

Every journey needs a Compass

Investor Presentation
Q2 2026

compass

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,” “will,” “would,” or “are convinced” 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 business strategy and goals; our expectations and projections about the company’s future cash needs and financial results; our expectations regarding the safety or efficacy or benefits of our investigational COMP360 psilocybin treatment, including as a treatment of TRD or PTSD; our plans and expectations regarding our clinical trials; any implication that preliminary results will be predictive of full safety and efficacy data from our phase 3 program; our expectations regarding the timing of our rolling submission of a new drug application, or NDA, for COMP360 psilocybin treatment in TRD and the timing of the review by the Food and Drug Administration, or FDA, of such NDA, including potential acceleration due to the grant of rolling review and award of a National Priority Voucher for COMP360 psilocybin treatment in TRD; the potential for the pivotal phase 3 program in TRD to support regulatory filings and approvals on an accelerated basis or at all; our expected timing of our commercial launch for COMP360 psilocybin treatment in TRD, if approved by the FDA, including the timing and substance of decisions by the U.S. Drug Enforcement Administration, or the DEA, and states to reschedule COMP360 psilocybin treatment, if approved by FDA; our efforts and our ability to obtain adequate coverage and reimbursement; our ability to grow our organization and transition from a clinical-stage to a commercial-stage organization and effectively launch a commercial product, if regulatory approval is obtained; and our expectations regarding market adoption and commercial potential for COMP360. By their nature, these statements are subject to numerous risk and uncertainties, including the 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 full results and safety data from our Phase 3 clinical trials in TRD may not be consistent with the preliminary results to date; our need for 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; the rolling review process and/or the National Priority Voucher pilot program may not actually lead to a faster FDA review or approval process; our efforts to obtain FDA approval for our investigational COMP360 psilocybin treatment on an accelerated basis, or at all, may be unsuccessful; the timing and substance of decisions by the Drug Enforcement Administration and states to reschedule COMP360 psilocybin treatment, if approved by FDA; our efforts to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; even if approved, our COMP360 psilocybin treatment may not achieve an adequate level of acceptance by payors, health technology assessment bodies, healthcare professionals, patients and the medical community at large and market adoption may be limited; 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.



“We are convinced COMP360 will lead to a profound shift in mental health care – moving beyond daily or frequent administration – toward an option potentially involving just a few treatments in a year that could be life changing for patients”

Kabir Nath
Compass CEO

Preparing for the World's First Approval and Launch of a Classic Psychedelic

- **Compass** is leading the way in developing a new clinical standard for mental health care
- **COMP360** is an investigational, proprietary synthetic formulation of psilocybin for the treatment of mental health conditions with the potential to become the first FDA-approved classic psychedelic treatment
- We believe COMP360 has the potential to transform mental health care by moving beyond daily or frequent administration toward **just a few treatments per year**

Positioned to Establish the Field of Psychedelic Treatments

Compelling Clinical Profile

- Consistent results across two highly statistically significant positive Phase 3 trials demonstrating rapid onset and durable clinical benefit through ≥ 26 weeks
- Generally well-tolerated and safe profile
- Infrequent dosing

Accelerated Path to Market

- Rolling NDA submission and review underway with final submission expected in Q4 2026
- National Priority Review Voucher awarded in TRD
- Fits within existing site of care infrastructure
- Commercial organization established
- U.S. launch expected in H1 2027

Blockbuster Opportunity¹

- Target indications address large underserved markets
 - 4M U.S. patients with treatment-resistant depression (TRD)²
 - 13M U.S. patients with post-traumatic stress disorder (PTSD)³

1. Expectation based on Compass estimates and current market conditions. 2. Wing V, et al. Poster S97 Contemporary Estimate of the National Prevalence of Treatment-Resistant Depression in the United States. J Mood Anxiety Disord. Presented at ADAA 2026. 3. <https://www.va.gov/columbia-south-carolina-health-care/stories/hope-and-healing-initiatives-for-ptsd-awareness-and-veteran-support/> (accessed July 6, 2026)

Potential for COMP360 to Revolutionize how Mental Health is Treated

Largest Late-stage Clinical Program in Psychedelics

>1000 participants across
two Ph3 programs and a
Ph2b

Remarkable Consistency

Clinically meaningful efficacy in
a patient population with limited
treatment options

Durability with Infrequent Dosing*

Remarkable durability sustained through
at least 6 months with only 1 or
2 additional doses after initial dose

Rapid Onset of Action

Deep and dramatic reduction in
depressive symptoms as quickly as
the day following dosing

Well-Tolerated & Safe Profile

Generally well-tolerated and safe
profile, potentially making it easy for
patients and clinicians to try

* Durability data across the two phase 3 programs (COMP005 and COMP006)

Based on preliminary clinical data that are subject to change as data collection, validation, and analysis continue.; Label has not been determined as COMP360 is not yet approved by the FDA

Unmet Need in Treatment-Resistant Depression (TRD)

TRD Patients Urgently in Need of New Treatment Options

23M Americans experience major depressive disorder (MDD) each year¹



12M MDD patients drug-treated in the past year¹



4M MDD patients fail ≥ 2 antidepressants and considered TRD¹

WHY TREATMENT RESISTANCE MATTERS

55+

Antidepressants approved for MDD²

Only 1

FDA-approved medicine for TRD
(Spravato®)

~1 in 3

Treated patients fail ≥ 2 antidepressants²

1. Wing V, et al. Poster S97 Contemporary Estimate of the National Prevalence of Treatment-Resistant Depression in the United States. J Mood Anxiety Disord. Presented at ADAA 2026.. 2. US Food and Drug Administration. Major Depressive Disorder (MDD): Developing Drugs for Treatment. Guidance for Industry. June 2018. <https://www.fda.gov/media/113988/download>. Accessed March 26, 2026.

TRD Places Higher Burden on Patients, Communities and Healthcare Systems Compared to MDD

Prolonged Disease Course¹

TRD depressive episodes **average 571 days** and are **2X longer than MDD**

Increased Clinical Risk^{2,3,4,5}

Increased relapse rate and decreased remission rate after at least 2 antidepressants
Higher comorbidities with 61% experiencing pain, 50% anxiety, 35% suffering from migraines

Decreased Productivity^{4,6}

70% greater work time loss
Caregivers spend **~23 hours** per week on care

Increased Mortality⁷

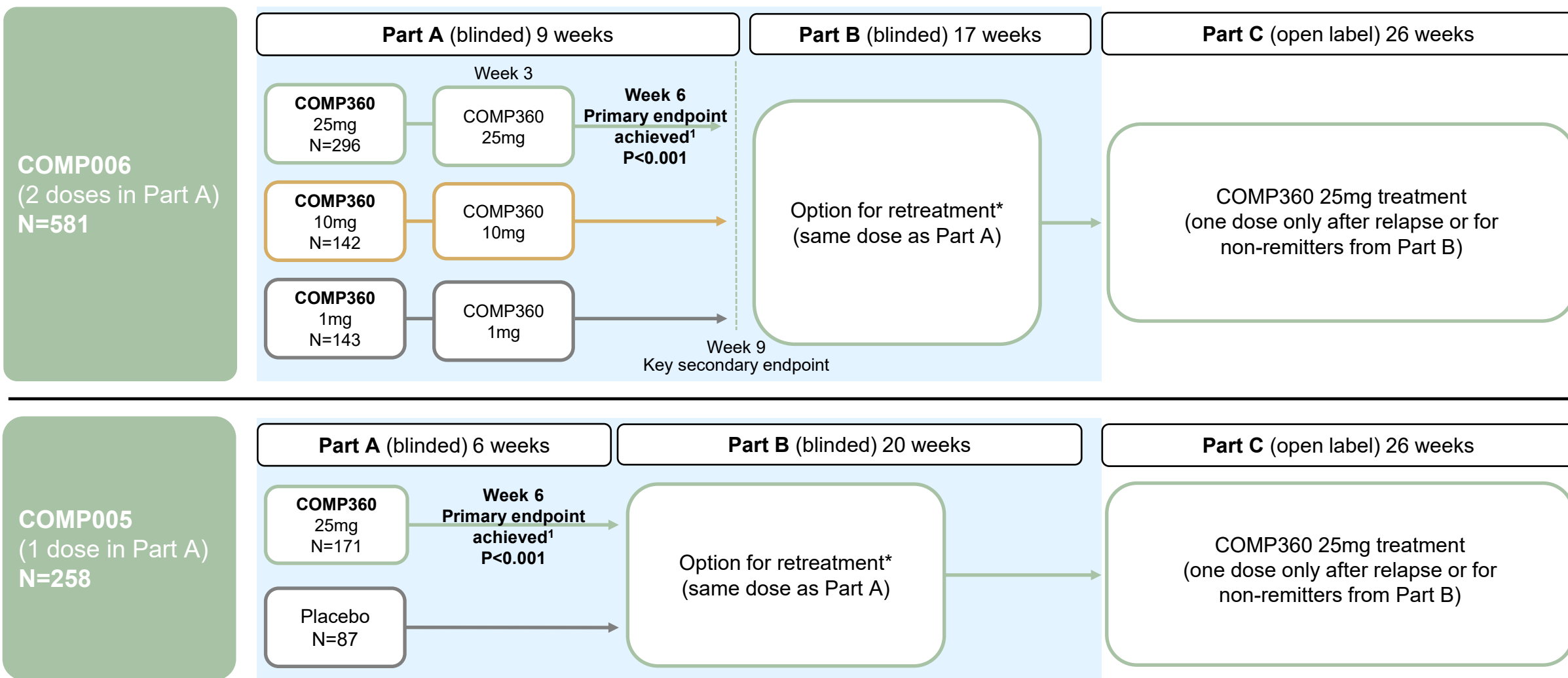
51% increased risk of mortality due to suicide
17-30% increased risk of all-cause mortality

1. Wu B, et al. PLoS One. 2019;14(8):e0220763. 2..Rush AJ, et al. Am J Psychiatry. 2006;163(11):1905-17 3. Pappa S, et al. BJPsych Open. 2024;10(1):e32.. 4. Compass Pathways data on file. 5. Kubitz N, et al. PLoS One. 2013;8(10):e76882. 6. Amos TB, et al. J Clin Psychiatry. 2018;79(2):17m11725. 7. Gustafsson TT, et al. J Affect Disord. 2025;368:136-142 .

COMP360 Phase 3

Data in TRD

Rigorously Designed Phase 3 Program



1. Primary endpoint = change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 6.

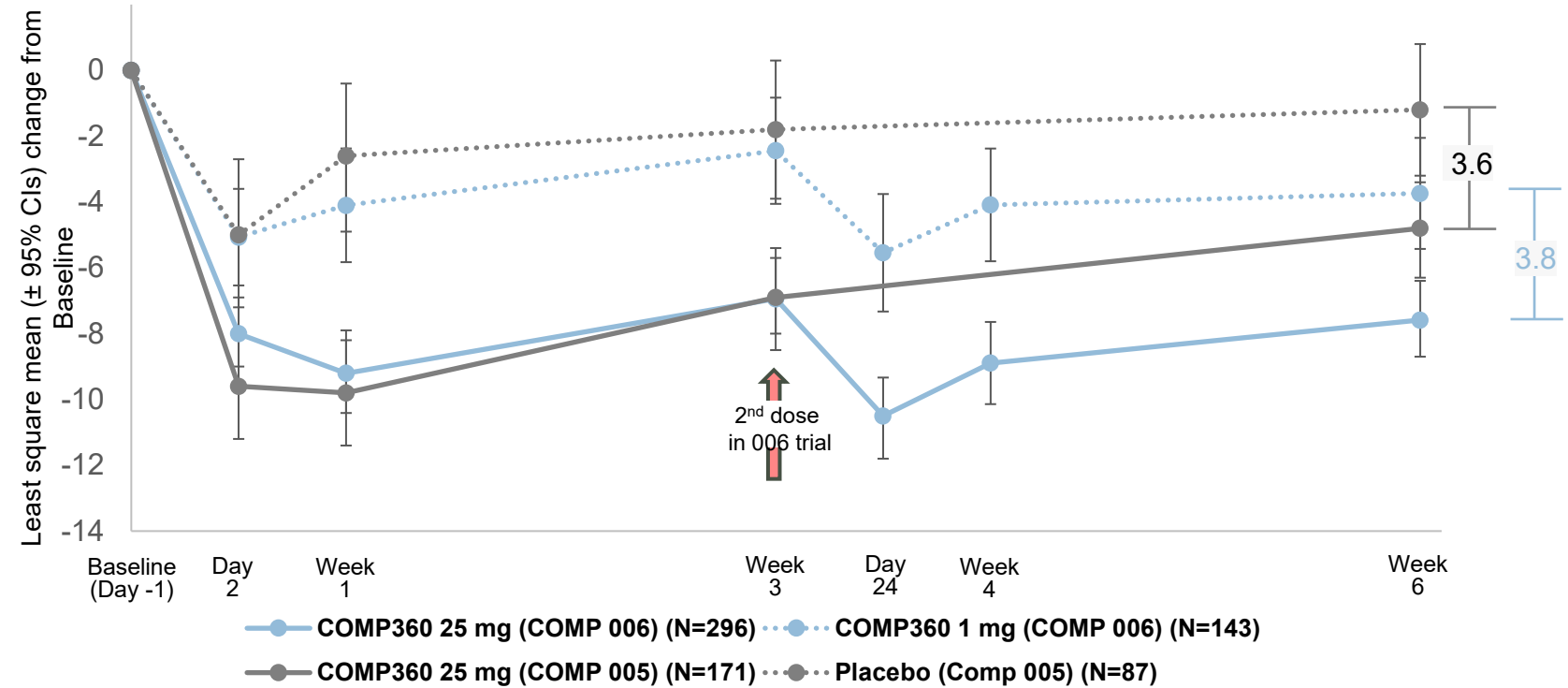
*Re-dosing for non-remitters from Part A or Part B could occur several weeks after transition to Part B or Part C, respectively, due to scheduling requirements. Participants were permitted to take protocol-allowed antidepressant treatments in Part B and C of the study.

Positive Primary Endpoints Achieved for COMP005 & COMP006 in Highly Chronic* TRD Population

Consistent improvement in magnitude of MADRS total score between two Phase 3 studies

2nd administration at Week 3 shows potential for a **deeper treatment effect**

Highly Chronic TRD Population: Current depressive episodes lasted on average over three years



*Cross-trial comparisons should be interpreted with caution. Differences between trials, including but not limited to study designs, protocols, and timing of assessments.

Note: CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery-Åsberg Depression Rating Scale

Note that the two phase 3 studies have different but complementary protocols.

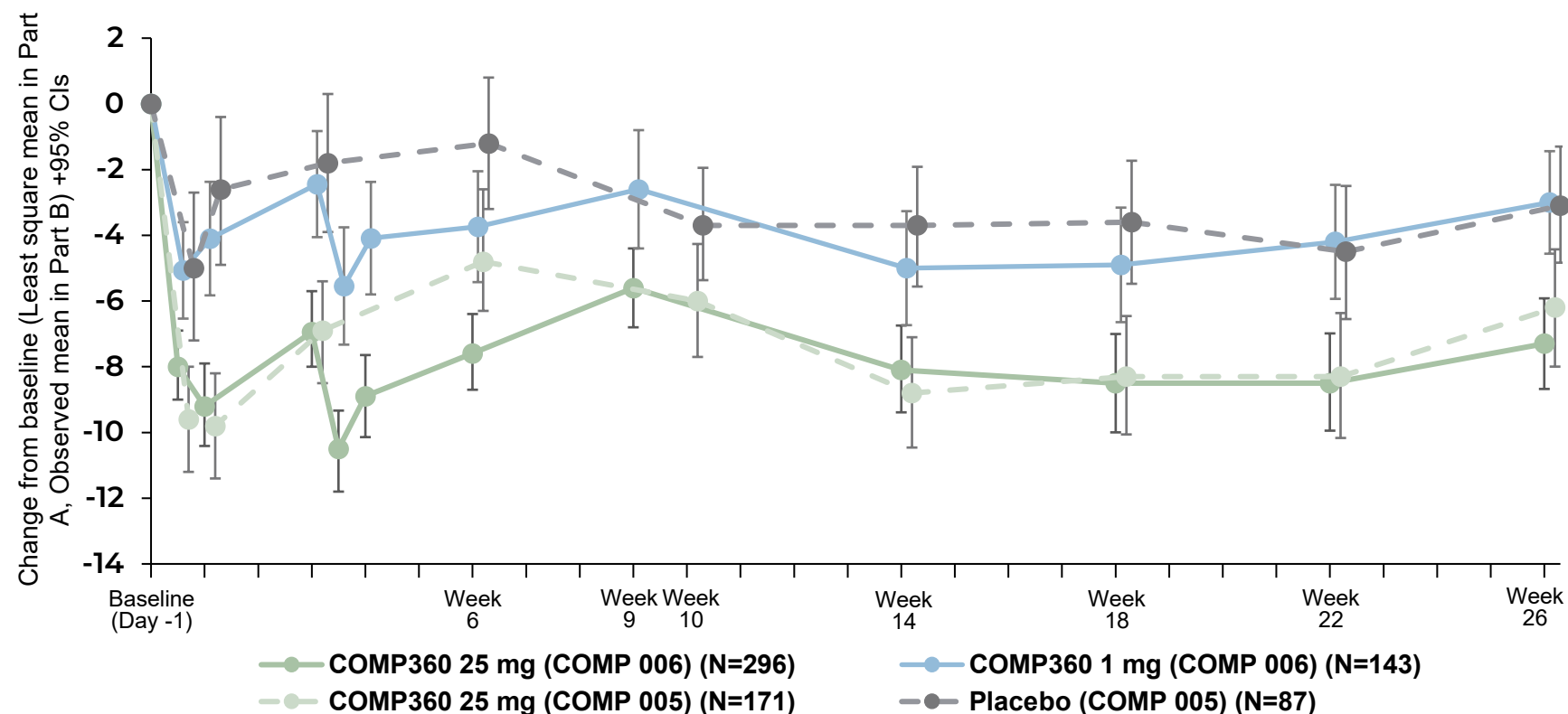
*Participants in COMP006 had current depressive episodes lasting on average over three years and an average of more than six lifetime depressive episodes

Remarkable Durability Through 6 Months* Across Ph3 Trials

Consistent separation between 25mg and control arms maintained over 26 weeks in both studies

Confirms validity, consistency and durability of efficacy signal over 26 weeks

Clear benefit of additional dose, either as fixed dose after 3 weeks (006) or later in 10-14 week timeframe (005)



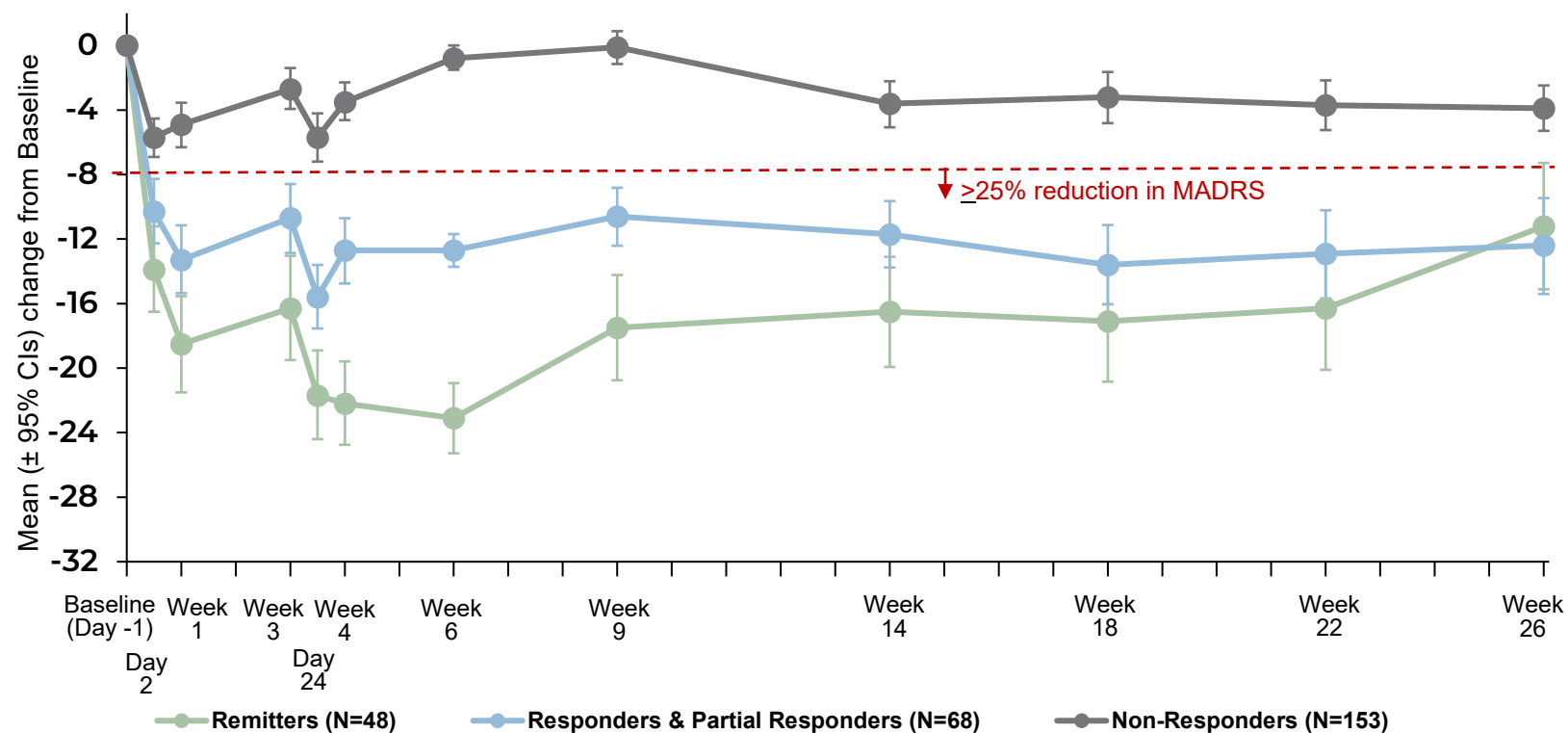
*Cross-trial comparisons should be interpreted with caution. Differences between trials, including but not limited to study designs, protocols, and timing of assessments, number or timing of doses and participant populations can meaningfully influence outcomes and limit the validity of any comparison.

COMP 005 Part B (post Week 6) and COMP 006 Part B (post Week 9) results are based on observed data only (CFB Mean $\pm$ 95% CI). retreatment in Part B based on pre-specified criteria and receive either what they were randomized into or antidepressant - CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery-Asberg Depression Rating Scale

COMP006: Rapid and Durable Response– Unique in TRD

39% of participants in 25mg arm achieved clinically meaningful reduction in MADRS* at Week 6 and on average maintained response at least through Week 26

28% of those who achieved clinically meaningful reduction in MADRS but had not remitted by 6 weeks went into remission after additional dose in Part B



Definitions (n at Week 6):

Remitters (n=48) = MADRS ≤12 and no single item ≥4;

Responders and Partial Responders (n=68) = % CFB in MADRS ≥ 25% and do not meet remission criterion;

Non-Responder (n=153) = % CFB in MADRS ≤ 25%

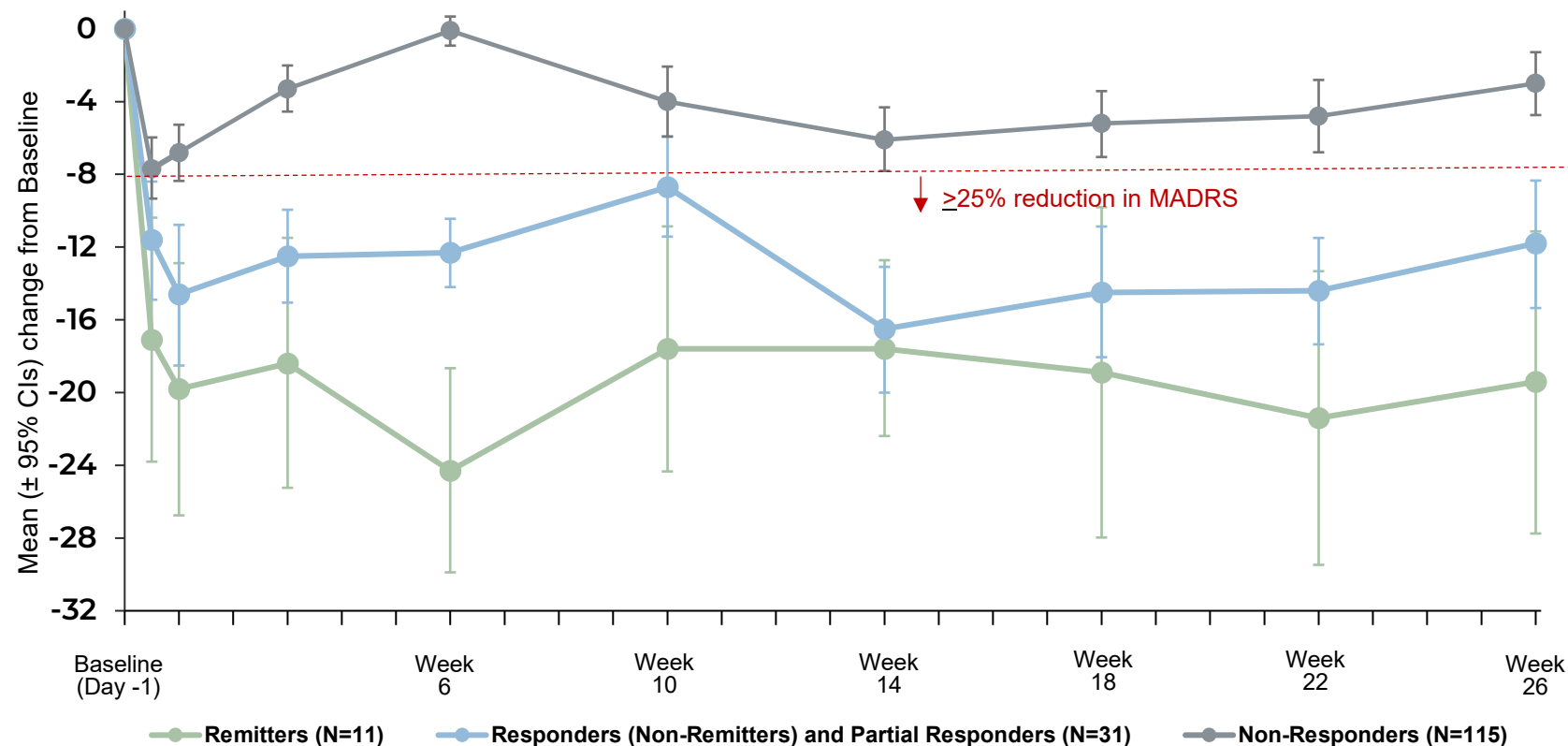
*Clinically meaningful reduction in MADRS defined as a ≥25% reduction from baseline in MADRS total score at Week 6. This graph is a post hoc analysis. Total n at 6 weeks = 269 (based on ITT)

CI = Confidence Interval; CFB = change from baseline; MADRS = Montgomery-Åsberg Depression Rating Scale

COMP005: Rapid and Durable Response– Unique in TRD

25% of participants in 25mg arm achieved clinically meaningful reduction in MADRS* at Week 6 and on average maintained response at least through Week 26

Over 40% of those who achieved clinically meaningful reduction in MADRS but had not remitted by 6 weeks went into remission after additional dose in Part B



Definitions (n at Week 6):

Remitters (n=11) = MADRS ≤12 and no single item ≥4;

Responders and Partial Responders (n=31) = % CFB in MADRS ≥ 25% and do not meet remission criterion;

Non-Responder (n=115) = % CFB in MADRS ≤ 25%

*Clinically meaningful reduction in MADRS defined as a >25% reduction from baseline in MADRS total score at Week 6. This graph is a post hoc analysis. Total n at 6 weeks = 157 (based on ITT)

CI = Confidence Interval; CFB = change from baseline; MADRS = Montgomery–Åsberg Depression Rating Scale

COMP360 Generally Well-Tolerated with a Safe Profile

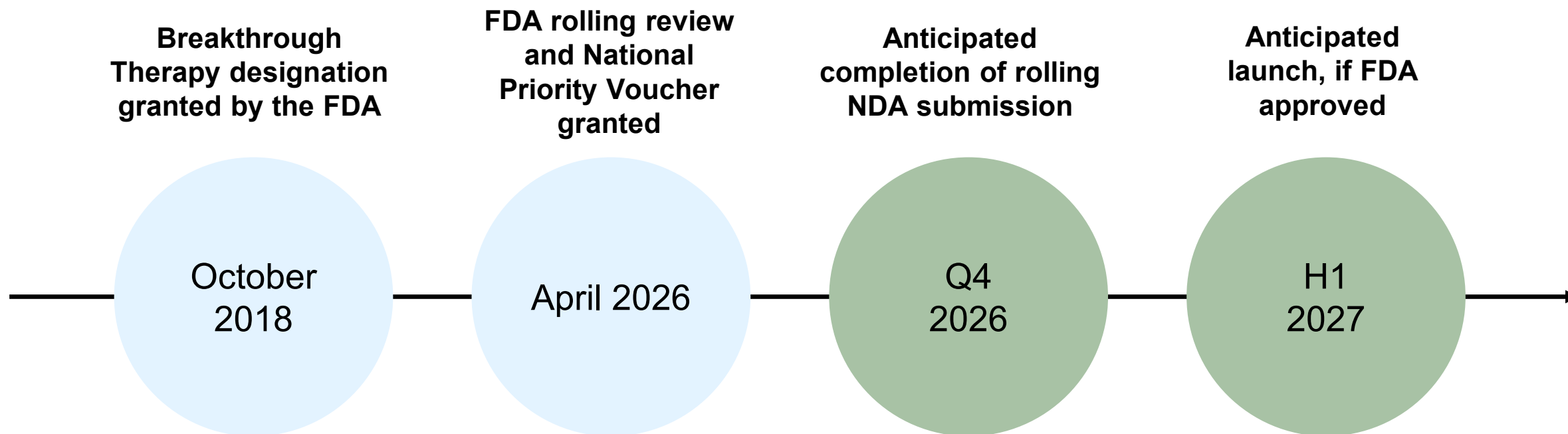
Majority of AEs transient,
occurring on the day of
administration

Safety data consistent with
known profile of COMP360
psilocybin with no new safety
signals identified

SAEs were low overall across
both trials

Commercial Readiness

On Track for COMP360 Launch in H1 2027, if FDA Approved



Advanced commercial launch prep work underway including payer discussions, enabling product distribution, setting up patient support mechanisms, preparing for field force execution and ongoing stakeholder education

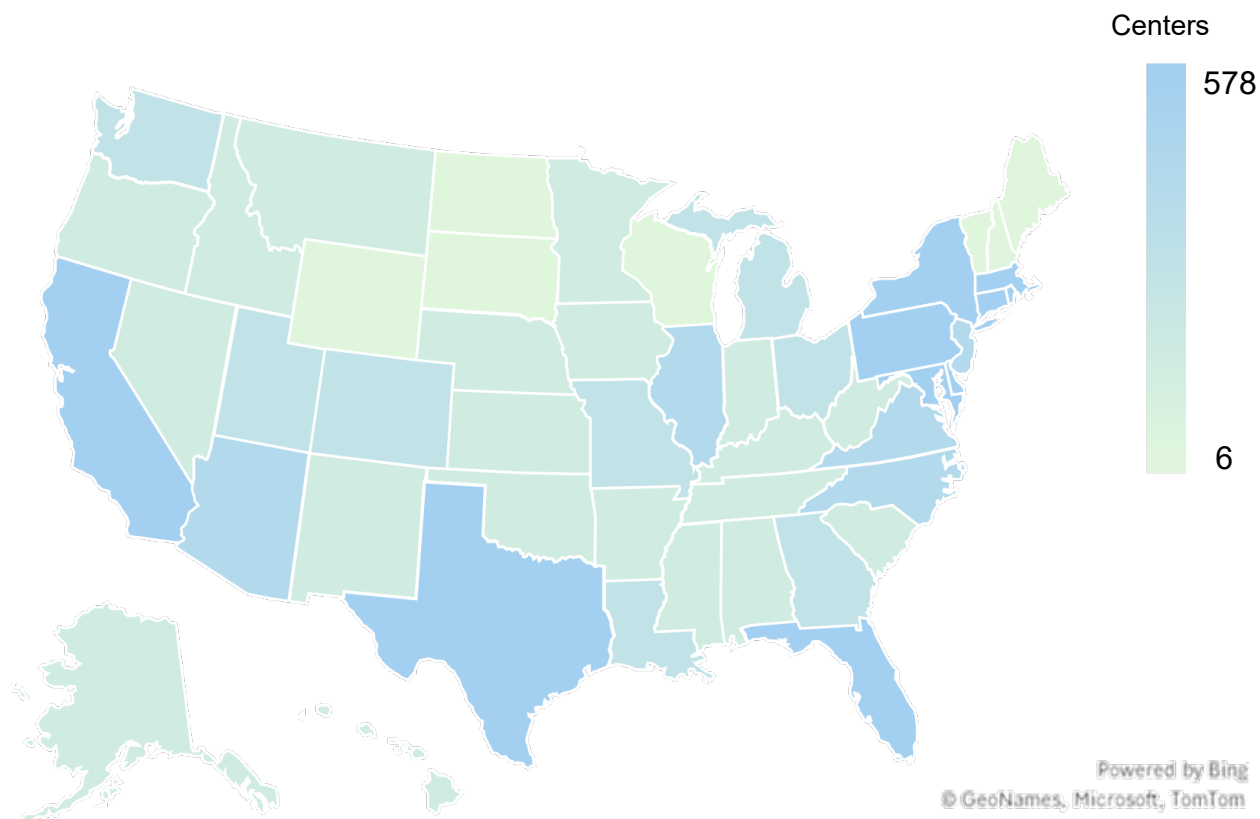
Well-established Infrastructure of Interventional Psychiatry Treatment Centers in Place and Preparing to Offer COMP360

Established Practice Patterns

- ☛ Dedicated rooms/areas for treatments that require multi-hour monitoring
- ☛ Operational and scheduling capabilities with team-based workforce
- ☛ Scaling to meet patient demand

At approval, our top priority is site and patient experience:

- ☛ Training & education
- ☛ REMS certification
- ☛ Reimbursement assistance
- ☛ Patient support hub



>8,100 Spravato® treatment clinics in US¹

1. www.spravatohcp.com/find-treatment-center – data pulled 07/31/2026

Prescribing, Dosing and Reimbursement Expected to Easily Integrate within Current Clinical Practice

Prescribing

Prescribed by an HCP licensed to prescribe medication to patients

Dose Administration

Patient self-administers oral capsule, monitored by a licensed HCP during session
Dosing and monitoring to take place at a certified treatment center

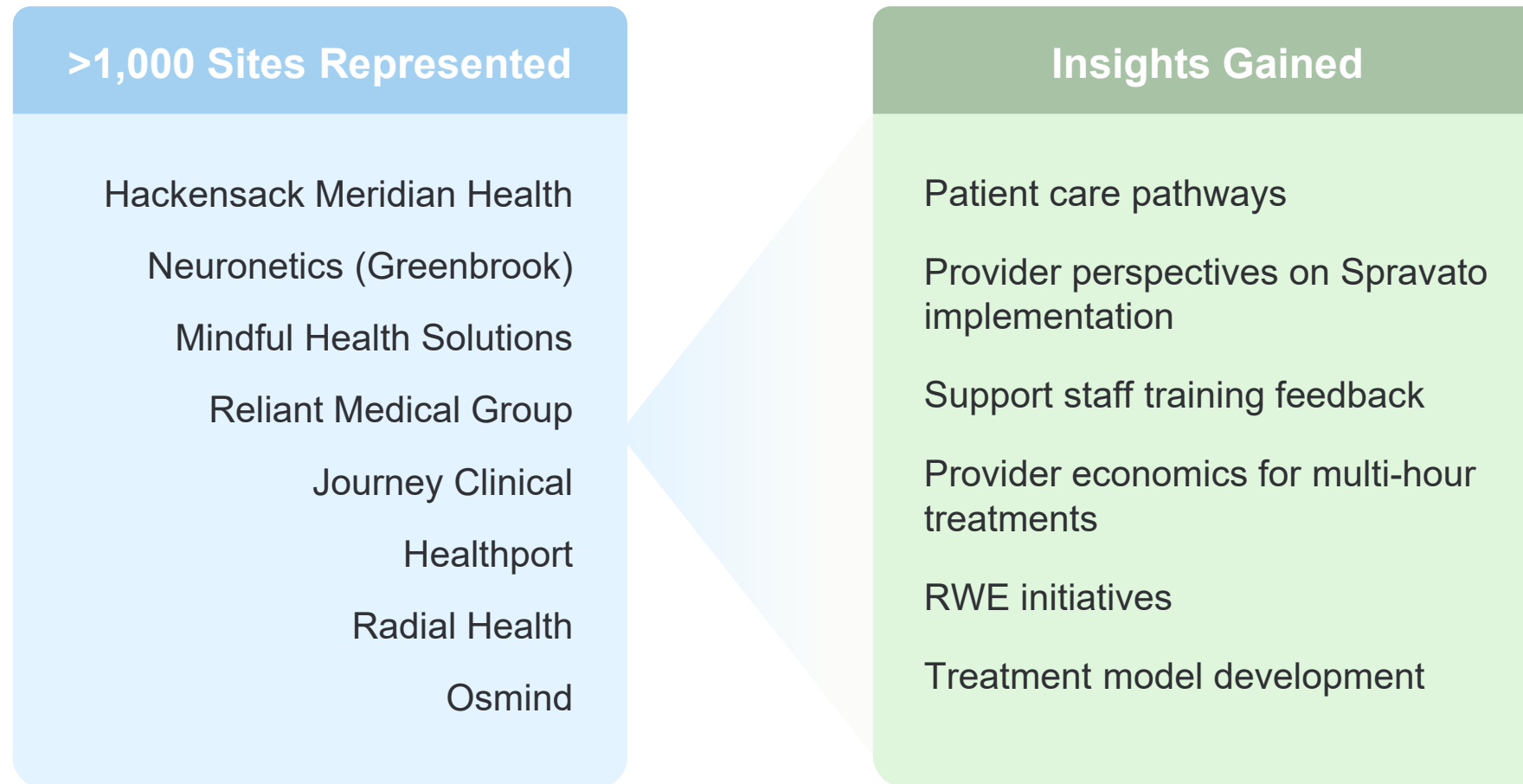
Reimbursement²

COMP360 expected to be available through specialty pharmacy and buy-and-bill – drug reimbursed through pharmacy benefit. Evaluation and Monitoring (E/M) CPTIII codes specifically for psychedelics- billed by the hour through medical benefit

1. Coding and reimbursement for COMP360 have not yet been established and are subject to change from current thinking

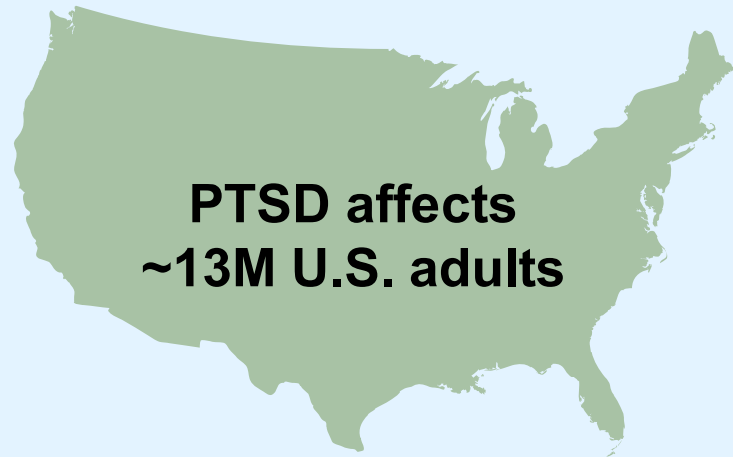
Note: CPT stands for Current Procedural Terminology. It's a system of codes created by the American Medical Association (AMA) to describe medical procedures and services. These codes are used for billing purposes and are part of the national coding system under the Health Information Portability and Accountability Act (HIPAA). 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

Launch Strategy Informed by Strategic Collaborators, Representing a Spectrum of Provider Archetypes



Expanding the Potential of COMP360: Post-Traumatic Stress Disorder

PTSD: High Unmet Need with Opportunity to Leverage TRD Foundation



- Chronic and debilitating psychiatric condition
- Characterized by intrusive memories, avoidance, negative mood/cognition, and hyperarousal

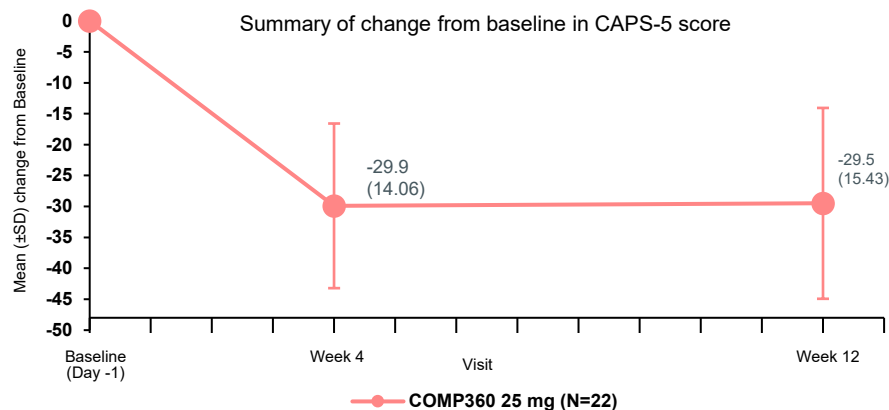
Significant unmet need

- Lack of innovation over the past 25+ years
- Existing treatment paradigm limited by adherence, access and efficacy challenges

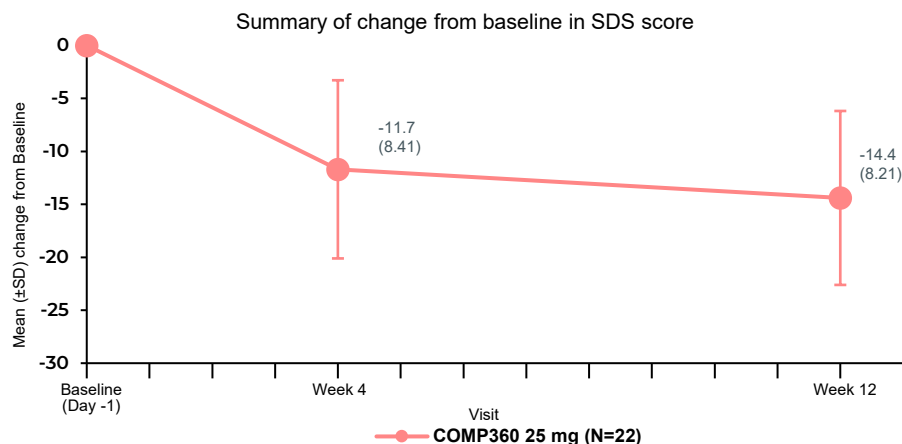
Strong strategic fit

- PTSD has high overlap with TRD population
- Opportunity to leverage established clinical and commercial capabilities
- Existing interventional psychiatry infrastructure supports PTSD treatment

Positive Phase 2a Results: Meaningful and Durable Improvements in PTSD



Baseline mean (SD): 25mg (N=22) = 47.5 (9.78)



Baseline mean (SD): 25mg (N=22) = 22.7 (5.38)

■ Safety Profile Consistent with TRD Studies

- Generally safe and well-tolerated with no treatment emergent serious adverse events reported; no participants re-started SSRI's or antidepressants after COMP360 administration.
- Most frequent TEAES (>10%) were headache, nausea, crying, fatigue, hallucination, muscle tightness, paraesthesia, visual impairment

■ Meaningful Improvements Observed Across PTSD Measures

- Early onset and sustained change from baseline in CAPS-5 observed at week 4 and week 12

■ Sustained Benefit

- 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

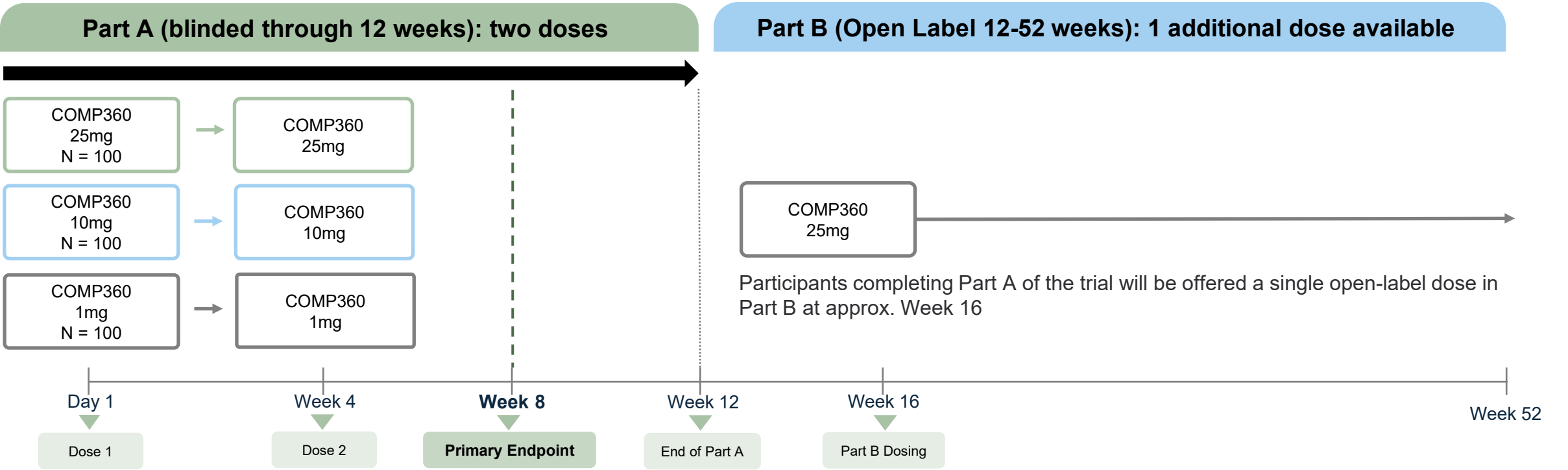
- N=22, multi-center open-label, single administration of 25mg COMP360 (mean baseline of 47.5 CAPS-5 total score considered severe)

Phase 2b/3 trial underway

PTSD Phase 2b/3 Trial Design

Multicenter, randomized, double-blind, controlled trial, with an open label extension, to investigate the efficacy, safety, and tolerability of COMP360 in 300 adult participants with PTSD

Primary Endpoint: To determine if two administrations of COMP360 at a dose of 25mg compared to two administrations of 1 mg lead to improvement of PTSD symptoms (CAPS-5) at Week 8



Notes:
In both Part A and Part B COMP360 may be administered adjunctively to a single permitted oral antidepressant. 10mg arm included to help prevent unblinding and examine efficacy of this dose as a secondary outcome. In Part B, participants will receive a single open-label treatment with COMP360 25 mg if deemed clinically suitable.

Robust Patent Portfolio Supporting COMP360 Exclusivity

Composition Patents

Drug Substance (DS)

- Crystalline drug substance
- Pharmaceutical-grade purity
- Long-term stability
- Reproducibility
- Identified from first reported large scale synthesis of psilocybin

DS patents challenged at US patent office and upheld.

Drug Product (DP)

- Orally administered formulation
- Target product profile (potency, stability, content uniformity)
- Identified after extensive screening and failure of prior formulations to meet FDA requirements

Method Patents

Method of Treatment (MoT)

- Coverage of priority indications: TRD and PTSD
- Dosing regimens to achieve remission
- Adjunctive treatment with standard of care (SSRI)

Orange Book Patent Exclusivity – Expected >2038

- DS, DP, and MoT patents are listed on the FDA’s “orange book”
- Provides exclusivity beyond FDA New Chemical Exclusivity (NCE)
- Generics must address all “orange book” patents before market entry

Large Orange Book Patent Portfolio

COMP360

- 9 Issued and 7 pending patents

Future Indications

- 5 issued and 5 pending patents

Multidisciplinary Executive Team with Deep Experience Bringing Innovative CNS Therapies to Patients



Kabir Nath
Chief Executive Officer

Combines nearly three decades of global biopharmaceutical leadership with a deeply personal commitment to mental health, leading our mission while fostering a culture of openness, purpose, and innovation.



Dr Guy Goodwin,
Chief Medical Officer

Leading psychiatrist and neuroscience researcher whose expertise in mood disorders and psychedelic treatments drives the company's commitment to rigorous, evidence-based innovation in mental health treatment.



Lori Englebert, Chief
Commercial Officer

Brings extensive launch experience and a track record of tackling complex healthcare challenges, leading our commercial strategy with a focus on maximizing patient impact and commercial success.



Dr Michael Gold,
Chief R&D Officer

Highly respected neuroscience R&D leader with 30 years of industry experience, dedicated to advancing rigorous, patient-centered research and accelerating access to innovation



Dr Steve Levine, Chief
Patient Officer

Board-certified psychiatrist and pioneer in interventional psychiatry who brings more than 20 years of clinical experience to advancing equitable access to innovative, patient-centered mental health treatments.



Teri Loxam,
Chief Financial Officer

Leverages decades of multidisciplinary experience leading organizations through pivotal moments, building the financial and operational foundation needed to deliver innovative treatments to patients

Collectively, our executive team brings more than 165+ years of clinical and biopharmaceutical experience spanning neuroscience R&D, commercialization and public company leadership.

compass

⌚Unlocking pathways ⚡to be.

For More Information:

Stephen Schultz, SVP Investor Relations

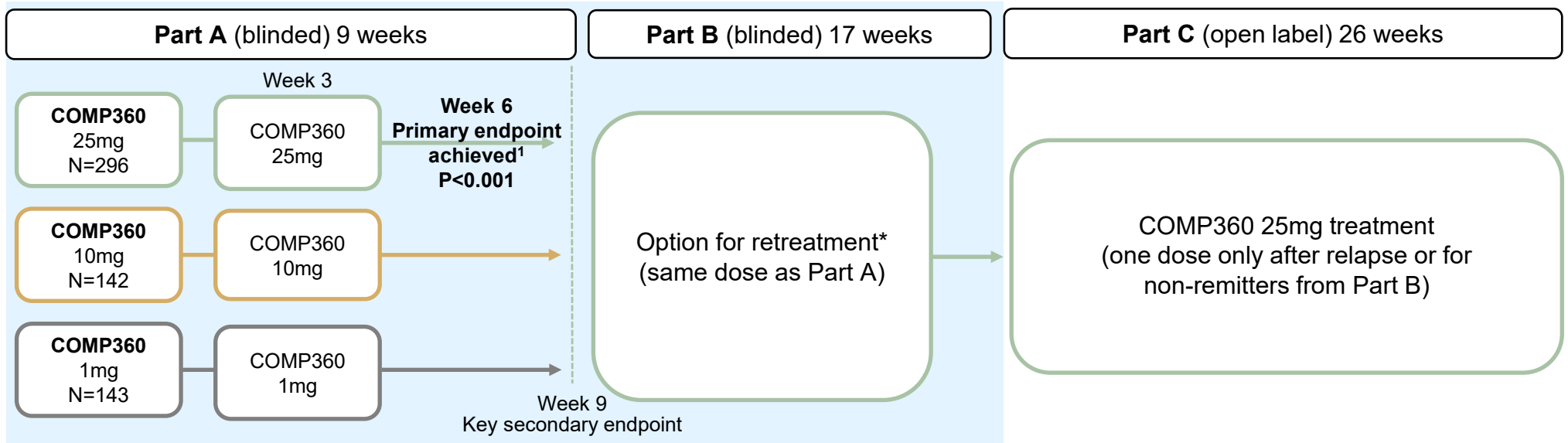
+1 401 290 7324 | Stephen.Schultz@compasspathways.com | IR@compasspathways.com

Appendix

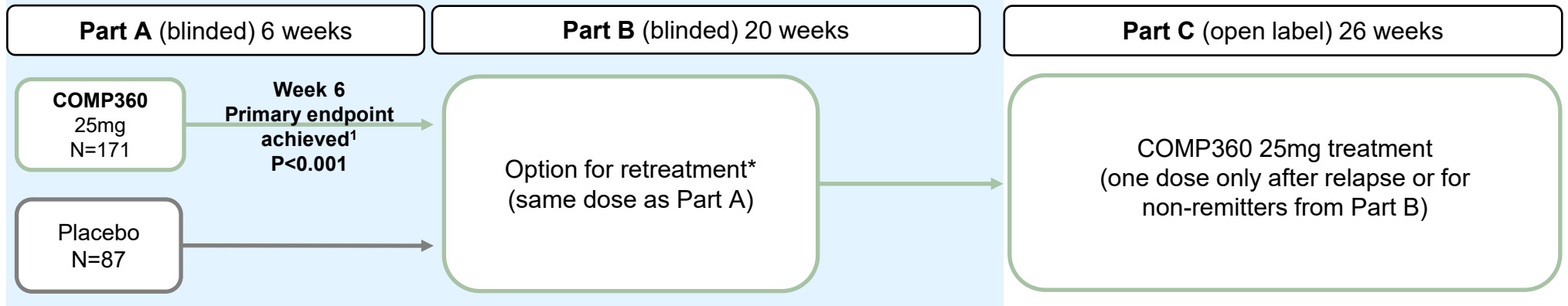
Phase 3 Program in TRD

Phase 3 Program in TRD: Trial Designs

COMP006
(2 doses in Part A)
N=581



COMP005
(1 dose in Part A)
N=258



1. Primary endpoint = change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 6.

*Retreatment for non-remitters from Part A or Part B could occur several weeks after transition to Part B or Part C, respectively, due to scheduling requirements. Participants were permitted to take protocol-allowed antidepressant treatments in Part B and C of the study.

COMP005 & COMP006 – Participant Baseline Demographics In Line with Known TRD Epidemiology

COMP005	COMP360 25 mg (N=171)	Placebo (N=87)
Female, n (%)	93 (54.4)	47 (54.0)
Race, n (%)		
White	149 (87.1)	78 (89.7)
Asian	11 (6.4)	4 (4.6)
Black or African American	6 (3.5)	2 (2.3)
American Indian or Alaska Native	0	1 (1.1)
Other	5 (2.9)	2 (2.3)
Age, years, mean (SD)	45.9 (13.4)	45.3 (14.4)
Min, Max	19, 77	22, 72
Age ≥65 years old	15 (8.8)	11 (12.6)
Prior psilocybin experience, n (%)	5 (2.9)	5 (5.7)
Prior psychedelic experience including psilocybin, n (%)*	8 (4.7)	6 (6.9)
BMI kg/m², mean (SD)	28.4 (6.2)	27.7 (6.1)

COMP006	COMP360 25 mg (N=296)	COMP360 10 mg (N=142)	COMP360 1 mg (N=143)
Female, n (%)	160 (54.1)	68 (47.9)	69 (48.3)
Race, n (%)			
White	255 (86.1)	123 (86.6)	129 (90.2)
Asian	14 (4.7)	6 (4.2)	6 (4.2)
Black or African American	8 (2.7)	3 (2.1)	4 (2.8)
American Indian or Alaska Native	0	0	1 (0.7)
Other/not reported	19 (6.4)	10 (7.0)	3 (2.1)
Age, years, mean (SD)	46.2 (13.7)	42.9 (12.8)	45.5 (13.1)
Min, Max	18, 79	19, 73	20, 75
Age ≥65 years old	29 (9.8)	9 (6.3)	13 (9.1)
Prior psilocybin experience, n (%)	12 (4.1)	5 (3.5)	5 (3.5)
Prior psychedelic experience including psilocybin, n (%)	20 (6.8)	8 (5.6)	9 (6.3)
BMI kg/m², mean (SD)	28.0 (6.2)	28.4 (6.4)	28.0 (6.5)

*planned limit was 15%

BMI = Body Mass Index; n=number of observed participants; SD = standard deviation

COMP005 & COMP006 – Participant Characteristics Treatment History and Baseline MADRS

COMP005	COMP360 25 mg (N=171)	Placebo (N=87)
Number of failed treatments in the current depressive episode, n (%)		
1	2 (1.2)	1 (1.1)
2	114 (66.7)	62 (71.3)
3	45 (26.3)	19 (21.8)
4	10 (5.8)	4 (4.6)
5	0	1 (1.1)
Number of treatments withdrawn from the screening period, n (%)		
0	58 (33.9)	26 (29.9)
1	38 (22.2)	32 (36.8)
2	50 (29.2)	21 (24.1)
>2	25 (14.6)	8 (9.2)
MADRS total score at baseline, mean (SD)	31.5 (5.5)	31.5 (5.9)
MADRS total score severity at baseline, n (%)		
Mild (11-19)	1 (0.6)	2 (2.3)
Moderate (20-30)	73 (42.7)	33 (37.9)
Severe (≥31)	97 (56.7)	52 (59.8)

COMP006	COMP360 25 mg (N=296)	COMP360 10 mg (N=142)	COMP360 1 mg (N=143)
Number of failed treatments in current depressive episode, n (%)			
1	1 (0.3)	1 (0.7)	0
2	190 (64.2)	105 (73.9)	98 (68.5)
3	74 (25.0)	32 (22.5)	34 (23.8)
4	29 (9.8)	4 (2.8)	11 (7.7)
5	2 (0.7)	0	0
Number of treatments withdrawn from the screening period, n (%)			
0	68 (23.0)	30 (21.1)	36 (25.2)
1	127 (42.9)	62 (43.7)	62 (43.4)
2	68 (23.0)	34 (23.9)	31 (21.7)
>2	33 (11.1)	16 (11.3)	14 (9.8)
MADRS total score at baseline, mean (SD)	32.0 (5.8)	32.1 (5.8)	32.5 (5.4)
MADRS total score severity at baseline, n (%)			
Subthreshold ≤10	2 (0.7)	0	0
Mild (11-19)	0	0	0
Moderate (20-30)	115 (38.9)	54 (38.0)	49 (34.3)
Severe (≥31)	179 (60.5)	88 (62.0)	94 (65.7)

MADRS = Montgomery-Åsberg Depression Rating Scale; n=number of observed participants; SD = standard deviation.

COMP005 & COMP006 – Participant Characteristics

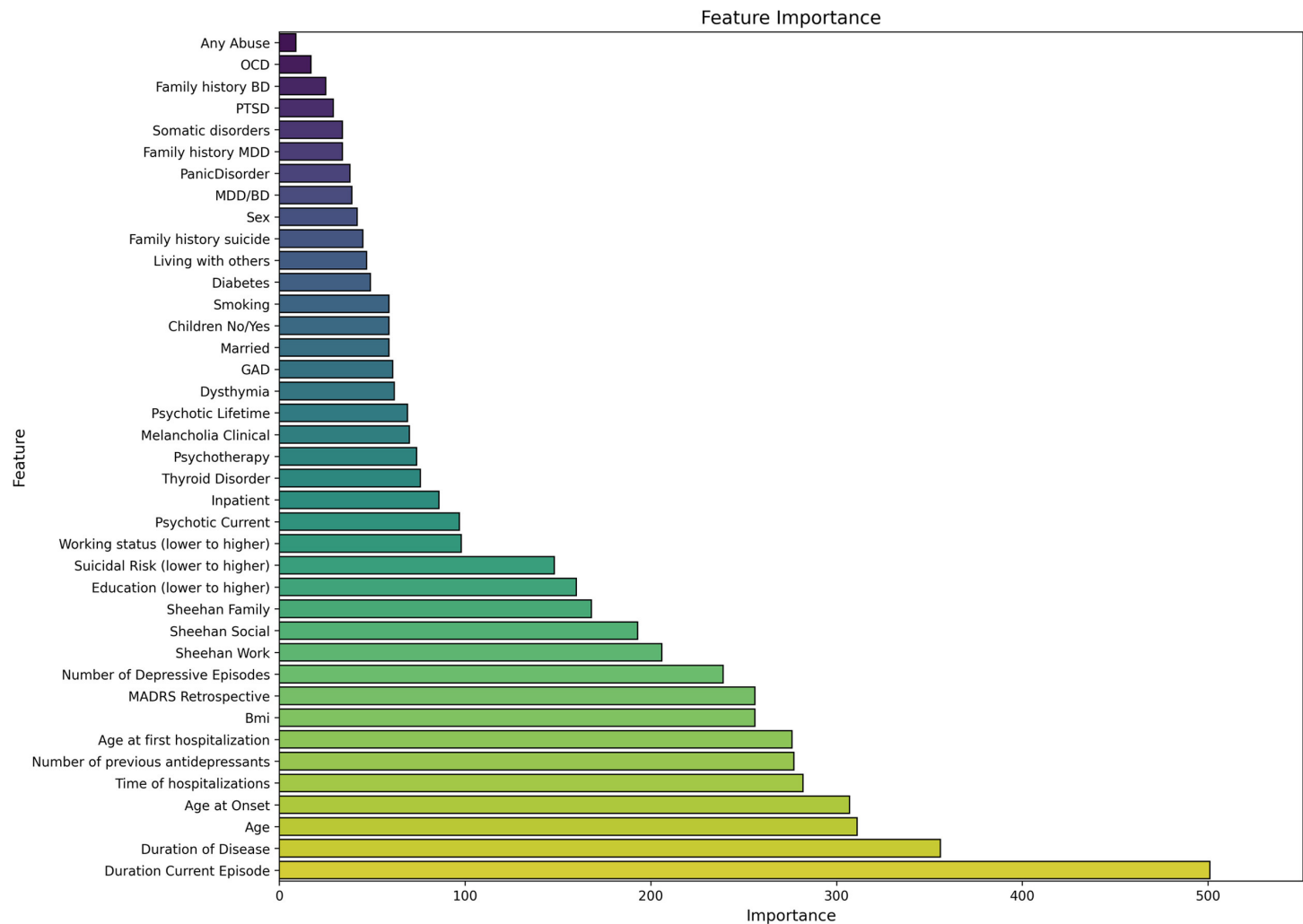
Depression Diagnosis History

COMP005	COMP360 25 mg (N=171)	Placebo (N=87)
Length of current depressive episode		
Mean Months (SD)	34.1 (29.1)	38.6 (33.0)
< 1 year	30 (17.5)	20 (23.0)
1-2 years	52 (30.4)	19 (21.8)
>2 years	89 (52.0)	48 (55.2)
Number of lifetime depressive episodes		
Mean (SD)	7.7 (10.9)	7.2 (7.6)
2-5	107 (62.6)	54 (62.1)
6-10	40 (23.4)	21 (24.1)
>10	23 (13.5)	12 (13.8)

COMP006	COMP360 25 mg (N=296)	COMP360 10 mg (N=142)	COMP360 1 mg (N=143)
Length of current depressive episode			
Mean Months (SD)	45.5 (42.7)	37.7 (38.8)	38.4 (45.0)
< 1 year	53 (17.9)	37 (26.1)	30 (21.0)
1-2 years	73 (24.7)	35 (24.6)	41 (28.7)
>2 years	170 (57.4)	70 (49.3)	72 (50.3)
Number of lifetime depressive episodes			
Mean (SD)	6.3 (7.4)	5.4 (6.6)	7.0 (12.5)
1	1 (0.3)	0	0
2-5	199 (67.2)	109 (76.8)	99 (69.2)
6-10	61 (20.6)	21 (14.8)	30 (21.0)
>10	29 (9.8)	10 (7.0)	10 (7.0)

n=number of observed participants; SD = standard deviation

Duration of Current Episode Strongest Predictor of Non-Response in TRD



Source: European Neuropsychopharmacology. Volume 98, September 2025, Pages 26-34 (<https://www.sciencedirect.com/science/article/pii/S0924977X25001294>)

COMP006 – Phase 3 Data

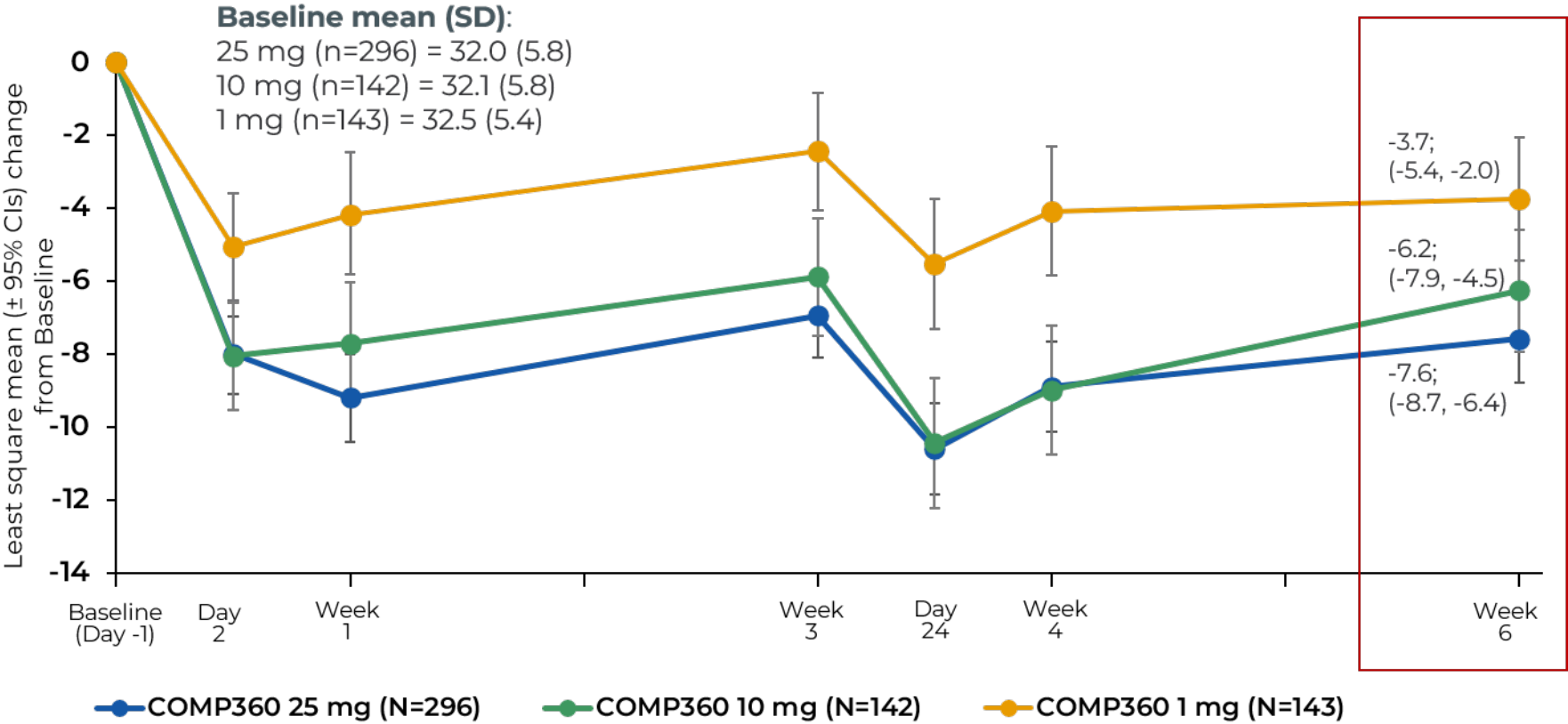
COMP006 - Primary Endpoint Met – Change in MADRS at Week 6

Statistically significant difference of -3.8 MADRS between 25mg vs 1mg at Week 6 (p<0.001)

Statistically significant treatment differences in 25mg vs 1mg and 10mg vs 1 mg found at all timepoints post administration

Rapid onset of action with the effect occurring the day after the administration (Day 2)

39% of participants in 25mg arm achieved a clinically meaningful reduction in MADRS at Week 6*



Visit	25mg vs 1 mg LS Mean Difference (95% CI) P-value	10mg vs 1 mg LS Mean Difference (95% CI) P-value
Day 2	-2.9 (-4.6, -1.2) <0.001	-3.0 (-5.0, -1.0) 0.002
Week 1	-5.0 (-7.0, -3.0) <0.001	-3.5 (-5.9, -1.2) 0.001
Week 3	-4.4 (-6.3, -2.5) <0.001	-3.4 (-5.6, -1.2) 0.001
Day 24	-5.0 (-7.1, -2.9) <0.001	-4.9 (-7.4, -2.5) <0.001
Week 4	-4.8 (-6.9, -2.7) <0.001	-4.9 (-7.3, -2.5) <0.001
Week 6 (Primary)	-3.8 (-5.8, -1.8) <0.001	-2.5 (-4.8, -0.2) 0.017

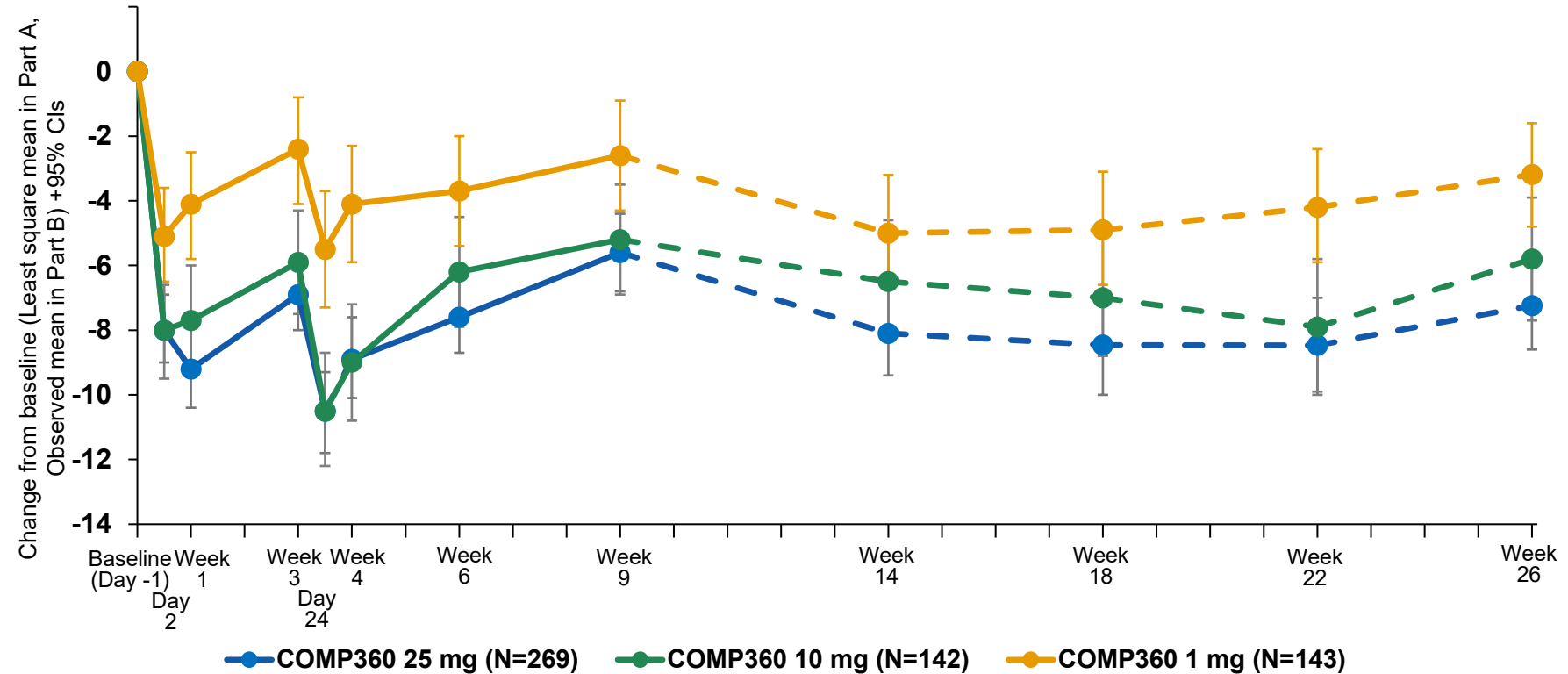
*Clinically meaningful reduction in MADRS defined as a >25% reduction from baseline in MADRS total score at Week 6
CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery-Åsberg Depression Rating Scale

COMP006 – Rapid Onset and Sustained Durability to Week 26

Rapid effect from 25mg evident from day after administration: apparent after both first and second fixed doses in Part A

Persistent treatment effect of 25mg arm over full 26 weeks

58% of patients in 25mg arm received retreatment after Week 9

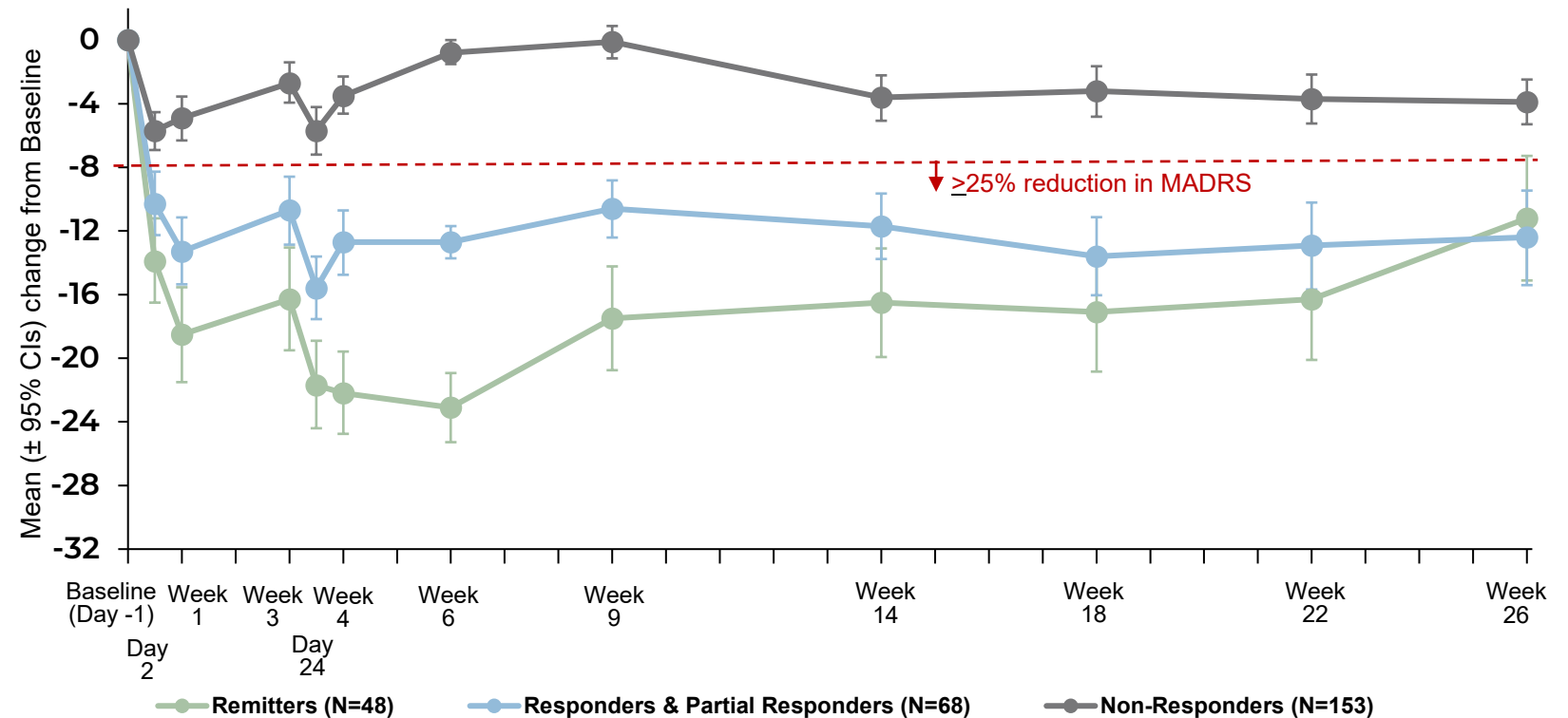


*retreatment based on pre-specified criteria and receive either what they were randomized into or antidepressant
COMP 006 Part B results (post Week 9) are based on observed data only (CFB Mean $\pm$ 95% CI)
CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery-Åsberg Depression Rating Scale

COMP006 - COMP360 Response Can Be Rapid and Durable – Unique in TRD

39% of participants in 25mg arm achieved clinically meaningful reduction in MADRS* at Week 6 and on average maintained response at least through Week 26

28% of those who achieved clinically meaningful reduction in MADRS but had not remitted by 6 weeks went into remission after additional dose in Part B



Definitions (n at Week 6):

Remitters (n=48) = MADRS ≤ 12 and no single item ≥ 4 ;

Responders and Partial Responders (n=68) = % CFB in MADRS $\geq 25\%$ and do not meet remission criterion;

Non-Responder (n=153) = % CFB in MADRS $\leq 25\%$

*Clinically meaningful reduction in MADRS defined as a $\geq 25\%$ reduction from baseline in MADRS total score at Week 6. This graph is a post hoc analysis. Total n at 6 weeks = 269 (based on ITT)
CI = Confidence Interval; CFB = change from baseline; MADRS = Montgomery-Åsberg Depression Rating Scale

COMP006 – Adverse Events through 26 weeks

COMP006 Through 26 Weeks	COMP360 25 mg	COMP360 10 mg	COMP360 1 mg
	N=296	N=142	N=143
	n (%)	n (%)	n (%)
Any TEAE up to Week 26	280 (94.6)	132 (93.0)	124 (86.7)
Any Serious TEAE up to Week 26	17 (5.7)	5 (3.5)	9 (6.3)
Any TEAE with onset on day of dosing	265 (89.5)	119 (83.8)	88 (61.5)
Resolved ≤ 1 Day	255 (86.1)	113 (79.6)	78 (54.5)
Resolved > 1 and ≤ 2 Days	60 (20.3)	22 (15.5)	12 (8.4)
Resolved > 2 Days	80 (27.0)	32 (22.5)	21 (14.7)

COMP006 Through 26 Weeks (≥10% Incidence in 25mg) MedDRA TEAE Preferred Term	COMP360 25 mg	COMP360 10 mg	COMP360 1 mg
	N=296	N=142	N=143
	n (%)	n (%)	n (%)
Any TEAE	280 (94.6)	132 (93.0)	124 (86.7)
Nausea	133 (44.9)	50 (35.2)	18 (12.6)
Headache	118 (39.9)	53 (37.3)	49 (34.3)
Anxiety	83 (28.0)	38 (26.8)	29 (20.3)
Hallucination, visual	51 (17.2)	27 (19.0)	5 (3.5)
Fatigue	49 (16.6)	26 (18.3)	19 (13.3)
Illusion or Perceptual Disturbance*	48 (16.2)	19 (13.4)	4 (2.8)
Dizziness	47 (15.9)	25 (17.6)	9 (6.3)
Crying	41 (13.9)	15 (10.6)	6 (4.2)
Blood pressure increased	35 (11.8)	10 (7.0)	4 (2.8)

MedDRA = Medical Dictionary for Regulatory Activities; N=number of participants in the treatment group in the Safety Analysis Set by administration; n = number of participants.
 *Illusion and Perceptual Disturbance categories have been combined in this presentation due to some recent changes in MedDRA classification

COMP006 – SAEs Similar in 25mg and 1mg Arms and Low in Number Overall

MedDRA TEAE Preferred Term	COMP360 25 mg	COMP360 10 mg	COMP360 1 mg
	N=296	N=142	N=143
	n (%)	n (%)	n (%)
Any TESAE	17 (5.7)	5 (3.5)	9 (6.3)
Suicidal ideation	4 (1.4)	2 (1.4)	4 (2.8)
Suicidal behaviour	0	0	1 (0.7)
Suspected suicide*	1 (0.3)	0	0
Suicide attempt	0	0	1 (0.7)
Syncope	1 (0.3)	0	1 (0.7)
Major depression	1 (0.3)	0	0
Anxiety	1 (0.3)	0	0
Flashback	1 (0.3)	0	0
Cervical spinal stenosis	1 (0.3)	0	0
Renal neoplasm	0	0	1 (0.7)
Pelvic pain	1 (0.3)	0	0
Adjustment disorder with mixed disturbance of emotion and conduct	1 (0.3)	0	0

MedDRA TEAE Preferred Term	COMP360 25 mg	COMP360 10 mg	COMP360 1 mg
	N=296	N=142	N=143
	n (%)	n (%)	n (%)
Pneumonia	0	1 (0.7)	0
Radius fracture	1 (0.3)	1 (0.7)	0
Road traffic accident	1 (0.3)	0	0
Tibia fracture	1 (0.3)	0	0
Ulna fracture	1 (0.3)	0	0
Alanine aminotransferase increased	1 (0.3)	0	0
Aspartate aminotransferase increased	1 (0.3)	0	0
Brain neoplasm	1 (0.3)	0	0
Thyroid neoplasm	1 (0.3)	0	0
Cerebrovascular accident	0	0	1 (0.7)
Toxic encephalopathy	0	1 (0.7)	0
Tremor	1 (0.3)	0	0

*Suspected Suicide determined by the investigator as not related to the treatment, based on the specific circumstances and timing

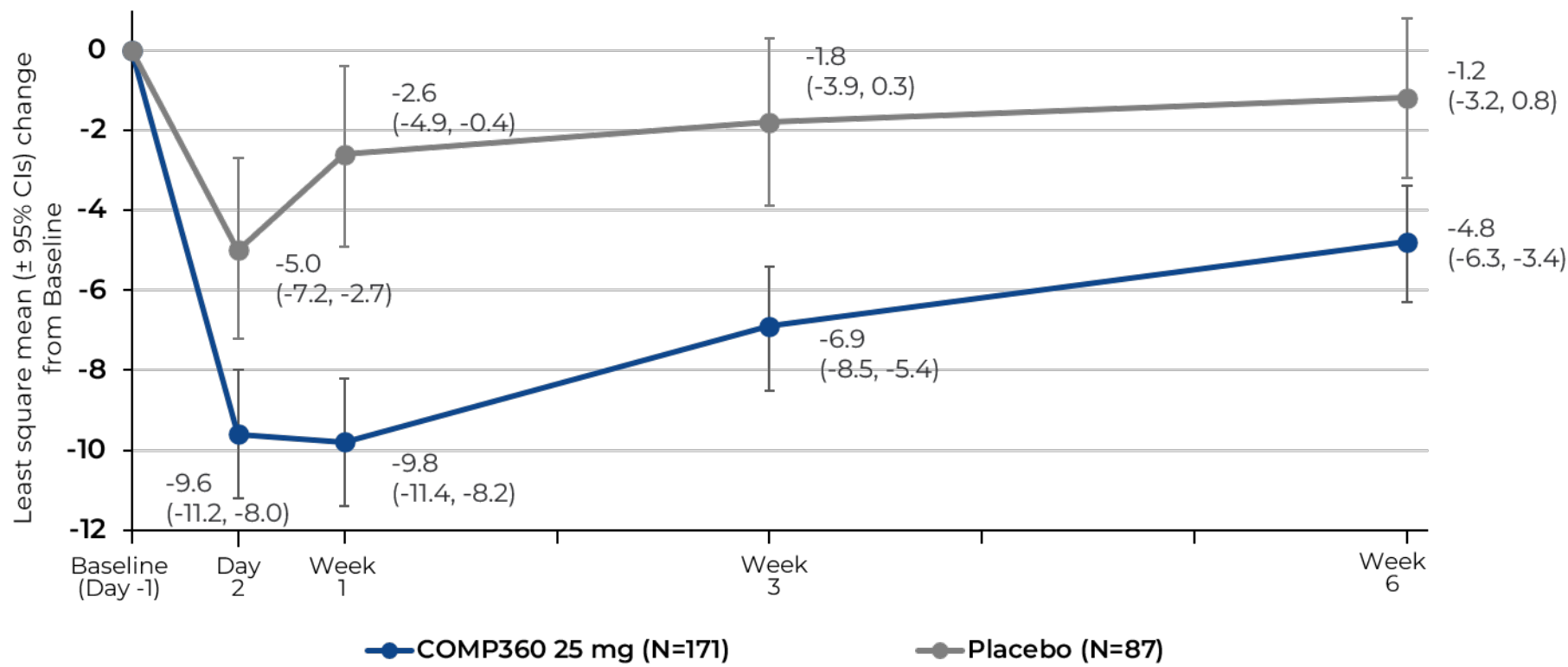
MedDRA = Medical Dictionary for Regulatory Activities; N=number of participants in the treatment group in the Safety Analysis Set by administration; n = number of participants.

COMP005 – Phase 3 Data

COMP005 - Primary Endpoint Achieved – Change in MADRS at Week 6

Highly statistically significant difference of -3.6 MADRS between 25mg vs placebo at Week 6 ($p<0.001$)

Statistical significance at all timepoints beginning the day after administration (Day 2) demonstrates rapid onset of action



Baseline mean (SD):
25 mg (n=171) = 31.5 (5.5)
Placebo (n=87) = 31.5 (5.9)

Visit	LS Mean Difference (95% CI) P-value
Day 2	-4.7 (-7.0, -2.3), $p<0.001$
Week 1	-7.2 (-9.6, -4.8), $p<0.001$
Week 3	-5.2 (-7.4, -2.9), $p<0.001$
Week 6 (Primary)	-3.6 (-5.7, -1.5), $p<0.001$

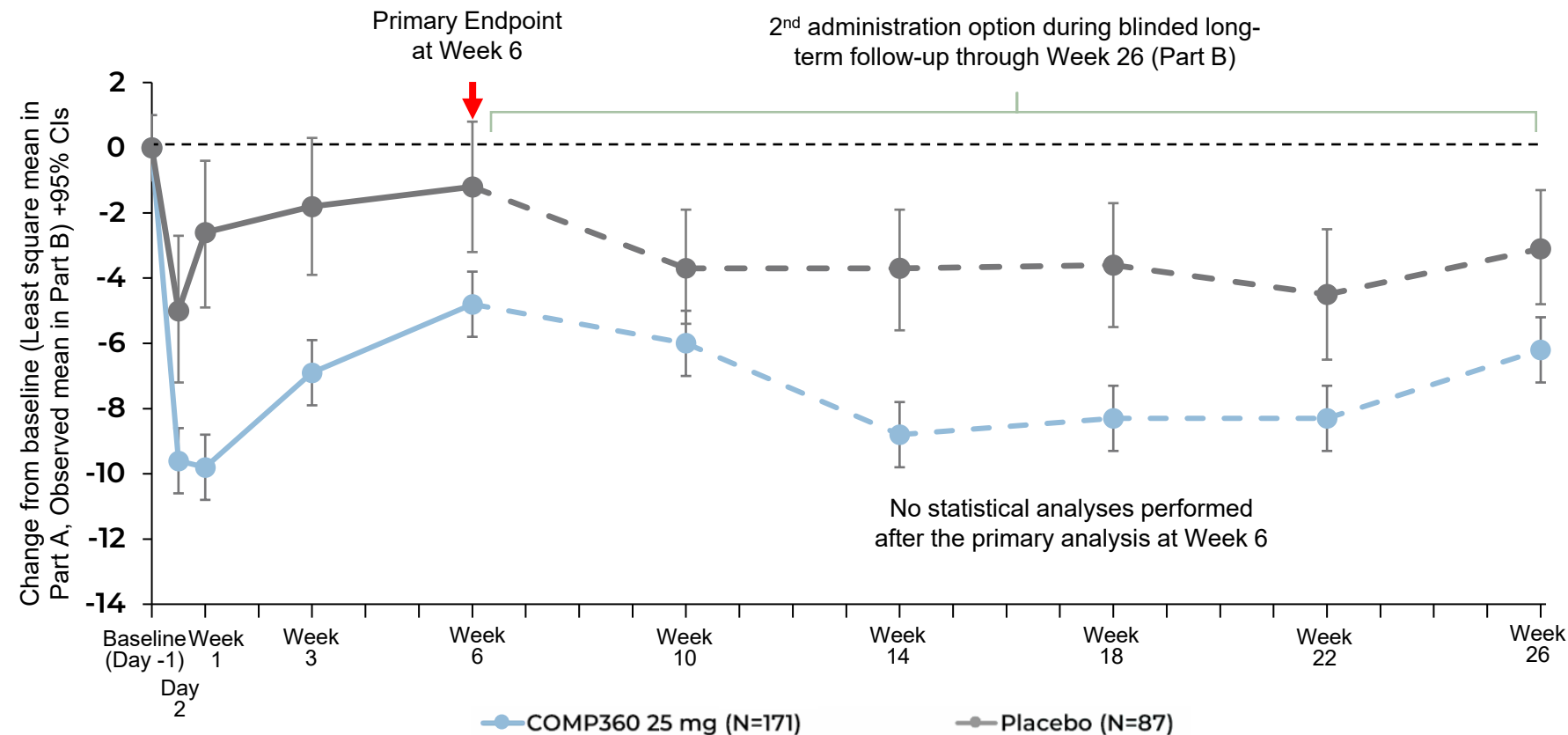
CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery–Åsberg Depression Rating Scale; SD=standard deviation.

COMP005 – Sustained Durability to Week 26

Consistent separation from placebo through randomized and blinded part B up to Week 26

Option for 2nd administration* of COMP360 after Week 6 during blinded long-term follow-up (Part B)

70% of patients in 25mg arm and 53% in placebo arm received a 2nd administration after Week 6

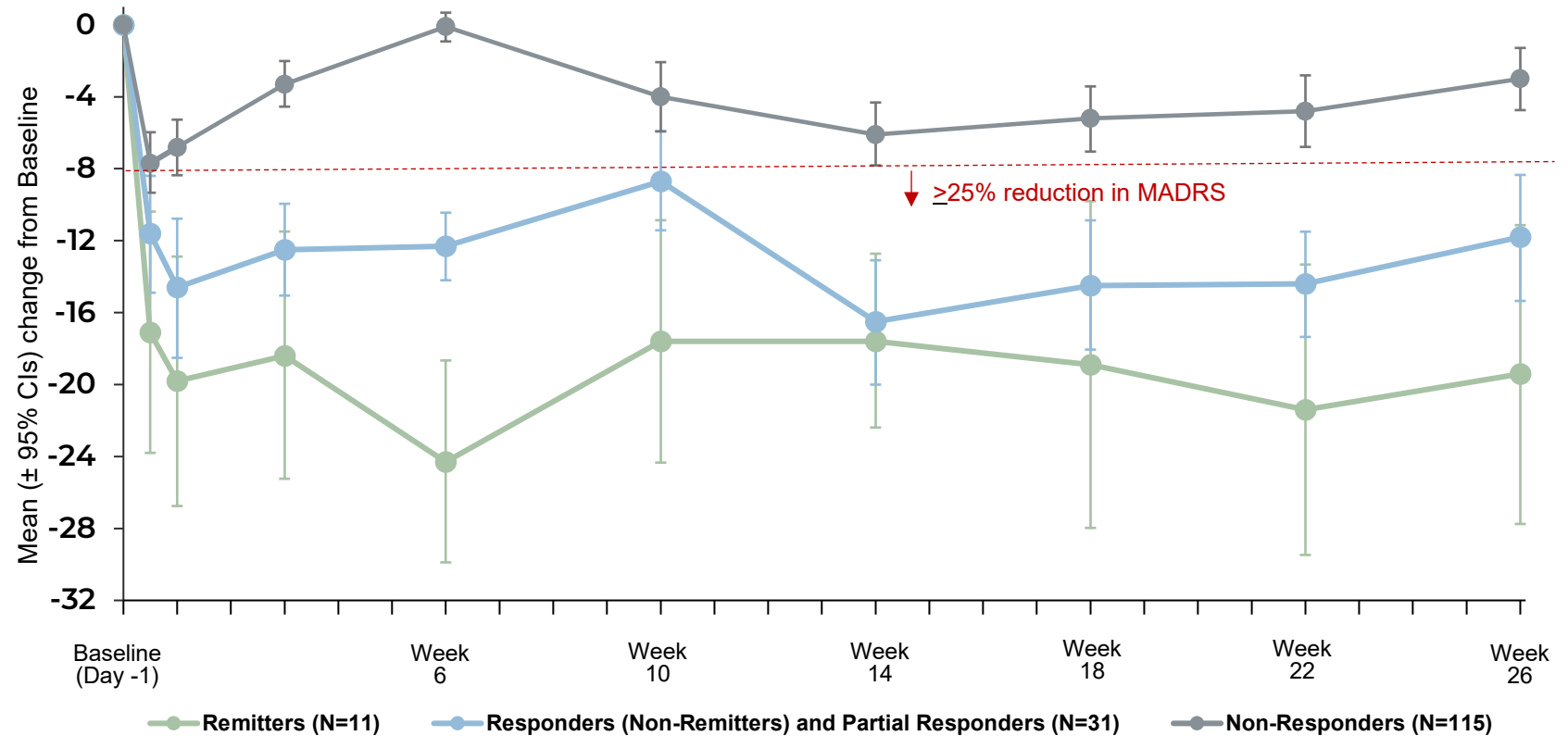


*2nd administration based on pre-specified criteria and receive either what they were randomized into or antidepressant
CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery-Åsberg Depression Rating Scale

COMP005 - COMP360 Response Can Be Immediate and Durable – Unique in TRD

25% of participants in 25mg arm achieved clinically meaningful reduction in MADRS* at Week 6 and on average maintained response at least through Week 26

Over 40% of those who achieved clinically meaningful reduction in MADRS but had not remitted by 6 weeks went into remission after additional dose in Part B



Definitions (n at Week 6):

Remitters (n=11) = MADRS ≤12 and no single item ≥4;

Responders and Partial Responders (n=31) = % CFB in MADRS ≥ 25% and do not meet remission criterion;

Non-Responder (n=115) = % CFB in MADRS ≤ 25%

*Clinically meaningful reduction in MADRS defined as a >25% reduction from baseline in MADRS total score at Week 6. This graph is a post hoc analysis. Total n at 6 weeks = 157 (based on ITT)

CI = Confidence Interval; CFB = change from baseline; MADRS = Montgomery-Åsberg Depression Rating Scale

COMP005 – Adverse Events through 26 weeks

COMP005 Through 26 weeks	COMP360 25 mg	Placebo
	N=171	N=87
	n (%)	n (%)
Any TEAE up to Week 26	145 (84.8)	52 (59.8)
Any Serious TEAE up to Week 26	8 (4.7)	2 (2.3)
Any TEAE time of onset day of dosing	121 (70.8)	25 (28.7)
Resolved ≤ 1 Day	115 (67.3)	24 (27.6)
Resolved > 1 and ≤ 2 Days	16 (9.4)	2 (2.3)
Resolved > 2 Days	22 (12.9)	5 (5.7)

COMP005 Through 26 Weeks (>10% Incidence in 25mg) MedDRA TEAE Preferred Term	COMP360 25 mg	Placebo
	N=171	N=87
	n (%)	n (%)
Any TEAE	145 (84.8)	52 (59.8)
Headache	61 (35.7)	16 (18.4)
Nausea	44 (25.7)	5 (5.7)
Hallucination, visual	27 (15.8)	0
Anxiety	22 (12.9)	3 (3.4)

N=number of participants in the treatment group in the Safety Analysis Set by administration; n = number of participants; TEAE = treatment emergent adverse event

COMP005 – SAEs Through Week 26

MedDRA TEAE Preferred Term	COMP360 25 mg	Placebo
	N=171	N=87
	n (%)	n (%)
Any TESAE	8 (4.7)	2 (2.3)
Suicidal ideation	4 (2.3)	0
Depression suicidal	1 (0.6)	0
Major depression	0	1 (1.1)
Cellulitis	1 (0.6)	0
Diverticulitis	1 (0.6)	0
Urinary tract infection bacterial	0	1 (1.1)
Clavicle fracture	1 (0.6)	0
Rib fracture	1 (0.6)	0
Pneumothorax	1 (0.6)	0
Anaphylactic reaction	1 (0.6)	0

MedDRA = Medical Dictionary for Regulatory Activities; N=number of participants in the treatment group in the Safety Analysis Set by administration; n = number of participants.

COMP001 – Phase 2b

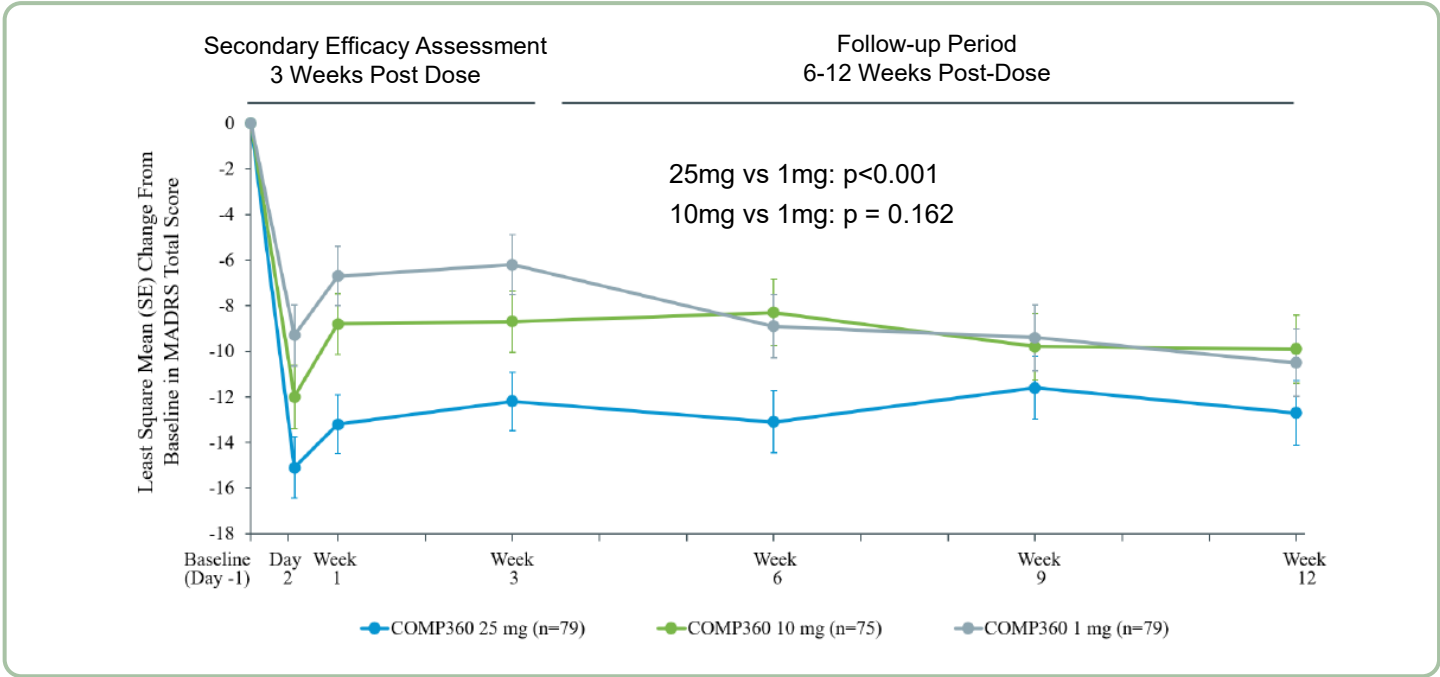
Phase 2b Trial Results Demonstrated the Potential for a Rapid, Sustained Response in TRD

Published in The NEW ENGLAND JOURNAL of MEDICINE*

In a randomized, controlled, double-blind trial, three groups of participants were given a single dose (either 1mg, 10mg or 25 mg) of COMP360 psilocybin

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

The primary endpoint of this study was the change from baseline in MADRS total score at week 3 (25mg vs 1mg).



Clinical Effect: statistically significant and clinically meaningful reduction in depression (25mg vs 1 mg)

Rapid onset of action: The effect occurred the day after the administration

Safety: 90% of TEAEs were mild and moderate and 77% of them resolved on the same or next day. most frequent TEAEs across the 10mg and 25mg doses were headaches, nausea, fatigue, insomnia and anxiety

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)

*N Engl J Med 2022;387:1637-48. DOI: 10.1056/NEJMoa2206443

Thank You

⌚Unlocking pathways ⚡to be.

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