

**CONFIDENTIAL**



# **COMP360 Phase 3 Program Topline Results COMP005 & COMP006**

February 17, 2026

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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 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, among other things, statements regarding 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 of our investigational COMP360 psilocybin treatment, including as a treatment for treatment of TRD or PTSD; our plans and expectations regarding our clinical trials, including our phase 3 trials in TRD and our phase 2b/3 trial in PTSD; our expectations regarding the time periods for the release of data from Part B of the COMP006 Phase 3 trial for TRD; our expectations regarding discussions with the FDA, including discussions regarding potential NDA acceleration strategies, including potential for rolling NDA submission and review for COMP360 psilocybin treatment in TRD; our expectations regarding potential commercial launch timelines and our 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 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, on an accelerated timeline or at all; our expectations regarding the commercial potential for COMP360 and our expectations regarding the benefits of our investigational COMP360 psilocybin treatment. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Compass’s control and which could cause actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements.

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# Welcome

## **Kabir Nath**

Chief Executive Officer

## **Dr Guy Goodwin**

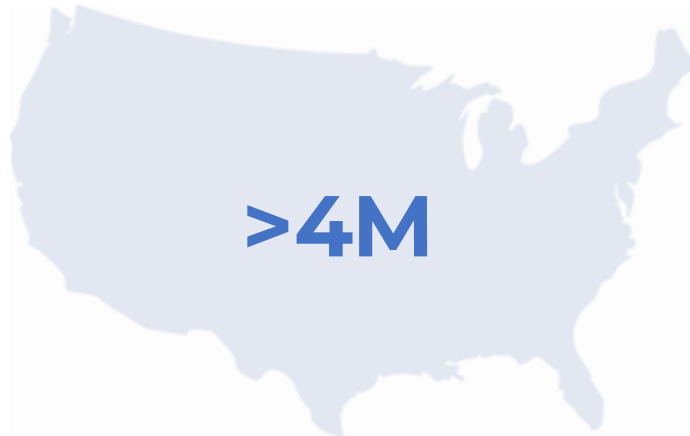
Chief Medical Officer

## **Lori Englebert**

Chief Commercial Officer



# Tremendous Unmet Need in Treatment Resistant Depression (TRD)



**U.S. adults experiencing TRD each year<sup>1</sup>**

**Only 1**



**Medicine approved and used for TRD**

## **High Patient Burden vs. MDD**

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- Chronic condition
- Increased co-morbidities
- 3x longer episodes<sup>2</sup>
- Greater worktime loss<sup>3</sup>
- >50% increased risk of suicide<sup>4</sup>
- Poorer quality of life
- Disproportionate economic impact<sup>5</sup>



# Phase 3 Program Key Highlights

- **Two** highly statistically significant positive Phase 3 trials of COMP360 in TRD at primary endpoint\* at Week 6
  - Over **1,000 participants** across Phase 3 trials and Phase 2b trial
  - Both Phase 3 trials continuing to 52 weeks
- **Extremely rapid onset** with statistical significance demonstrated from the day immediately following administration and maintained at all measured timepoints through Week 6 in both clinical trials
- **Deep and durable response** achieved in significant number of participants
  - **25%** of participants in 005 achieved a clinically meaningful reduction in MADRS\*\* at Week 6 with durability lasting out through at least 26 weeks after just 1 or 2 doses of 25 mg
  - Over **40%** of those that had a clinically meaningful reduction in MADRS but had not remitted by Week 6 went into remission after 2<sup>nd</sup> dose in 005 Part B
  - **39%** of participants in 006 achieved clinically meaningful reduction in MADRS at Week 6
- COMP360 has been generally well-tolerated, with a safe profile, with majority of AEs resolving on the day of treatment

\*Primary endpoint for both trials is the change from baseline in the MADRS (Montgomery-Åsberg Depression Rating Scale) total score at Week 6.

\*\*Clinically meaningful reduction in MADRS defined as a  $\geq 25\%$  reduction from baseline in MADRS total score



## Phase 3 Program Key Highlights (cont'd)

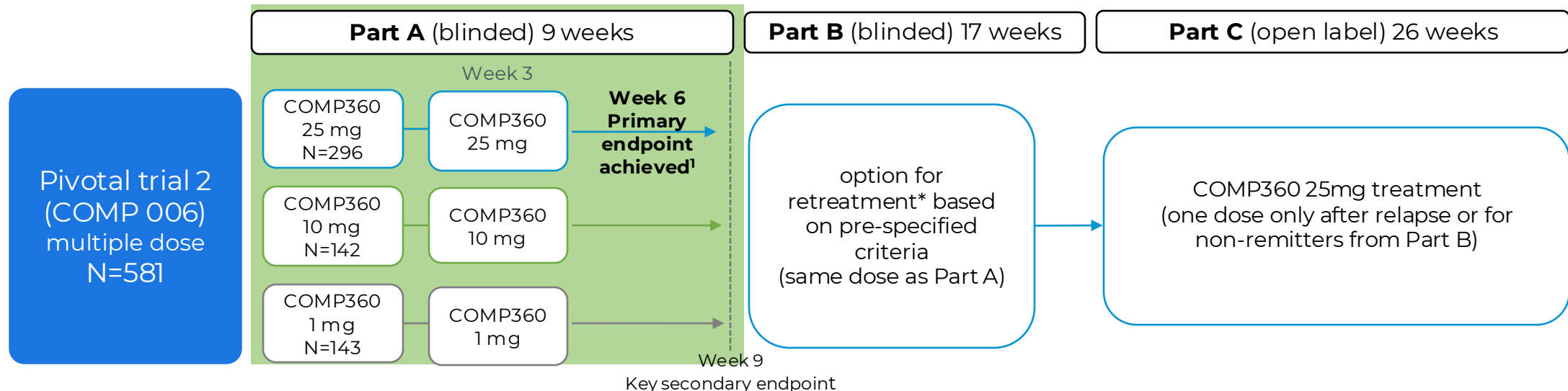
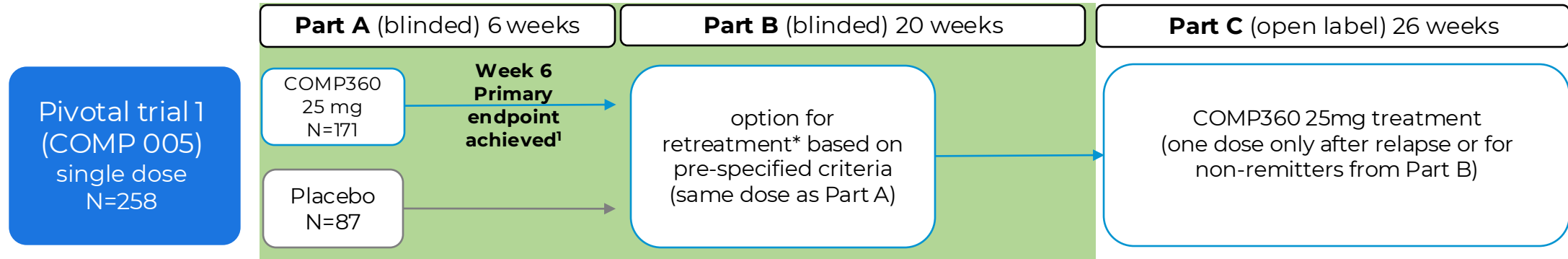
- The emerging clinical profile of **COMP360 is redefining rapidity and durability for TRD patients**
  - No approved drug offers clinically meaningful efficacy with both rapid onset and sustained durability with a single treatment
- The robust benefit/risk profile of COMP360 supports a potentially **highly compelling, novel paradigm for patients and providers** where effectiveness may be determined almost immediately after a single treatment
  - Patients with a clinically meaningful reduction in MADRS to the first treatment have shown the potential for sustained benefit through at least 26 weeks, after one or two doses
- COMP360 has **Breakthrough Therapy designation** from the FDA and we are planning to meet as soon as possible with the FDA to discuss a rolling submission and review, and **expect to complete an NDA submission in Q4**



# Phase 3 Trial Design and Demographics



# Phase 3 Program: Overview of Pivotal Trial Designs



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.



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

| <b>COMP005</b>                                                   | <b>COMP360 25 mg (N=171)</b> | <b>Placebo (N=87)</b> |
|------------------------------------------------------------------|------------------------------|-----------------------|
| <b>Female, n (%)</b>                                             | 93 (54.4)                    | 47 (54.0)             |
| <b>Race, n (%)</b>                                               |                              |                       |
| 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)               |
| <b>Age, years, mean (SD)</b>                                     | 45.9 (13.4)                  | 45.3 (14.4)           |
| Min, Max                                                         | 19, 77                       | 22, 72                |
| Age ≥65 years old                                                | 15 (8.8)                     | 11 (12.6)             |
| <b>Prior psilocybin experience, n (%)</b>                        | 5 (2.9)                      | 5 (5.7)               |
| <b>Prior psychedelic experience including psilocybin, n (%)*</b> | 8 (4.7)                      | 6 (6.9)               |
| <b>BMI kg/m<sup>2</sup>, mean (SD)</b>                           | 28.4 (6.2)                   | 27.7 (6.1)            |

| <b>COMP006</b>                                                  | <b>COMP360 25 mg (N=296)</b> | <b>COMP360 10 mg (N=142)</b> | <b>COMP360 1 mg (N=143)</b> |
|-----------------------------------------------------------------|------------------------------|------------------------------|-----------------------------|
| <b>Female, n (%)</b>                                            | 160 (54.1)                   | 68 (47.9)                    | 69 (48.3)                   |
| <b>Race, n (%)</b>                                              |                              |                              |                             |
| 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)                     |
| <b>Age, years, mean (SD)</b>                                    | 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)                    |
| <b>Prior psilocybin experience, n (%)</b>                       | 13 (4.4)                     | 5 (3.5)                      | 5 (3.5)                     |
| <b>Prior psychedelic experience including psilocybin, n (%)</b> | 19 (6.4)                     | 7 (4.9)                      | 9 (6.3)                     |
| <b>BMI kg/m<sup>2</sup>, mean (SD)</b>                          | 28.0 (6.2)                   | 28.6 (7.1)                   | 27.8 (6.7)                  |

\*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

| <b>COMP005</b>                                                              | <b>COMP360<br/>25 mg<br/>(N=171)</b> | <b>Placebo<br/>(N=87)</b> |
|-----------------------------------------------------------------------------|--------------------------------------|---------------------------|
| <b>Number of failed treatments in the current depressive episode, n (%)</b> |                                      |                           |
| 1                                                                           | 2 (1.2)                              | 1 (1.1)                   |
| 2                                                                           | 113 (66.1)                           | 63 (72.4)                 |
| 3                                                                           | 46 (26.9)                            | 18 (20.7)                 |
| 4                                                                           | 10 (5.8)                             | 4 (4.6)                   |
| 5                                                                           | 0                                    | 1 (1.1)                   |
| <b>Number of treatments withdrawn from the screening period, n (%)</b>      |                                      |                           |
| 0                                                                           | 58 (33.9)                            | 26 (29.9)                 |
| 1                                                                           | 38 (22.2)                            | 32 (36.8)                 |
| 2                                                                           | 49 (28.7)                            | 22 (25.3)                 |
| >2                                                                          | 26 (15.2)                            | 7 (8.0)                   |
| <b>MADRS total score at baseline, mean (SD)</b>                             | 31.5 (5.5)                           | 31.5 (5.9)                |
| <b>MADRS total score severity at baseline, n (%)</b>                        |                                      |                           |
| 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)                 |

| <b>COMP006</b>                                                          | <b>COMP360<br/>25 mg<br/>(N=296)</b> | <b>COMP360<br/>10 mg<br/>(N=142)</b> | <b>COMP360<br/>1 mg<br/>(N=143)</b> |
|-------------------------------------------------------------------------|--------------------------------------|--------------------------------------|-------------------------------------|
| <b>Number of failed treatments in current depressive episode, n (%)</b> |                                      |                                      |                                     |
| 1                                                                       | 1 (0.3)                              | 1 (0.7)                              | 0                                   |
| 2                                                                       | 190 (64.2)                           | 105 (73.9)                           | 99 (69.2)                           |
| 3                                                                       | 74 (25.0)                            | 32 (22.5)                            | 33 (23.1)                           |
| 4                                                                       | 29 (9.8)                             | 4 (2.8)                              | 11 (7.7)                            |
| 5                                                                       | 2 (0.7)                              | 0                                    | 0                                   |
| <b>Number of treatments withdrawn from the screening period, n (%)</b>  |                                      |                                      |                                     |
| 0                                                                       | 68 (23.0)                            | 31 (21.8)                            | 36 (25.2)                           |
| 1                                                                       | 127 (42.9)                           | 61 (43.0)                            | 62 (43.4)                           |
| 2                                                                       | 68 (23.0)                            | 35 (24.6)                            | 31 (21.7)                           |
| >2                                                                      | 33 (11.1)                            | 15 (10.6)                            | 14 (9.8)                            |
| <b>MADRS total score at baseline, mean (SD)</b>                         | 32.0 (5.8)                           | 32.1 (5.8)                           | 32.5 (5.4)                          |
| <b>MADRS total score severity at baseline, n (%)</b>                    |                                      |                                      |                                     |
| 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

| <b>COMP005</b>                                | <b>COMP360<br/>25 mg<br/>(N=171)</b> | <b>Placebo<br/>(N=87)</b> |
|-----------------------------------------------|--------------------------------------|---------------------------|
| <b>Length of current depressive episode</b>   |                                      |                           |
| Mean Months (SD)                              | 34.6 (30.1)                          | 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)                 |
| <b>Number of lifetime depressive episodes</b> |                                      |                           |
| 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)                 |

| <b>COMP006</b>                                | <b>COMP360<br/>25 mg<br/>(N=296)</b> | <b>COMP360<br/>10 mg<br/>(N=142)</b> | <b>COMP360<br/>1 mg<br/>(N=143)</b> |
|-----------------------------------------------|--------------------------------------|--------------------------------------|-------------------------------------|
| <b>Length of current depressive episode</b>   |                                      |                                      |                                     |
| 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)                           |
| <b>Number of lifetime depressive episodes</b> |                                      |                                      |                                     |
| Mean (SD)                                     | 6.3 (7.4)                            | 5.4 (6.6)                            | 7.0 (12.5)                          |
| 1                                             | 1 (0.3)                              | 0                                    | 0                                   |
| 2-5                                           | 198 (66.9)                           | 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

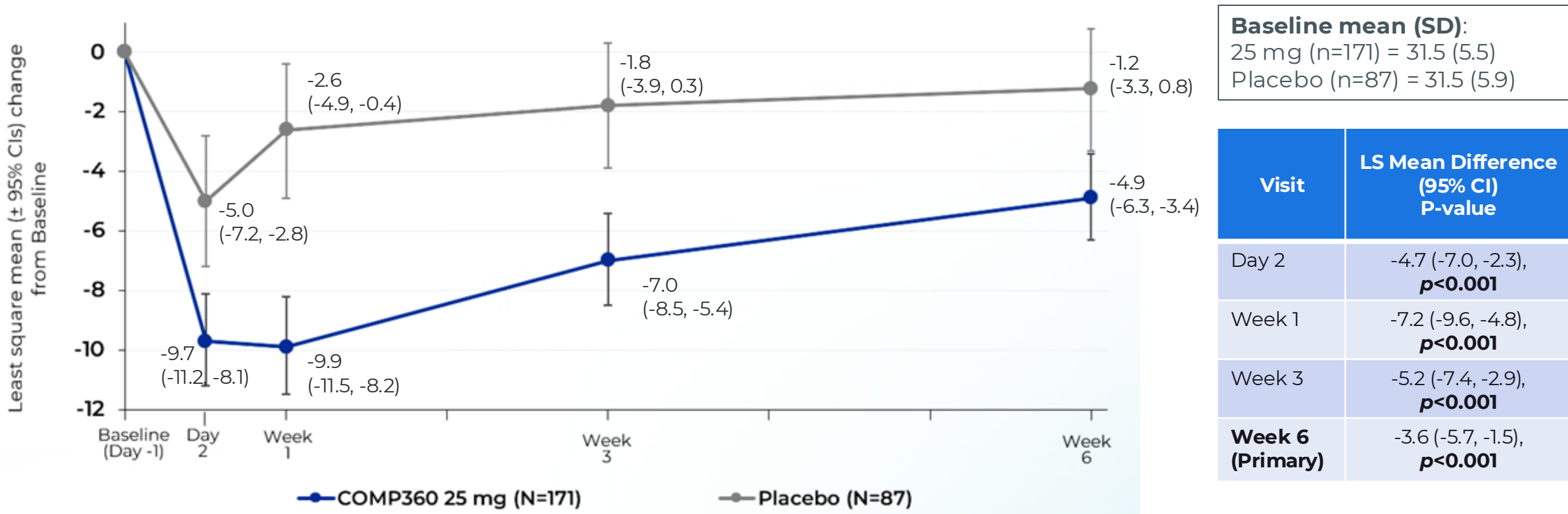




# COMP005 Efficacy Data

# 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

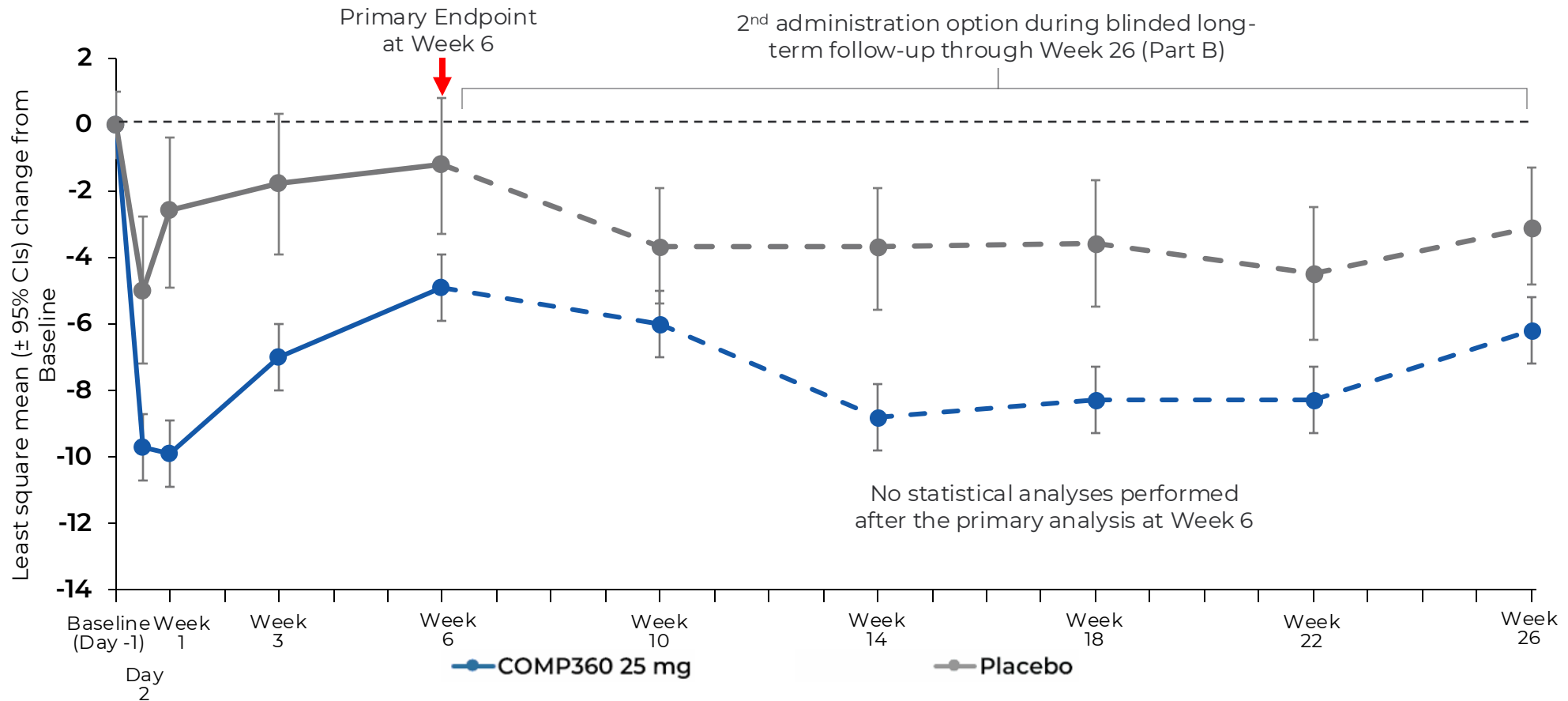


CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery-Åsberg Depression Rating Scale; SD=standard deviation.



# COMP005 – Sustained Durability to Week 26

- Consistent separation from placebo through randomized and blinded part B up to Week 26
- Option for 2<sup>nd</sup> 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

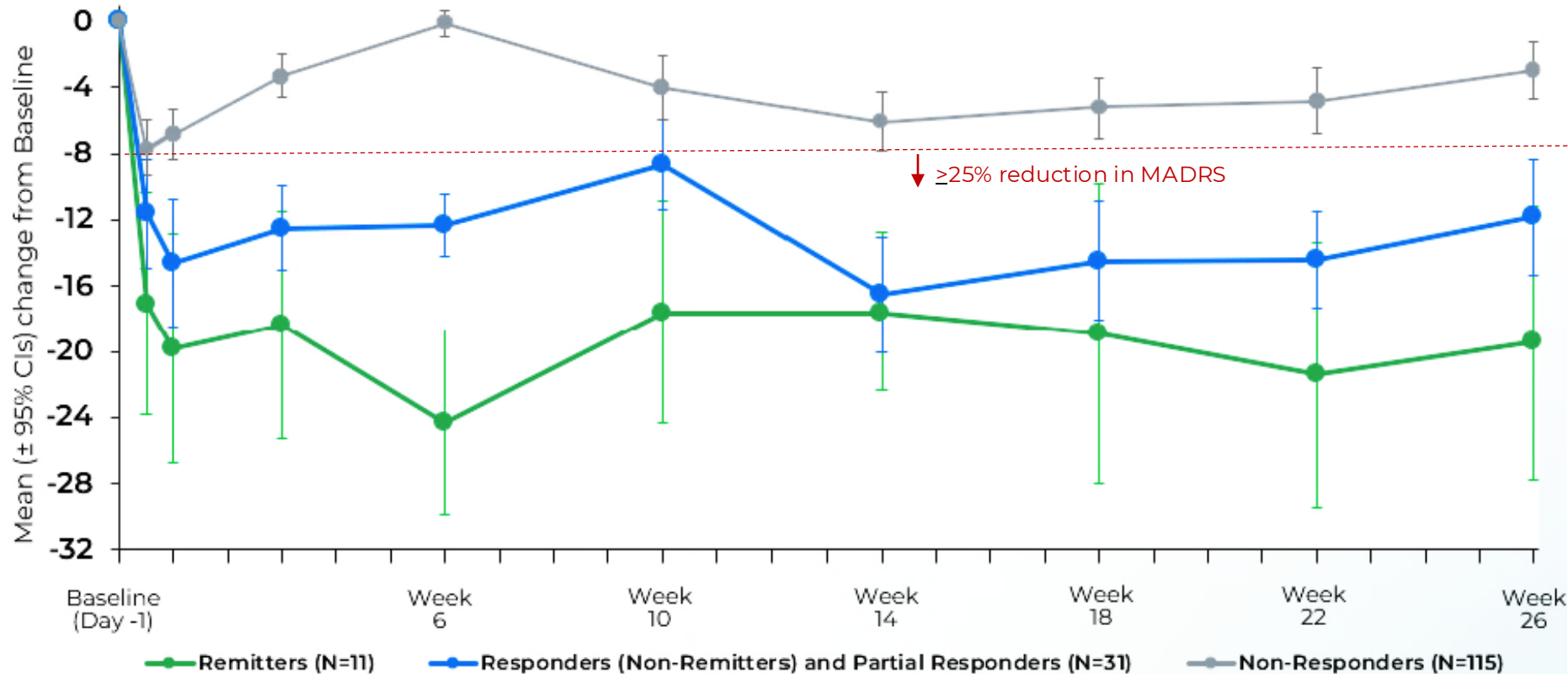


\*2<sup>nd</sup> administration based on pre-specified criteria and receive either what they were randomized into or antidepressant  
CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery-Åsberg Depression Rating Scale



# COMP005 – Durability Through Week 26 by Response Status

- **25%** of participants in 25mg arm achieved clinically meaningful reduction in MADRS\* at Week 6 and maintained response at least through Week 26
- Magnitude of MADRS improvement among responders demonstrates consistent, durable and clinically meaningful effect
- Over **40%** of those who achieved clinically meaningful reduction in MADRS but had not remitted by 6 weeks went into remission after 2<sup>nd</sup> dose in Part B



## Definitions (n at Week 6):

**Remitters (n=11)** = MADRS  $\leq 12$  and no single item  $\geq 4$

**Responders and Partial Responders (n=31)** = % CFB in MADRS  $\geq 25\%$  and do not meet remission criterion

**Non-Responder (n=115)** = % CFB in MADRS  $\leq 25\%$

Total n at 6 weeks = 157 (8% dropout)

\*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.

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

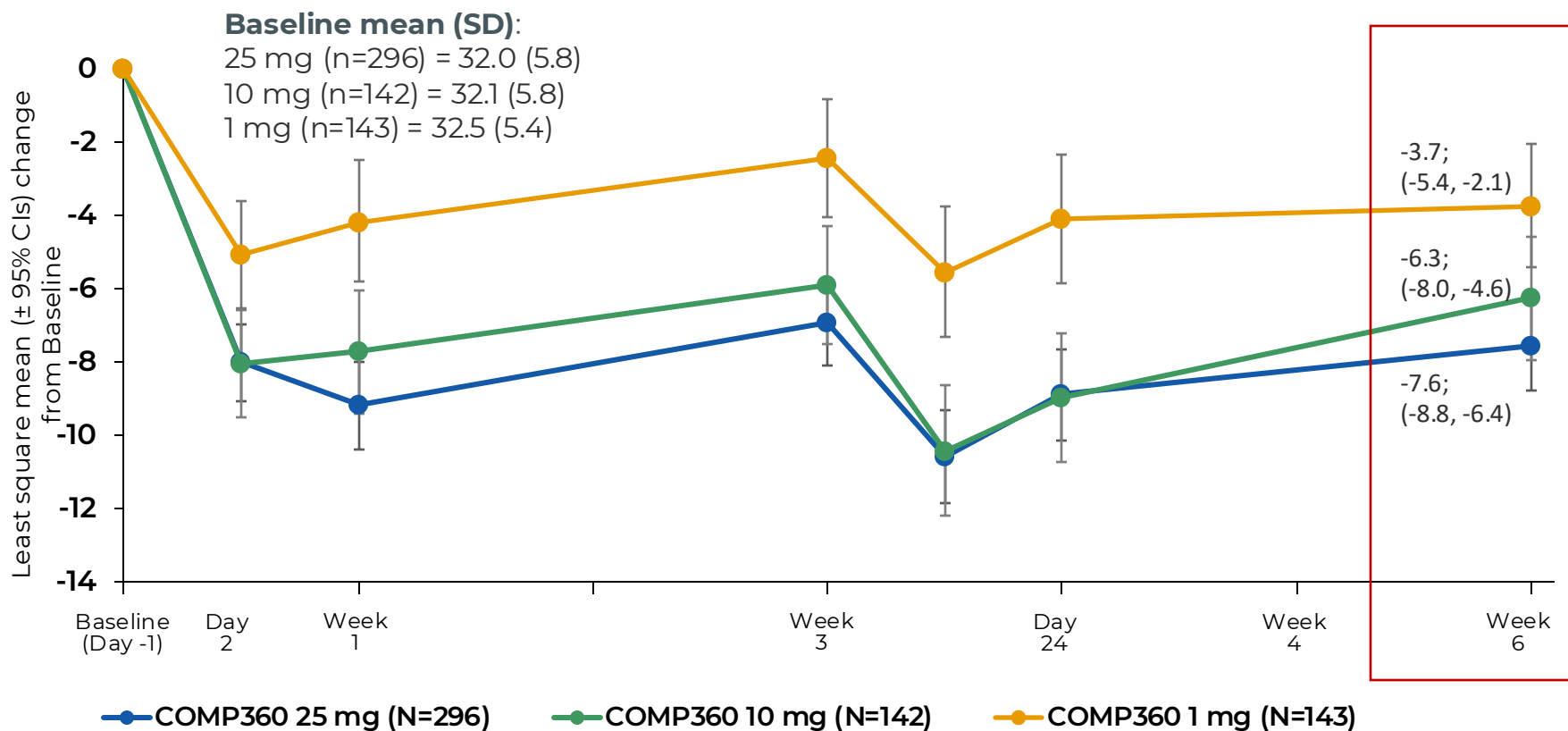




# COMP006 Efficacy Data

# 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<br>LS Mean<br>Difference<br>(95% CI)<br>P-value | 10mg vs 1 mg<br>LS Mean<br>Difference<br>(95% CI)<br>P-value |
|-------------------------|--------------------------------------------------------------|--------------------------------------------------------------|
| Day 2                   | -2.9 (-4.6, -1.2)<br><0.001                                  | -3.0 (-5.0, -1.0)<br>0.002                                   |
| Week 1                  | -5.0 (-7.0, -3.0)<br><0.001                                  | -3.6 (-5.9, -1.2)<br>0.001                                   |
| Week 3                  | -4.5 (-6.4, -2.5)<br><0.001                                  | -3.4 (-5.6, -1.2)<br>0.001                                   |
| Day 24                  | -5.0 (-7.1, -2.9)<br><0.001                                  | -4.9 (-7.4, -2.4)<br><0.001                                  |
| Week 4                  | -4.8 (-6.9, -2.7)<br><0.001                                  | -4.9 (-7.3, -2.5)<br><0.001                                  |
| <b>Week 6 (Primary)</b> | <b>-3.8 (-5.8, -1.8)<br/>&lt;0.001</b>                       | <b>-2.5 (-4.9, -0.2)<br/>0.016</b>                           |

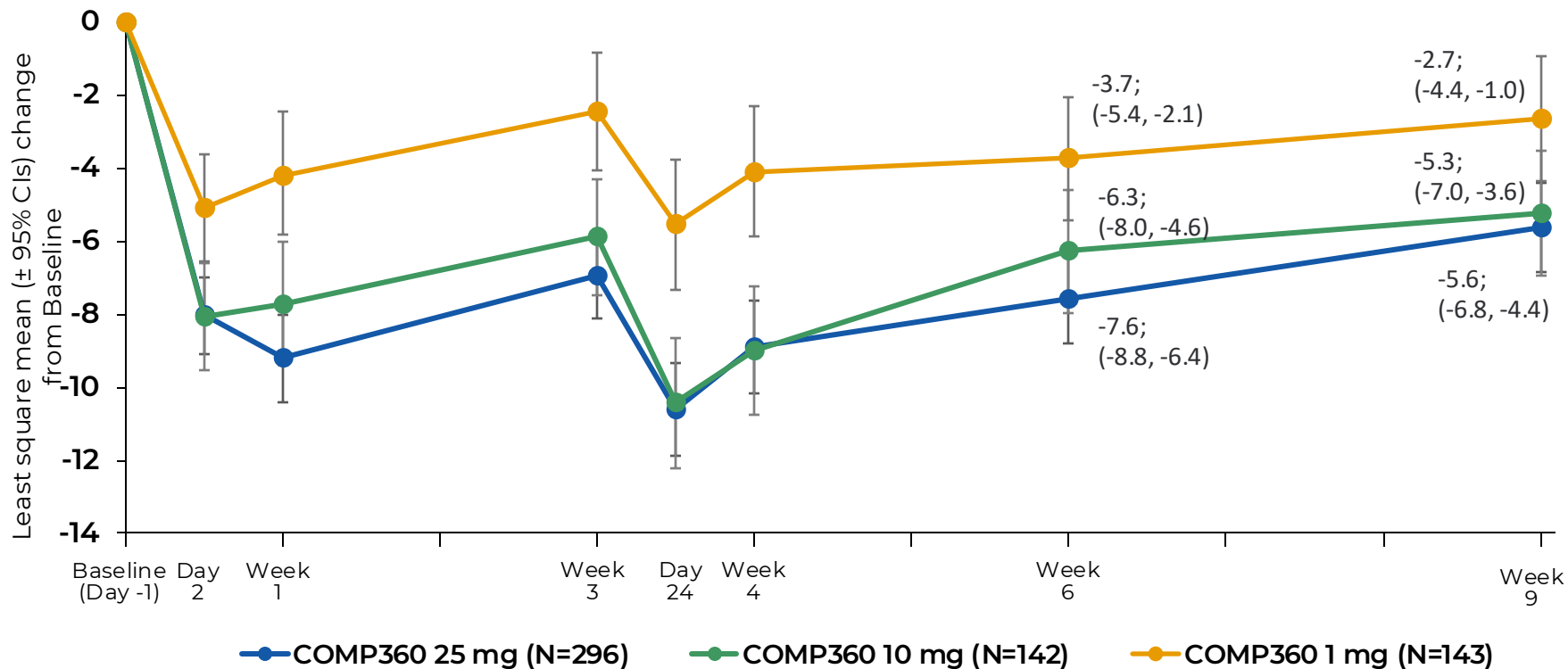
\*Clinically meaningful reduction in MADRS defined as a ≥25% reduction from baseline in MADRS total score at Week 6

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



# COMP006 – Key Secondary Met – Change in MADRS at Week 9

- Statistical significance maintained through Week 9



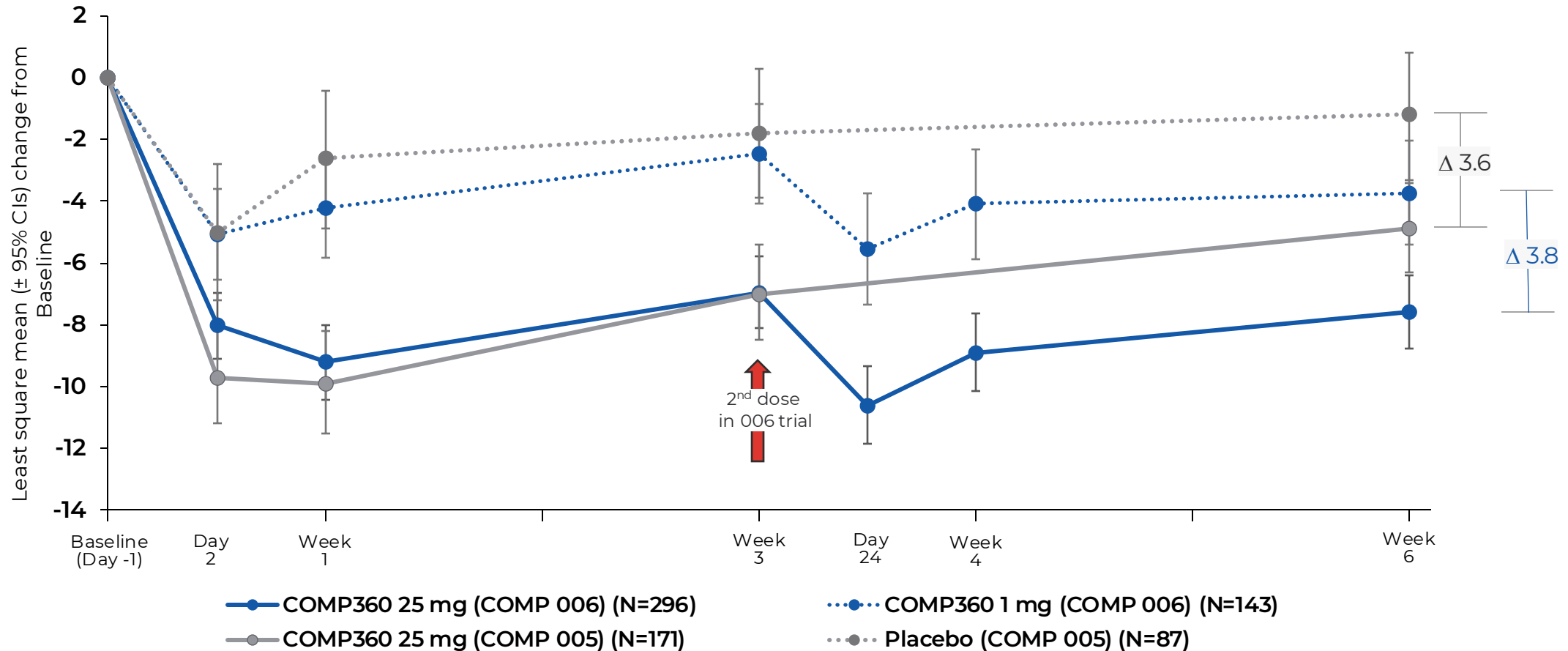
| Visit                         | 25mg vs 1 mg<br>LS Mean<br>Difference<br>(95% CI)<br>P-value | 10mg vs 1 mg<br>LS Mean<br>Difference<br>(95% CI)<br>P-value |
|-------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|
| <b>Week 6<br/>(Primary)</b>   | -3.8 (-5.8, -1.8)<br><0.001                                  | -2.5 (-4.9, -0.2)<br>0.016                                   |
| <b>Week 9<br/>(Secondary)</b> | -2.9 (-5.0, -0.9)<br>0.002                                   | -2.6 (-5.0, -0.2)<br>0.016                                   |

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



# COMP005 & COMP006 Primary Endpoint Comparison\*

- Consistent magnitude of MADRS total score improvement between two Phase 3 studies
- 2<sup>nd</sup> administration at Week 3 shows potential for a deeper treatment effect than a single administration



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

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



# Safety Data

## COMP005 and COMP006



# Safety Summary

- COMP360 is generally well-tolerated, with a safe profile, with the majority of AEs resolving on day of treatment
- Safety data is consistent with known safety profile of COMP360 – no new safety signals identified
- For the data available to date across both trials, the rate for SAE suicidal ideation was less than 1%. There was only one event of SAE suicidal behavior, which occurred in the 1 mg arm in COMP006.
  - To date there have been no attempted or completed suicides
- The DSMB noted that there is no evidence of a clinically meaningful imbalance between treatment arms in suicidality in either study

## **COMP005: In 25 mg arm (Part A and B):**

- Most TEAEs occurred on the days of administration (66%), with the vast majority (88%) resolving within a day
- Most common TEAEs reported were headache, nausea and visual hallucination
- There were 11 treatment-emergent serious adverse events (SAEs) from 8 participants (5%) overall

## **COMP006: In 25 mg arm (Part A):**

- Most TEAEs occurred on the days of administration (73%) with the vast majority (83%) resolving within a day
- Most common TEAEs were headache, nausea, anxiety and visual hallucination
- There were 6 treatment-emergent serious adverse events (SAEs) from 6 participants (2%) overall



# COMP005 & COMP006 Treatment-Emergent Adverse Events (TEAEs) for Part A

| COMP005                              | COMP360<br>25 mg | Placebo   |
|--------------------------------------|------------------|-----------|
|                                      | N=171            | N=87      |
|                                      | n (%)            | n (%)     |
| Any TEAE up to Week 6                | 120 (70.2)       | 34 (39.1) |
| Any Serious TEAE up to Week 6        | 4 (2.3)          | 1 (1.1)   |
| Any TEAE time of onset day of dosing | 118 (69.0)       | 23 (26.4) |
| Resolved ≤ 1 Day                     | 111 (64.9)       | 22 (25.3) |
| Resolved > 1 and ≤ 2 Days            | 15 (8.8)         | 2 (2.3)   |
| Resolved > 2 Days                    | 22 (12.9)        | 5 (5.7)   |

| COMP006                              | COMP360<br>25 mg | COMP360<br>10 mg | COMP360<br>1 mg |
|--------------------------------------|------------------|------------------|-----------------|
|                                      | N=296            | N=142            | N=143           |
|                                      | n (%)            | n (%)            | n (%)           |
| Any TEAE up to Week 9                | 274 (92.6)       | 125 (88.0)       | 116 (81.1)      |
| Any Serious TEAE up to Week 9        | 6 (2.0)          | 1 (0.7)          | 5 (3.5)         |
| Any TEAE with onset on day of dosing | 260 (87.8)       | 114 (80.3)       | 80 (55.9)       |
| Resolved ≤ 1 Day                     | 244 (82.4)       | 107 (75.4)       | 71 (49.7)       |
| Resolved > 1 and ≤ 2 Days            | 52 (17.6)        | 16 (11.3)        | 9 (6.3)         |
| Resolved > 2 Days                    | 71 (24.0)        | 26 (18.3)        | 20 (14.0)       |

Note: COMP006 safety includes 2 dose administrations and goes out to 9 weeks vs. 1 administration out to 6 weeks for COMP005

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 & COMP006

## Treatment-Emergent Adverse Events (TEAE) Incidence for Part A

| <b>COMP005</b><br>(≥5% Incidence) | <b>COMP360 25 mg</b>                | <b>Placebo</b> |
|-----------------------------------|-------------------------------------|----------------|
|                                   | N=171                               | N=87           |
|                                   | MedDRA TEAE Preferred Term<br>n (%) | n (%)          |
| Any TEAE                          | 86 (50.3)                           | 12 (13.8)      |
| Headache                          | 42 (24.6)                           | 10 (11.5)      |
| Nausea                            | 35 (20.5)                           | 3 (3.4)        |
| Hallucination, visual             | 24 (14.0)                           | 0              |
| Anxiety                           | 14 (8.2)                            | 2 (2.3)        |
| Dizziness                         | 10 (5.8)                            | 2 (2.3)        |
| Illusion                          | 9 (5.3)                             | 1 (1.1)        |

| <b>COMP006</b><br>(≥10% Incidence) | <b>COMP360 25 mg</b>                | <b>COMP360 10 mg</b> | <b>COMP360 1 mg</b> |
|------------------------------------|-------------------------------------|----------------------|---------------------|
|                                    | N=296                               | N=142                | N=143               |
|                                    | MedDRA TEAE Preferred Term<br>n (%) | n (%)                | n (%)               |
| Any TEAE                           | 254 (85.8)                          | 111 (78.2)           | 80 (55.9)           |
| Nausea                             | 118 (39.9)                          | 42 (29.6)            | 15 (10.5)           |
| Headache                           | 108 (36.5)                          | 43 (30.3)            | 41 (28.7)           |
| Anxiety                            | 62 (20.9)                           | 28 (19.7)            | 21 (14.7)           |
| Hallucination, visual              | 46 (15.5)                           | 24 (16.9)            | 3 (2.1)             |
| Illusion                           | 41 (13.9)                           | 16 (11.3)            | 3 (2.1)             |
| Dizziness                          | 41 (13.9)                           | 21 (14.8)            | 9 (6.3)             |
| Fatigue                            | 41 (13.9)                           | 23 (16.2)            | 16 (11.2)           |
| Crying                             | 35 (11.8)                           | 13 (9.2)             | 4 (2.8)             |
| Blood pressure increased           | 31 (10.5)                           | 6 (4.2)              | 4 (2.8)             |

Note: COMP006 safety includes 2 dose administrations and goes out to 9 weeks vs. 1 administration out to 6 weeks for COMP005



# COMP005 & COMP006

## Treatment-Emergent Serious Adverse Events (SAEs) for Part A

| <b>COMP005</b>      | <b>COMP360<br/>25 mg</b> | <b>Placebo</b> |
|---------------------|--------------------------|----------------|
|                     | N=171                    | N=87           |
|                     | <b>n (%)</b>             | <b>n (%)</b>   |
| Any SAE             | 4 (2.3)                  | 1 (1.1)        |
| Suicidal ideation   | 2 (1.2)                  | 0              |
| Depression suicidal | 1 (0.6)                  | 0              |
| Major depression    | 0                        | 1 (1.1)        |
| Cellulitis          | 1 (0.6)                  | 0              |
| Diverticulitis      | 1 (0.6)                  | 0              |

| <b>COMP006</b>           | <b>COMP360<br/>25 mg</b> | <b>COMP360<br/>10 mg</b> | <b>COMP360<br/>1 mg</b> |
|--------------------------|--------------------------|--------------------------|-------------------------|
|                          | N=296                    | N=142                    | N=143                   |
|                          | <b>n (%)</b>             | <b>n (%)</b>             | <b>n (%)</b>            |
| Any SAE                  | 6 (2.0)                  | 1 (0.7)                  | 5 (3.5)                 |
| Suicidal ideation        | 0                        | 1 (0.7)                  | 2 (1.4)                 |
| Suicidal behaviour       | 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                       |

Note: COMP006 safety includes 2 dose administrations and goes out to 9 weeks vs. 1 administration out to 6 weeks for COMP005

n = number of participants with TESAE; TESAE = treatment emergent serious adverse event



# COMP005 – Safety Data Through Week 26

## TEAEs

| MedDRA TEAE Preferred Term | COMP360 25 mg | Placebo   |
|----------------------------|---------------|-----------|
|                            | N=171         | N=87      |
|                            | n (%)         | n (%)     |
| Any TEAE                   | 111 (64.9)    | 23 (26.4) |
| Headache                   | 61 (35.7)     | 15 (17.2) |
| Nausea                     | 42 (24.6)     | 4 (4.6)   |
| Hallucination, visual      | 27 (15.8)     | 0         |
| Anxiety                    | 22 (12.9)     | 3 (3.4)   |
| Dizziness                  | 14 (8.2)      | 2 (2.3)   |
| Illusion                   | 11 (6.4)      | 1 (1.1)   |
| Blood pressure increased   | 9 (5.3)       | 3 (3.4)   |
| Insomnia                   | 9 (5.3)       | 3 (3.4)   |

## SAEs

| 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 AnalysisSet by administration; n = number of participants. Table shows TEAEs occurring in ≥ 5% in each treatment period.

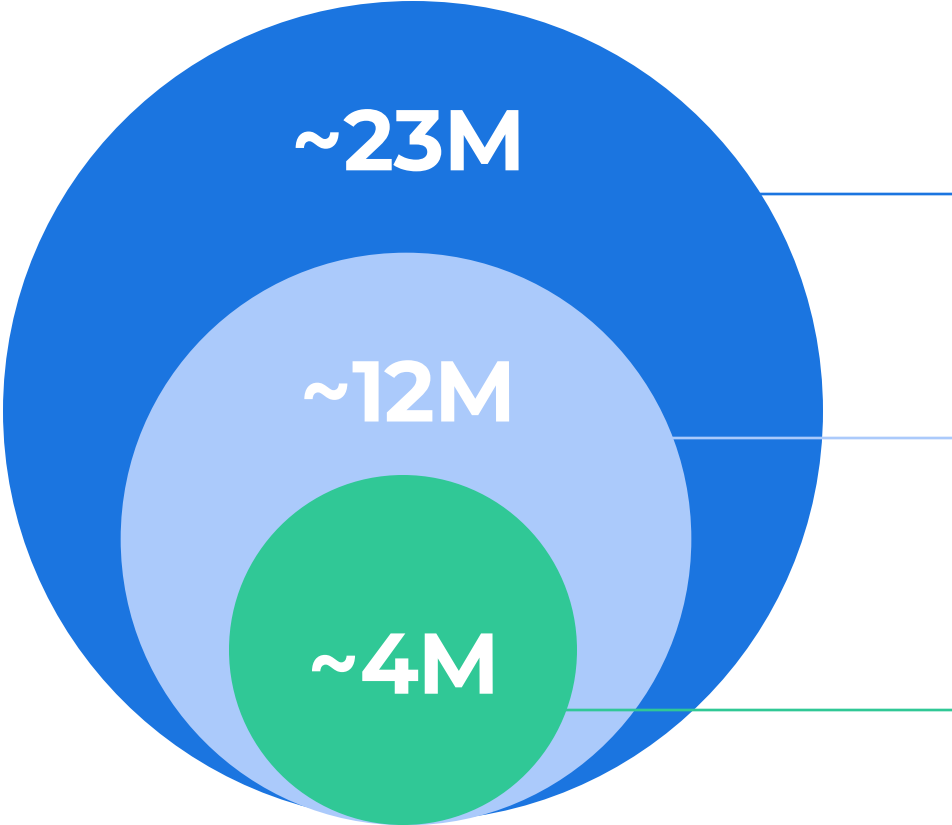




# Commercial update

Lori Englebort, Chief Commercial Officer

# Treatment-Resistant Depression (TRD) Affects Millions in the U.S.



Prevalence of U.S. adults experiencing major depression each year<sup>1</sup>

Adult patients who are drug treated for MDD in the past year<sup>2</sup>

MDD patients failed by ≥2 antidepressants and considered TRD<sup>2</sup>



**Over 55 medicines approved for MDD**



**Only 2 medicines approved for TRD and only one that is used, Spravato®**

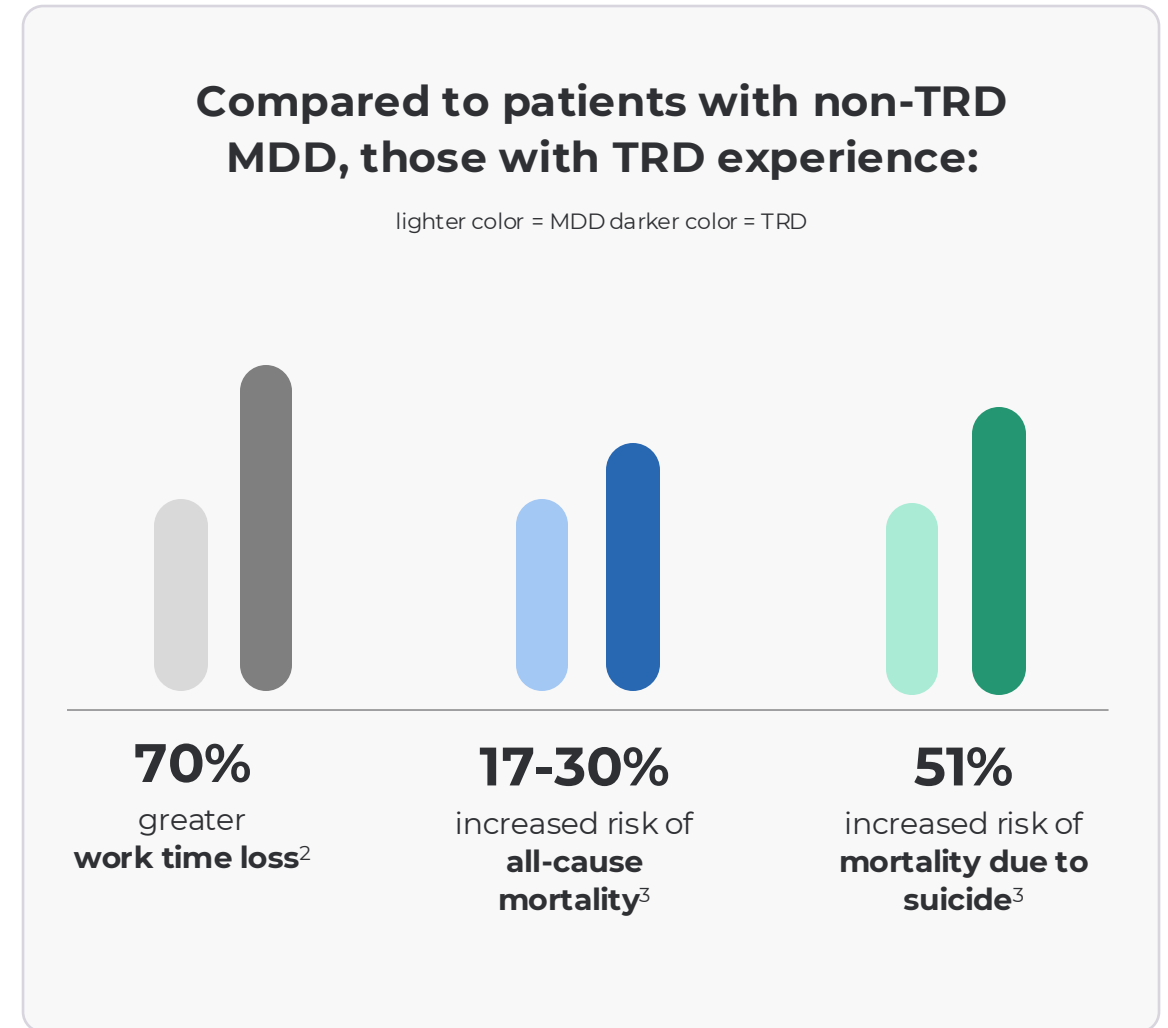
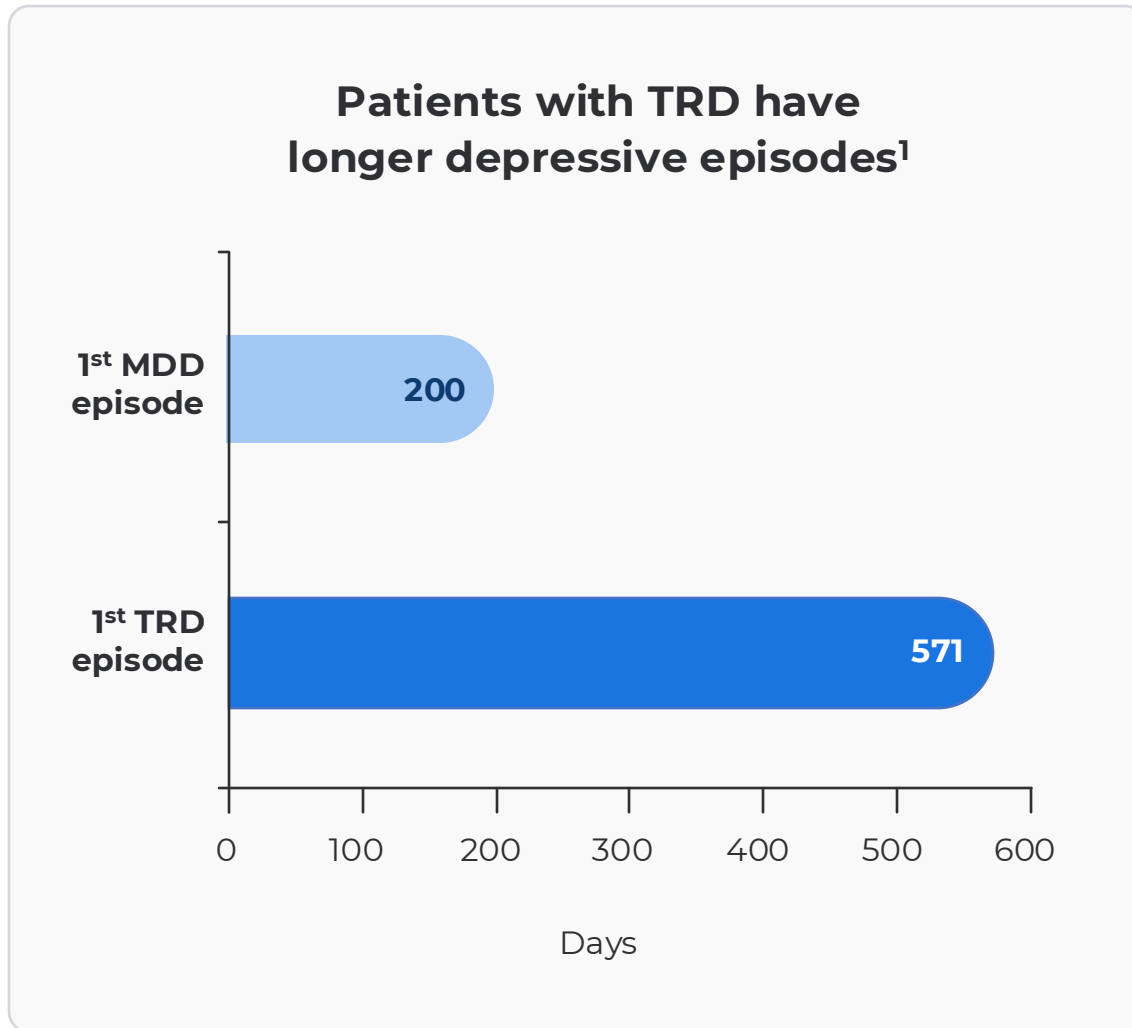
## TRD ▶

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>

1. <https://www.nimh.nih.gov/health/statistics/major-depression> Accessed June 21, 2025. 2. Data on file. 3. 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 May 21, 2025.



# TRD has a significantly greater impact on individuals' lives compared to MDD



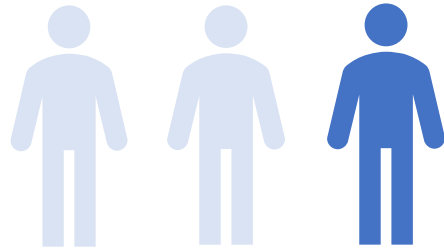
1. Wu B, et al. *PLoS One*. 2019;14(8):e0220763. 2. Amos TB, et al. *J Clin Psychiatry*. 2018;79(2):17m11725. 3. Gustafsson TT, et al. *J Affect Disord*. 2025;368:136-142.



# TRD Disproportionately Impacts the Annual Economic Burden of MDD

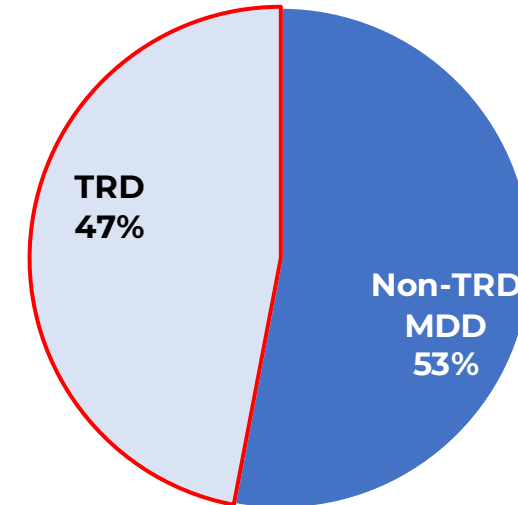
**1/3<sup>rd</sup>**

of MDD patients are failed by  $\geq 2$  antidepressants and considered treatment resistant<sup>1</sup>



**~\$93B**

Annual Economic Burden of drug-treated MDD<sup>1</sup>



TRD is associated with disproportionate health care costs and unemployment, suggesting **potentially large economic and societal gains with effective management<sup>1</sup>**



# Potentially Highly Differentiated and Compelling COMP360 Clinical Profile for TRD Patients and their Providers

|                                                 | COMP360 <sup>1</sup>                                                              | Spravato®                                                                                              | Traditional Antidepressants                                            |
|-------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Efficacy in TRD patient population <sup>2</sup> | Yes<br>(Positive trials: 2 ph3 trials; 1 ph2b)                                    | Yes<br>(FDA approved)                                                                                  | No                                                                     |
| Primary Endpoint                                | Change from baseline in MADRS at Week 6<br>005: 25mg vs. Pbo<br>006: 25mg vs. 1mg | Change from baseline in MADRS at Day 28<br>TRANSFORM 2: Esk+AD vs. Pbo+AD                              | Various: typically change from baseline in MADRS at Week 6 vs. placebo |
| Effect Size / p-value                           | 005: -3.6 (p<0.001)<br>006: -3.8 (p<0.001)                                        | TRANSFORM 2: -4.0 (p=0.02) <sup>4</sup>                                                                | Varies: Recent treatment approved = -3.8 (p=0.002) <sup>6</sup>        |
| Onset                                           | Stat sig day after dosing                                                         | Stat sig at day 28 (adj) <sup>4</sup>                                                                  | Avg 2 - 8 weeks                                                        |
| Durability                                      | At least 26 weeks after 1 or 2 doses <sup>3</sup>                                 | Induction: 2x/week in month 1<br>Maintenance: 1x/week in month 2, then every 1 or 2 weeks <sup>4</sup> | Daily dosing                                                           |
| Safety & Tolerability                           | Generally well-tolerated and safe profile                                         | Generally well-tolerated & safe                                                                        | Generally safe but chronic side effects common                         |
| Dose and Administration                         | 25mg oral capsule;<br>1 capsule / administration                                  | 56mg or 86mg intranasal;<br>2 or 3 devices / administration                                            | Various: oral tablet or capsules<br>QD or BID                          |
| Monitoring                                      | At least 6hrs post administration<br>by licensed HCP at certified center          | At least 2 hours post administration<br>by licensed HCP at certified center                            | n/a                                                                    |
| # of Patients Treated annually                  | n/a                                                                               | <100,000 patients <sup>5</sup>                                                                         | ~12M <sup>7</sup>                                                      |
| 2025 Revenue                                    | n/a                                                                               | \$1.5B <sup>5</sup>                                                                                    | n/a                                                                    |

1. As demonstrated through COMP005 Part A and Part B and COMP006 Part A clinical trial top line results; final profile will depend on FDA approval and label; expectations at this time

2. As proven through clinical trials specifically for a TRD patient population; COMP360 remains investigational and has not been approved by FDA or any other regulatory authority

3. For those who achieved clinically meaningful reduction in MADRS: ≥ 25% reduction from baseline in MADRS total score

4. Spravato® Prescribing Information and [www.spravatohcp.com](http://www.spravatohcp.com); For appropriateness, only comparing trials run prior to FDA approval (TRANSFORM 1 and 2)

5. IQVIA data for 2024 # of patients treated and J&J 2025 Q4 earnings call

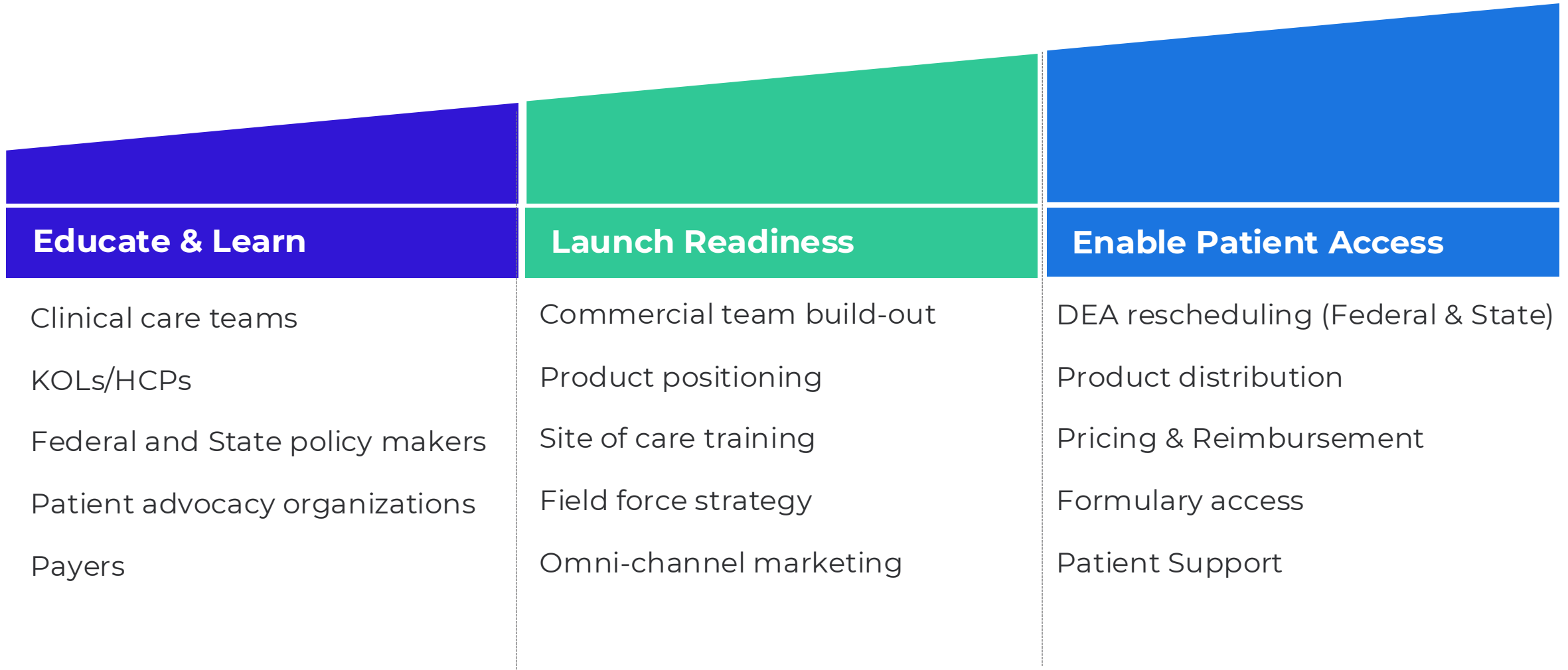
6. Data on file

7. [www.auvelityhcp.com](http://www.auvelityhcp.com)

Note: No head to head studies between COMP360 and Spravato or antidepressants have been run; while not indicated for TRD, traditional antidepressants are frequently used to treat TRD patients as there are limited treatment options currently indicated for this patient population



# We are Planning To Be Launch Ready by the End of the Year



NOTE: KOL = key opinion leaders; HCP = healthcare professional



# Summary

- The emerging clinical profile of **COMP360 is redefining rapidity and durability for TRD patients**
- **TRD is a chronic and extremely refractory condition with very few treatment options**
  - No approved drug offers clinically meaningful efficacy with both rapid onset and sustained durability with a single treatment
- The robust benefit/risk profile of COMP360 supports a potentially **highly compelling, novel paradigm for patients and providers** where effectiveness may be determined almost immediately after a single treatment
  - Patients with a clinically meaningful reduction in MADRS from the first treatment have shown the potential for sustained benefit through at least 26 weeks, after one or two doses
- **These results increase our conviction** in the potential importance of this treatment for TRD patients
- We are planning to meet as soon as possible with the FDA to discuss a rolling submission and review, and **expect to complete an NDA submission in Q4**
- COMP360 has **Breakthrough Therapy designation** from the FDA



# Thank you...

## Q&A

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