect any new information, events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

#### Market & Industry Data

Market & industry data projections, estimates, industry data and information contained in this presentation, including our general expectations about our market position and market opportunity, are based on information from third-party sources, publicly available information, our knowledge of our industry and assumptions based on such information and knowledge. Although we believe that our third party-sources are reliable, we cannot guarantee the accuracy or completeness of our sources. All of the projections, estimates, market data and industry information used in this presentation involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information. In addition, projections, estimates and assumptions relating to our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including, but not limited to, those described above, that could cause future performance to differ materially from our expressed projections, estimates and assumptions or those provided by third parties.



### **Key Highlights**

#### **Near-term Catalysts**

- Company is accelerating commercialization launch readiness plans by 9-12 months
- 9-week (Part A) data from COMP006 in Q1 2026
- 26-week (Part B) data from COMP005 in Q1 2026
- 26-week (Part B) COMP006 data expected in early Q3 2026

#### Large Market with Strong Unmet Need

- ~3M U.S. patients suffer from TRD, representing a large unmet need in psychiatry
- Spravato® (J&J) is guided to become a \$3 \$3.5B product by 2028, many TRD patients remain unresponsive or intolerant to current therapies
- PTSD affects an estimated 13 million adults in the U.S. each year, with limited effective treatment options
- COMP360 psilocybin treatment has the potential to deliver rapid, durable, and meaningful improvements

#### Late-stage Development

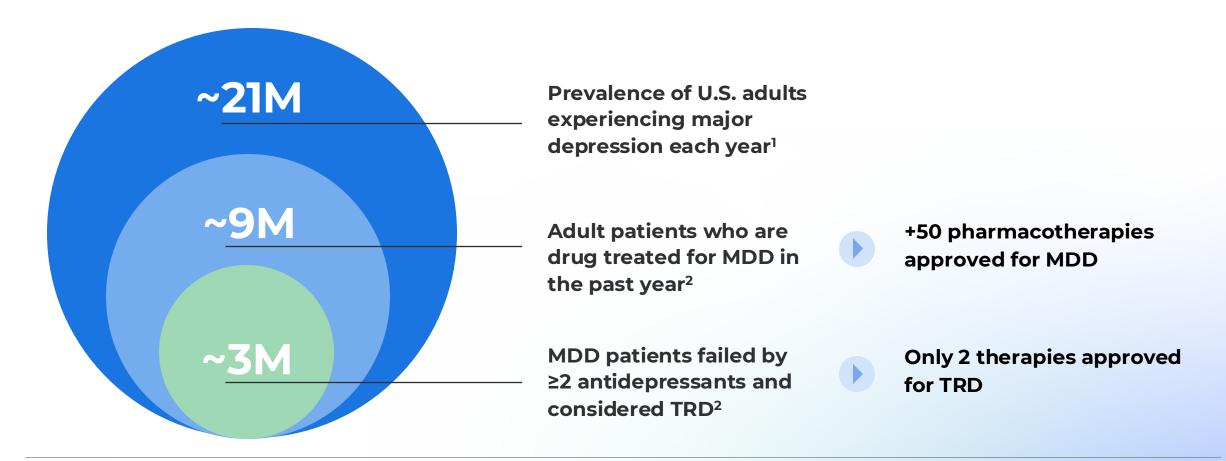
- Advancing two Phase 3 trials (COMP 005 and COMP 006) evaluating COMP360 in TRD
- Phase 2b results demonstrated significant, rapid, and durable antidepressant effects
- Positive discussions with FDA regarding potential acceleration scenarios, including rolling submission, for our NDA submission for COMP360 in TRD
- Phase 2 data of COMP360 showed a safe and differential profile in patients with PTSD

#### **Strong Cash Position**

- \$185.9 million as of September 30, 2025
- Sufficient cash runway into 2027, well beyond key catalysts



### Treatment-resistant Depression (TRD) affects millions in the U.S.





The definition of TRD adopted by the US Food and Drug Administration (FDA) is **failure to respond to two or more antidepressant regimens** despite adequate dose and duration and adherence to treatment<sup>3</sup>



## Compass is developing COMP360 to transform the lives of patients living with TRD

#### SSRIs / SNRIs / Antipsychotics



- +50 pharmacotherapies approved for MDD¹
- GI disruption, sexual dysfunction, suicidal ideation, etc.
- Delayed onset of efficacy versus rapid onset



### First multi-hour pharmacologic for TRD

- J&J has guided that Spravato will become a \$3 - \$3.5B product by 2028
- Patients may require weekly or bi-weekly visits to treatment centers per year to maintain treatment effect<sup>2</sup>

#### **COMP360**

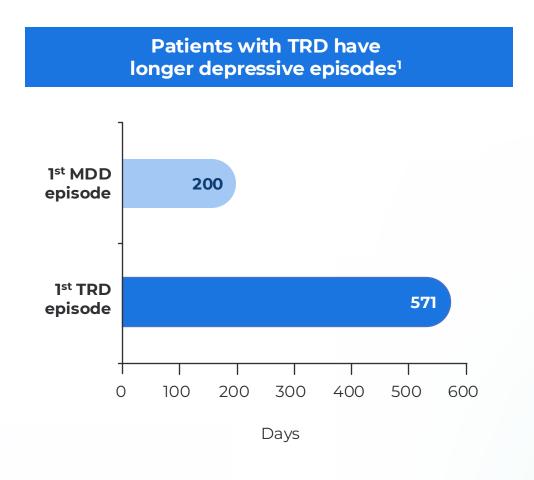
Robust clinical profile in a TRD market with a high unmet need in a large patient population

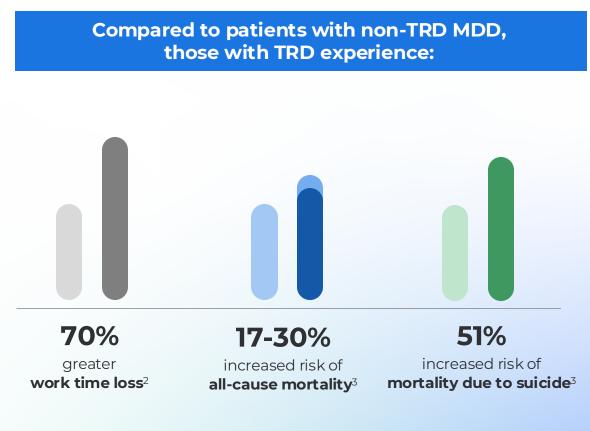
- Statistically significant and consistent clinical responses
- Rapid onset of treatment effect
- Durable effect after a single dose
- Significant reduction in treatment/patient burden

Opportunity for improved outcomes with two fixed doses in COMP006



# TRD patients are disproportionately impacted vs. non-TRD MDD patients

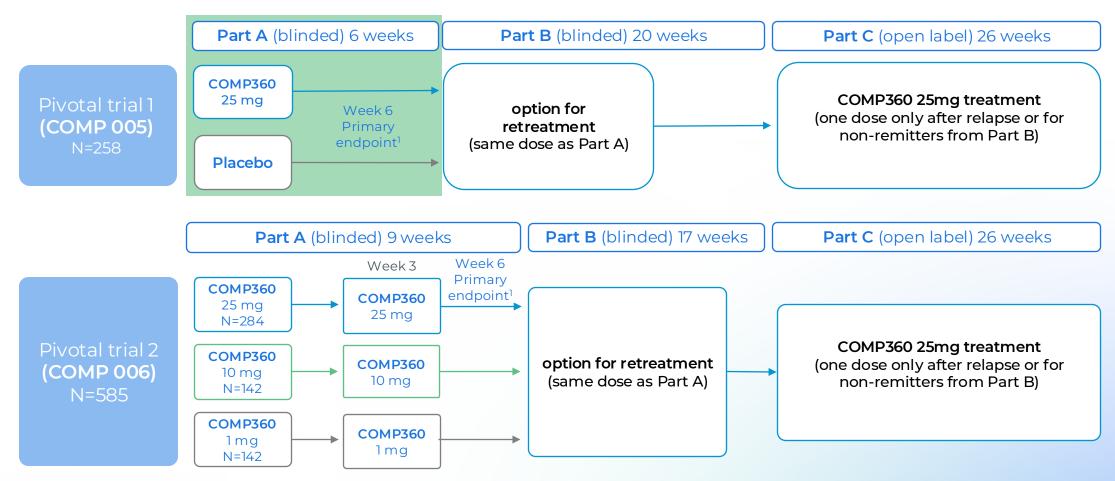








### Phase 3 program: Overview of pivotal trial designs



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

1. Primary endpoint = change from baseline in MADRS total score at Week 6. 2. Remitters are defined as patients with MADRS total score ≤12 and no single item ≥4. Note that it can take several weeks to organise a dosing session for non-remitters from Part A or Part B so re-dosing does not necessarily happen immediately at the start of Part B or Part C, respectively.



# Phase 3 COMP005 trial: Primary endpoint achieved with high statistical significance

- Clinically-meaningful mean treatment difference of -3.6 points on MADRS
- p<0.001; CI: 95% (-5.7, -1.5)
- Safety (statement provided by the DSMB chair June 23, 2025):
  - Based on the latest review of the data for the COMP 005 and COMP 006 studies, safety findings are consistent with previous studies of COMP360 and there are no new or unexpected safety findings. From this review of the data, there is no evidence of a clinically meaningful imbalance between treatment arms in suicidality in either study.

Part A (blinded) 6 weeks

Primary endpoint

COMP360 25
mg

Placebo

Note: The COMP005 trial is ongoing, the results are preliminary and have not been reviewed by FDA Statement on file from the DSMB Chair, dated June 19, 2025.



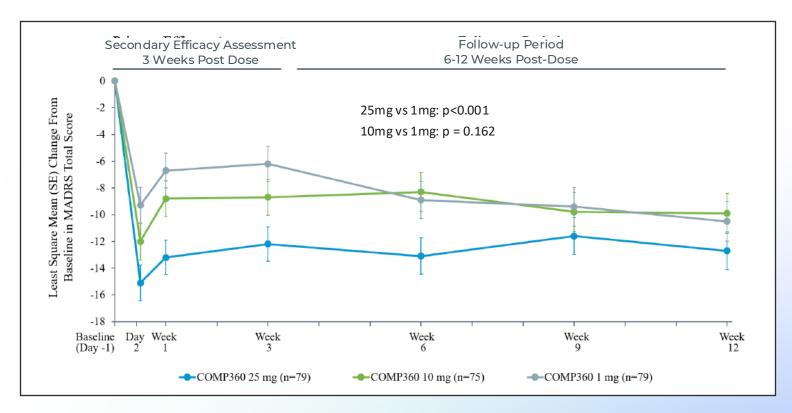
## Phase 2b trial: Results demonstrate the potential for a rapid, sustained response in TRD

Published in The NEW ENGLAND JOURNAL of MEDICINE\*

In a randomized, controlled, doubleblind trial, three groups of participants were given a single dose (either 1mg, 10mg or 25 mg) of COMP360 psilocybin alongside psychological support.

Results were measured as a change on the MADRS\* depression scale from baseline (a day prior to administration) over a 12-week period.

The primary endpoint of this study was the change from baseline in MADRS total score at week 3.



Clinical Effect: We saw a statistically significant and clinically meaningful reduction in depression symptoms Rapid onset of action: The effect occurred the day after the administration.

Durability: We saw a sustained response at week 12 – a positive indication for high potential as a monotherapy.

NOTE: \*\*Least square mean change from baseline in MADRS total score; MADRS = Montgomery-Åsberg Depression Rating Scale; the above analysis is from the NEJM Supplement and does not include the imputation for use of anti-depressants (see appendix for the trial protocol analysis)



### Phase 2b trial: COMP360 psilocybin treatment was generally well-tolerated

#### Treatment-emergent adverse events (TEAEs)

>90%

of TEAEs were of mild or moderate severity.

5

most frequent TEAEs across the 10mg and 25mg doses were headaches, nausea, fatigue, insomnia and anxiety.

>77%

of TEAEs occurring on the day of administration resolved on the same or next day; most were mild or moderate. There were no concerns with vital signs, ECG or clinical laboratory data in any of the treatment groups

TEAEs involving hallucinations (which only occurred in the 25mg and 10mg groups) and illusions (all groups) started and resolved on the day of administration.

TESAEs of suicidal ideation, suicidal behaviour and intentional self-injury were uncommon but occurred unevenly across groups in non-responders

- All patients who experienced these events during the trial had said during screening that they had had suicidal thoughts prior to the trial.
- 3 TESAEs of suicidal behavior in non-responders, at least 30 days post administration in the 25 mg arm emphasizing the need for a vigilant approach to the TRD condition.

# COMP004: Long-term data shows average efficacy of a single dose of 25mg COMP360 at 92 days

#### **Durable improvement in symptoms:**

52-week observational follow-up study from Phase 2b reveals single 25 mg COMP360 psilocybin dose offers longer-term antidepressant effects compared to lower doses, with average efficacy for a single dose of 25mg lasting about 12 weeks in all P2b participants (n=233)

Median time to depressive event was substantially longer (up to 189 days) in a post hoc analysis of the subgroup of participants that were enrolled in the '004 study (n=58)\*

#### Safety monitoring.

COMP360 was generally well tolerated. Three participants reported experiencing a treatment emergent serious adverse event (TESAE) post-enrollment to COMP004, occurring more than 6 months after a single dose administration and all deemed unrelated to study drug.

#### Published in March 2025 edition of the Journal of Clinical Psychiatry.

\*note the potential for some "survivor" bias in this group



# Our early commercial planning efforts are focused on ensuring appropriate TRD patients can access COMP360, if approved



#### **Educate & Learn**

KOLs/HCPs

Clinical care teams

**Patients** 

Payers

Federal and State policy makers



#### **Enable Awareness & Access**

Educating advocacy organizations

Developing a meaningful value proposition

Generating value and outcomes research

Engaging in permitted preapproval payer discussions



#### **Prepare for Launch**

Strategic collaborations

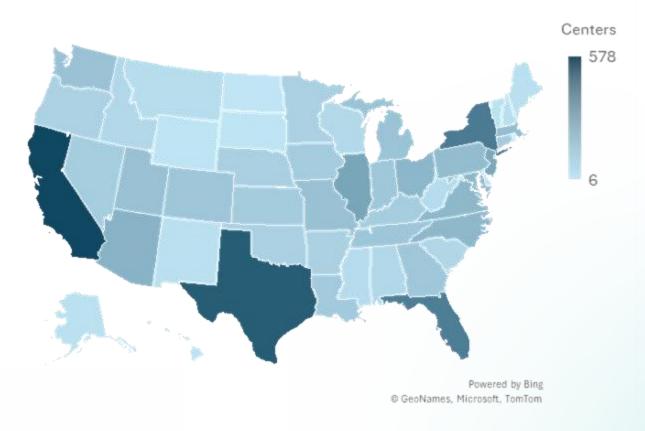
Identify potential implementation gaps for new sites potentially delivering COMP360

Leverage existing Spravato infrastructure



# Potential launch of COMP360 will leverage a well-established infrastructure of interventional psychiatry treatment centers

#### ~6,000 Spravato treatment centers in US¹



1.. www.spravatohcp.com/find-treatment-center – data pulled 6/10/2025

#### **Established Practice Patterns**

- Dedicated rooms/areas for longer treatments
- Operational and scheduling capabilities with team-based workforce
- Knowledge of and operational knowhow of payer reimbursement requirements
- Knowledge of and operational knowhow of Risk Evaluation and Mitigation Strategy (REMS) requirements
- Scaling to meet patient demand



# If approved, COMP360 prescribing, dosing, and reimbursement is expected to integrate within current clinical practice

#### **Prescribing**

Prescribed by an HCP licensed to prescribe medication to patients

#### **Dose administration**

Patient self-administers and is monitored by a licensed HCP¹ during session Dosing and monitoring to take place at a certified treatment center

#### Reimbursement<sup>2</sup>

COMP360 available through specialty pharmacy and buy-and-bill – drug reimbursed through **pharmacy benefit.** Evaluation and Monitoring (E/M) CPT<sup>3</sup> codes - billed by the hour through **medical benefit** 

- 1. Based on draft guidance by the FDA for psychedelic drug development (June 2023), credentials for a qualified HCP are stated a s: PhD, PsyD, MD, DO, MSW, LCPC, LMFT, NP
- 2. Coding and reimbursement for COMP360 have not yet been established and are subject to change from current thinking
- 3. CPT stands for Current Procedural Terminology. It's a system of codes created by the American Medical Association (AMA) to describe medical procedures and services. These codes are used for billing purposes and are part of the national coding system under the Health Information Portability and Accountability Act (HIPAA)

Note: CPT III codes accepted, and language released by AMA for Psychedelic Drug Monitoring Services; published in the CPT Manual and effective on January 1, 2024



### Phase 2 PTSD study safety profile (primary endpoint)

#### Summary of most frequent TEAES (≥10% prevalence)

COMP360 was generally well tolerated with no treatment emergent serious adverse events reported

No participants restarted SSRI's or antidepressants after COMP360 administration in study

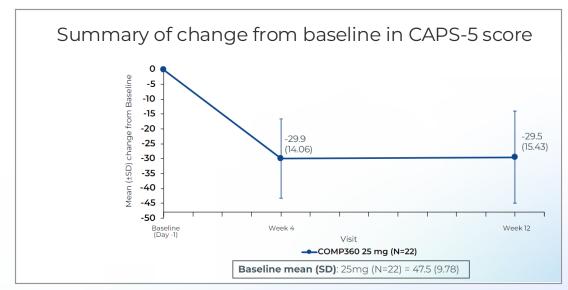
MedDRA TEAE Preferred Term (at least 5%)	COMP360 25 mg (N = 22)			
	Overall		COMP360 admin day	
	n (%)	Е	n (%)	E
Headache (PTs: Headache, Tension headache)	11 (50.0)	15	6 (27.3)	6
Nausea	8 (36.4)	9	6 (27.3)	6
Crying	6 (27.3)	6	6 (27.3)	6
Fatigue	6 (27.3)	6	4 (18.2)	4
Hallucination (PTs: visual, auditory, synaesthetic)	5 (22.7)	7	5 (22.7)	7
Muscle tightness	3 (13.6)	3	3 (13.6)	3
Paraesthesia	3 (13.6)	3	2 (9.1)	2
Visual impairment	3 (13.6)	3	3 (13.6)	3

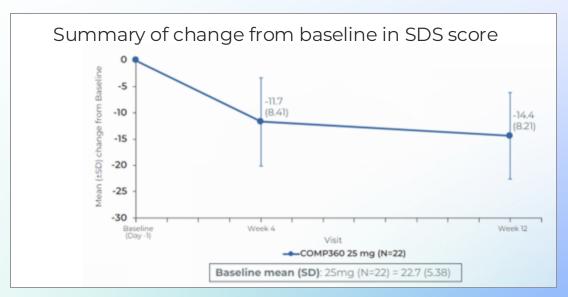
There were 2 events of suicidal ideation, the first event was a moderate and transient event on administration day who went on to be a responder. The second event was mild and occurred at Week 7 by a non-responder. Both events resolved during the study.



## Phase 2 PTSD study: meaningful and sustained symptom improvement

- N=22, multi-center open-label, single administration of 25mg
   COMP360 with psychological support
- Early onset and sustained change from baseline in CAPS-5 observed at week 4 and week 12
- Durability in CAPS-5 reductions from baseline seen at week 4 (29.5 points) and week 12 (29.9)
- Response in CAPS-5: 81.8% at week 4, 77.3% at week 12
- Remission in CAPS-5: 63.6% at week 4, 54.5% at week 12
- COMP360 was generally well tolerated with no treatment emergent serious adverse events reported
- No participants re-started SSRI's or antidepressants after COMP360 administration in study
- Mean baseline of 47.5 CAPS-5 total score, which is considered severe





### Appendix



### Phase 2b most frequent TEAEs ordered by the 25mg arm (at least 5% in any treatment group)

MedDRA TEAE	COMP360 25mg	COMP360 10mg	COMP360 lmg	Overall			
preferred term	N=79	N=75	N=79	N=233			
•	n (%)						
Headache	27 (34.2)	16 (21.3)	20 (25.3)	63 (27.0)			
Nausea	18 (22.8)	7 (9.3)	4 (5.1)	29 (12.4)			
Fatigue	12 (15.2)	5 (6.7)	7 (8.9)	24 (10.3)			
Insomnia	8 (10.1)	11 (14.7)	14 (17.7)	33 (14.2)			
Anxiety	7 (8.9)	13 (17.3)	3 (3.8)	23 (9.9)			
Mood altered	7 (8.9)	3 (4.0)	1 (1.3)	11 (4.7)			
Back pain	6 (7.6)	0	3 (3.8)	9 (3.9)			
Dizziness	6 (7.6)	1 (1.3)	1 (1.3)	8 (3.4)			
Suicidal ideation	5 (6.3)	5 (6.7)	4 (5.1)	14 (6.0)			
Myalgia	5 (6.3)	2 (2.7)	1 (1.3)	8 (3.4)			
Euphoric mood	4 (5.1)	5 (6.7)	4 (5.1)	13 (5.6)			
Depression	4 (5.1)	6 (8.0)	5 (6.3)	15 (6.4)			
Abdominal pain upper	4 (5.1)	2 (2.7)	1 (1.3)	7 (3.0)			
Irritability	4 (5.1)	2 (2.7)	1 (1.3)	7 (3.0)			
Panic reaction	4 (5.1)	1 (1.3)	1 (1.3)	6 (2.6)			
Depressed mood	3 (3.8)	5 (6.7)	4 (5.1)	12 (5.2)			
Paraesthesia	3 (3.8)	4 (5.3)	1 (1.3)	8 (3.4)			
Thinking abnormal	0	4 (5.3)	0	4 (1.7)			

TEAE incidence is higher in the 25mg group overall

Key mood-related TEAEs (euphoric mood, depression, depressed mood, suicidal ideation) do not have a higher incidence in the 25mg arm

Note: MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment emergent adverse event; N = number of participants in the population; n = number observed



### We're a biotechnology company...

...dedicated to accelerating patient access to evidence-based innovation in mental health.

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