A Randomized, Double-Blind, Placebo-Controlled, Phase 2b Trial with an Open-Label Extension to Determine the Safety and Efficacy of GH001 in Patients with Treatment-Resistant Depression

GH001-TRD-201

Clinicaltrials.gov ID: NCT05800860

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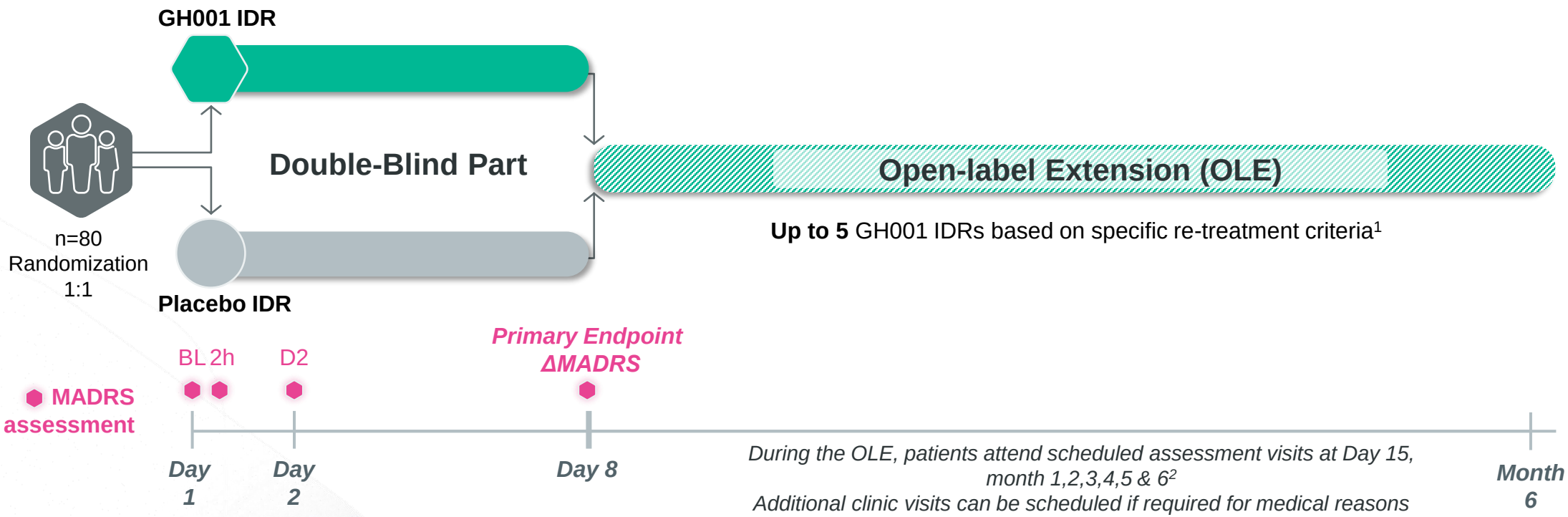
Phase 2b Trial of GH001 in Patients with TRD: Design (GH001-TRD-201)



[1]*Re-treatment criteria include the severity of depression and the effectiveness, tolerability, and number of previous IDRs. The patient meets one of the following criteria: i. has MADRS >18; or ii. has MADRS >10 and ≤18 and MADRS ≤10 has not been observed at D8 of the prior treatment or at any visit since then; or iii. has MADRS >10 and ≤18 and MADRS >18 has been observed since the most recent observation of MADRS ≤10*

[2]*Patients also attended assessment visits on Day 2 and Day 8 after each re-treatment*

As in previously completed trials, the GH001-TRD-201 trial is conducted under the supervision of a healthcare provider, but without any planned psychotherapeutic interventions before, during, or after dosing.

Sources: 1) NCT05800860. (2024). A Trial of GH001 in Patients With Treatment-Resistant Depression. ClinicalTrials.gov. Accessed August 23, 2024.

Abbreviations: BL = Baseline; D = Day; h = Hour; IDR = Individualized dosing regimen; MADRS = Montgomery–Åsberg Depression Rating Scale; OLE = Open-label extension; TRD = Treatment-resistant depression.

Key Inclusion Criteria

Patients included in this trial were required to meet the trial criteria for TRD as assessed by a study psychiatrist:

- **Recurrent or single MDD episode (per DSM-5 criteria)** without psychotic features, with current episode of ≤2 years (**MINI***).
- Current major depressive episode (MDE) **"valid" based upon the MGH-SAFER** criteria interview.
  - *SAFER is an independent interview conducted by an experienced clinician from Massachusetts General Hospital with the aim of confirming the diagnosis, treatment history, and severity of illness*
- **HAM-D-17 total score ≥20** (moderate to severe depression) at Screening and at Baseline.
- **Nonresponse** (≤25% improvement) to ≥2 and ≤5 oral antidepressant treatments started during the current episode, as assessed using the **MGH-ATRQ** *(evaluates the adequacy of prior and current antidepressant treatments)*.
- Antidepressant treatments taken at least at **the minimum dose, and for the minimum duration** (≥6 weeks).
- **Psychotherapy was not considered a treatment for the purposes of defining TRD**.

*Current MDD episode confirmed by the **MINI** - MINI is a short structured diagnostic interview designed to confirm current MDE and ensures consistency.

Abbreviations: BPRS+ = Brief Psychiatric Rating Scale positive symptoms; DSM-5 = Diagnostic and Statistical Manual of Mental Disorders HAM-D-17 = Hamilton Rating Scale for Depression; MDD = Major depressive disorder; MDE = Major depressive episode; MGH-ATRQ = Massachusetts General Hospital Antidepressant Treatment Response Questionnaire; MGH-SAFER = Massachusetts General Hospital State versus trait Assessibility Face and Ecological validity Rule of 3Ps; MINI = Mini-International Neuropsychiatric Interview; TRD = Treatment-resistant depression.

Measures to enrol true TRD patients and minimise placebo effect

Independent raters (eligibility assessment)	MGH-SAFER* (including remote assessment of HAM-D-17) performed by remote, trained independent raters
Blinding at sites	Patient-facing Clinical Trial Team – blinded Patient – blinded Study drug (GH001 or placebo) was in a blinding bag
Blinded independent raters (efficacy assessments)	Efficacy assessments MADRS, HAM-A and CGI-S were performed by blinded, trained, independent raters

*MGH-SAFER is an independent interview conducted by an experienced clinician from Massachusetts General Hospital with the aims of confirming diagnosis, treatment history, and severity of illness

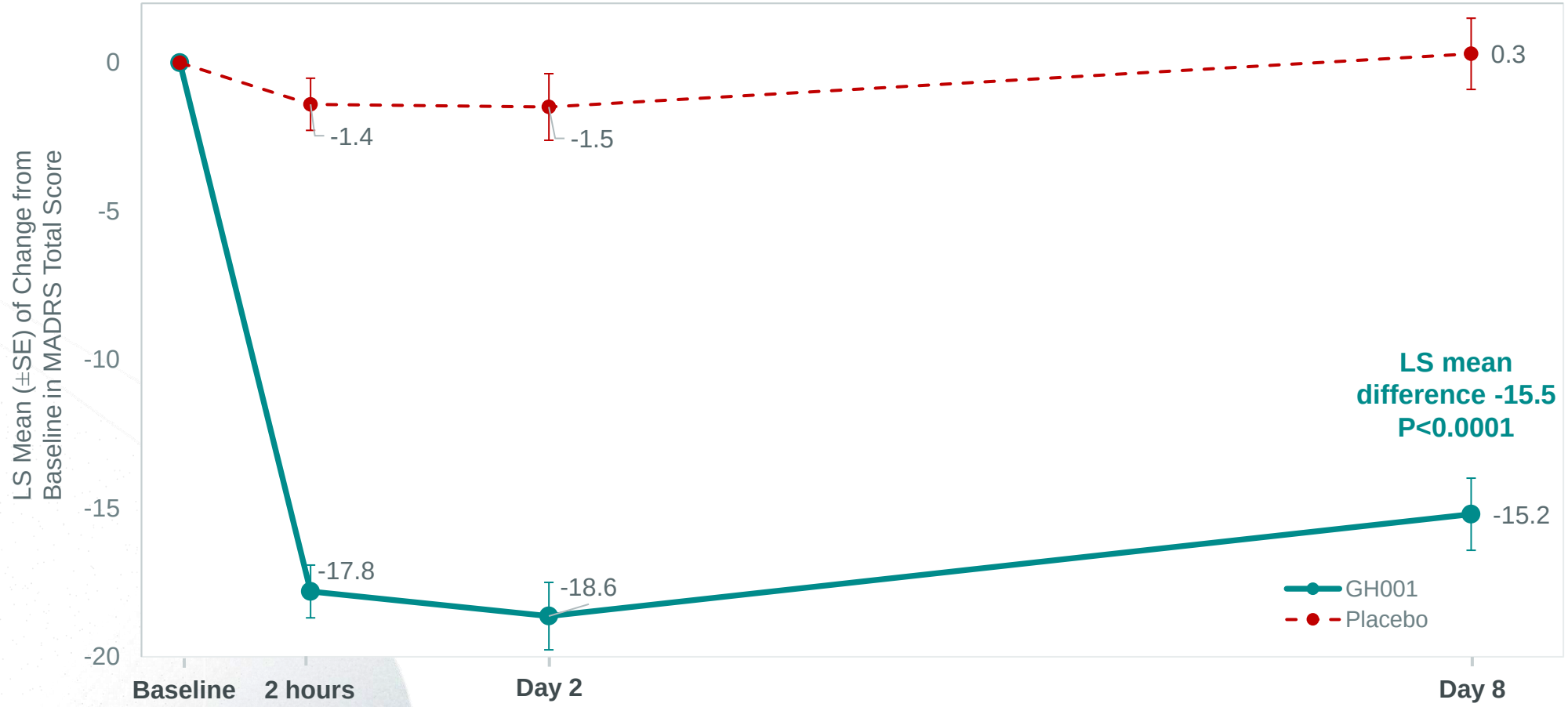
Abbreviations: CGI-S = Clinical Global Impression Severity; HAM-A = Hamilton Rating Scale for Anxiety; HAM-D-17 = Hamilton Rating Scale for Depression; MADRS = Montgomery-Åsberg Depression Rating Scale; MGH-SAFER = Massachusetts General Hospital State versus trait Assessability Face and Ecological validity Rule of 3Ps

Patient Disposition & Characteristics

		GH001 (N=40)	Placebo (N=41)
Patient Disposition			
Completed double-blind part, n (%)		40 (100)	41 (100)
Discontinued double-blind part, n (%)		0 (0)	0 (0)
Age, years, mean (SD)		41.6 (11.4)	43.9 (10.9)
Female, n (%)		24 (60)	22 (53.7)
Race, white, n (%)		40 (100)	41 (100)
BMI, kg/m^2, mean (SD)		24.8 (4.3)	27.5 (6.3)
Previously used any psychedelic (lifetime)		4 (10)	5 (12.2)
Baseline Disease Characteristics			
HAM-D-17 Total Score, mean (SD)		24.9 (2.7)	24.6 (2.3)
MADRS Total Score, mean (SD)		29 (5.4)	28.2 (4.6)
Major Depressive Episode (MDE) History at Baseline			
Number of MDEs	Mean (SD)	2.1 (1.4)	2.0 (1.1)
	≥3, n (%)	14 (35.0)	13 (31.7)
Time since first depressive episode, years, mean (SD)		11.3 (9.7)	12.2 (8.4)
Duration of current MDE, weeks, mean (SD)		50.8 (28.3)	63.3 (106.9)
GH001 IDR Dose Received and Duration			
Total IDR dose received[1], n (%)	6 mg	9 (22.5)	0 (0)
	6, 12 mg	21 (52.5)	0 (0)
	6,12,18 mg	10 (25)	41 (100)
Duration of psychoactive effects, minutes, mean (SD)	6 mg (or PBO first dose)[2]	12.8 (9.1)	0.4 (2.3)
	12 mg (or PBO second dose)[2]	15.1 (9.8)	0.1 (0.8)
	18 mg (or PBO third dose)[2]	18.0 (15.2)	0.2 (1.1)

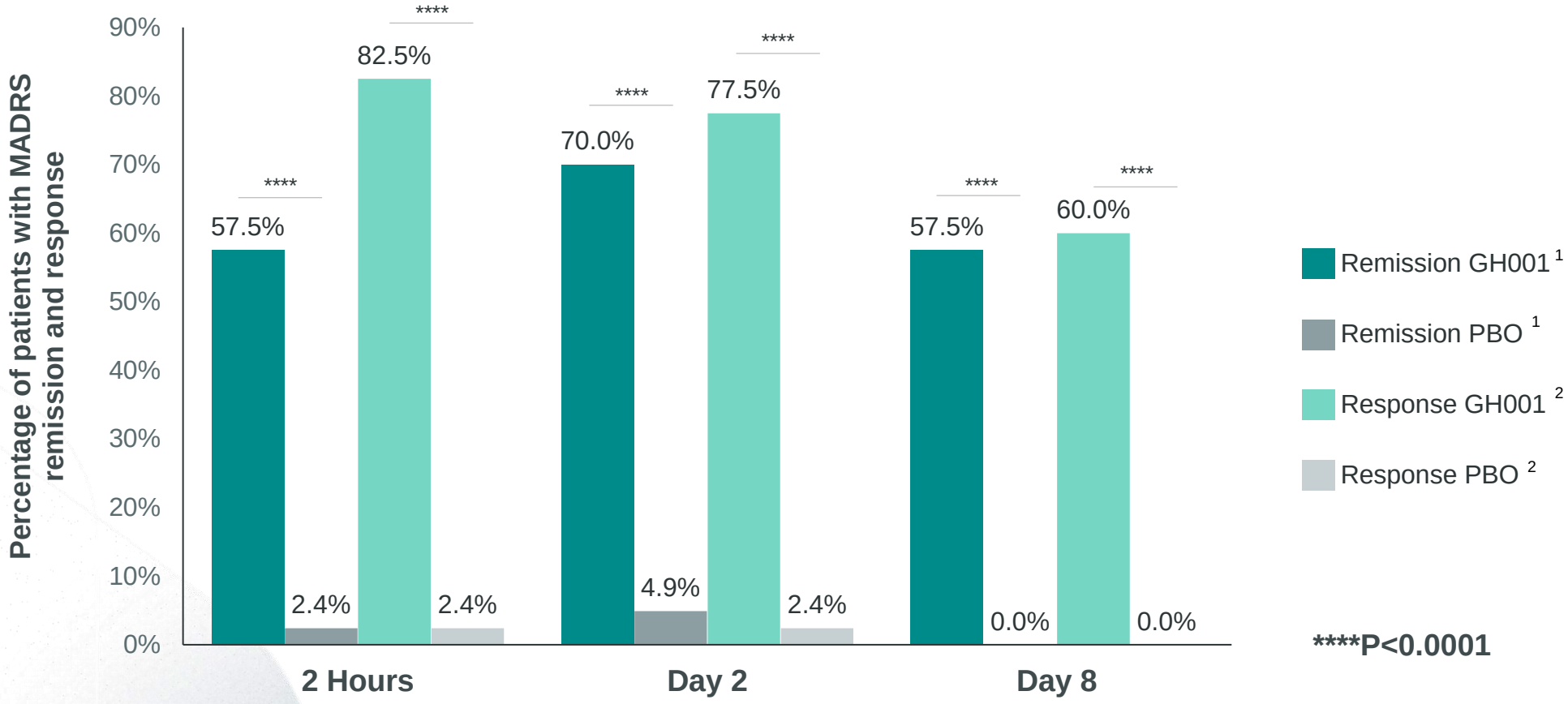
[1] For patients in the GH001/placebo groups, up to 3 doses of GH001 or placebo were administered; [2] Includes all patients who received respective dose of GH001/placebo, irrespective of total dose
Abbreviations: BMI = Body mass index; HAM-D-17 = Hamilton Rating Scale for Depression; MADRS = Montgomery-Åsberg Depression Rating Scale; MDE = Major Depressive Episode; IDR = Individualized dosing regimen; SD = Standard deviation' PBO = Placebo

Primary endpoint: GH001 led to -15.5 mean MADRS reduction from baseline on Day 8 compared with placebo (p<0.0001)



Abbreviations: LS = Least Squares; MADRS = Montgomery-Åsberg Depression Rating Scale; SE = Standard error

Secondary endpoints: GH001 Led to 57.5% Remission Rate[1] at Day 8 vs 0% in Placebo



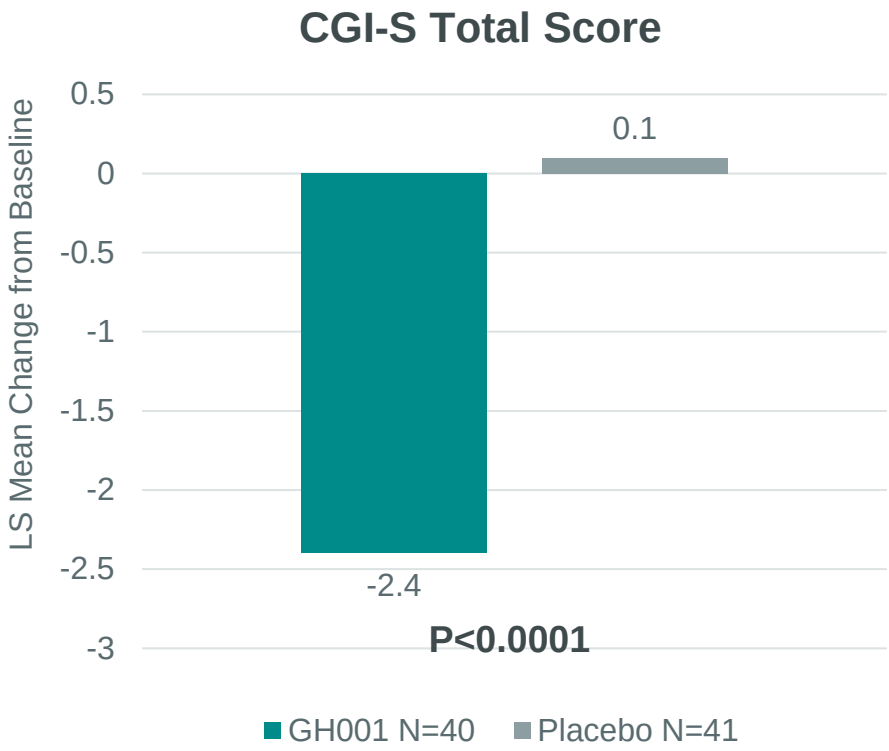
[1] *Remission defined as a patient with a MADRS total score ≤10*
[2] *Response defined as a patient with ≥50% reduction from baseline in total MADRS score*

Abbreviations: D = Day; MADRS = Montgomery-Åsberg Depression Rating Scale; PBO = Placebo

Secondary endpoints: GH001 led to CGI-S total score difference of -2.5 on Day 8 compared with placebo (p<0.0001)

CGI-S reflects the severity of the patient's illness as perceived by the clinician

CGI-S Results	GH001 (N=40)	Placebo (N=41)	P value
BL total score, mean (SD)	4.8 (0.7)	5.0 (0.6)	-
Day 8 total score, mean (SD)	2.4 (1.6)	5.0 (0.6)	-
LS mean (SE) change from BL to Day 8	**-2.4 (0.2)**	**0.1 (0.2)**	-
LS mean difference GH001 vs placebo	**-2.5 (0.3)**	-	**<0.0001**

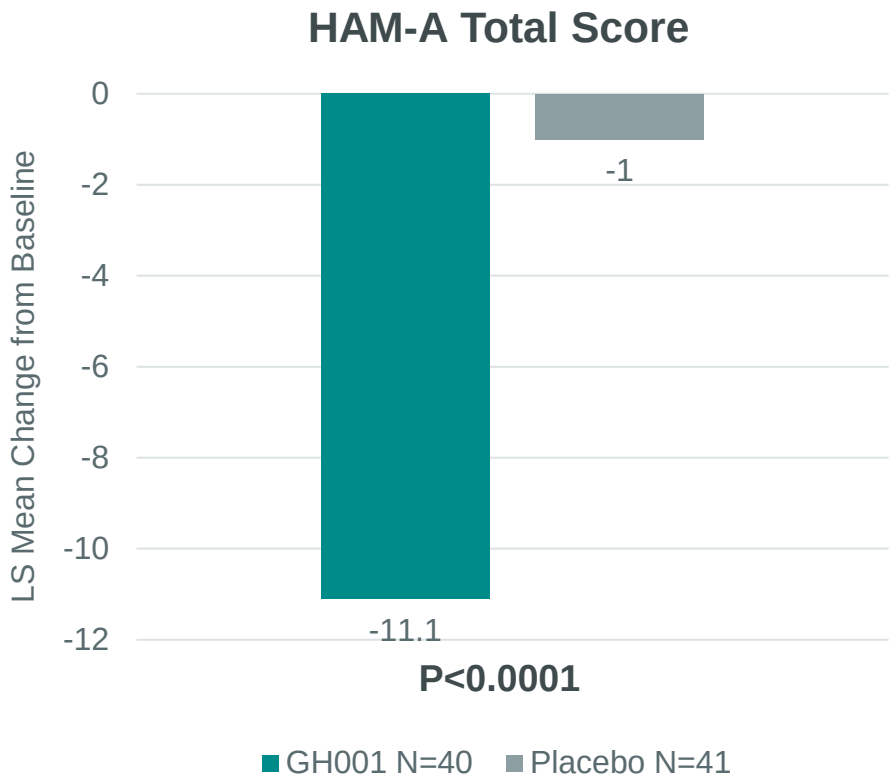


Abbreviations: BL = Baseline; CGI-S = Clinical Global Impression – Severity Scale Score; LS = Least squares; SD = Standard deviation; SE = Standard error.

Secondary endpoints: GH001 led to HAM-A total score difference of -10.0 on Day 8 compared with placebo (p<0.0001)

HAM-A assesses severity of anxiety symptoms

HAM-A results	GH001 (N=40)	Placebo (N=41)	P value
BL total score, mean (SD)	21.1 (6.5)	21.2 (6.1)	-
Day 8 total score, mean (SD)	10.0 (8.6)	20.1 (5.8)	-
LS mean (SE) change from BL to Day 8	**-11.1 (1.0)**	**-1.0 (1.0)**	
LS mean difference GH001 vs placebo	**-10.0 (1.4)**	-	**<0.0001**

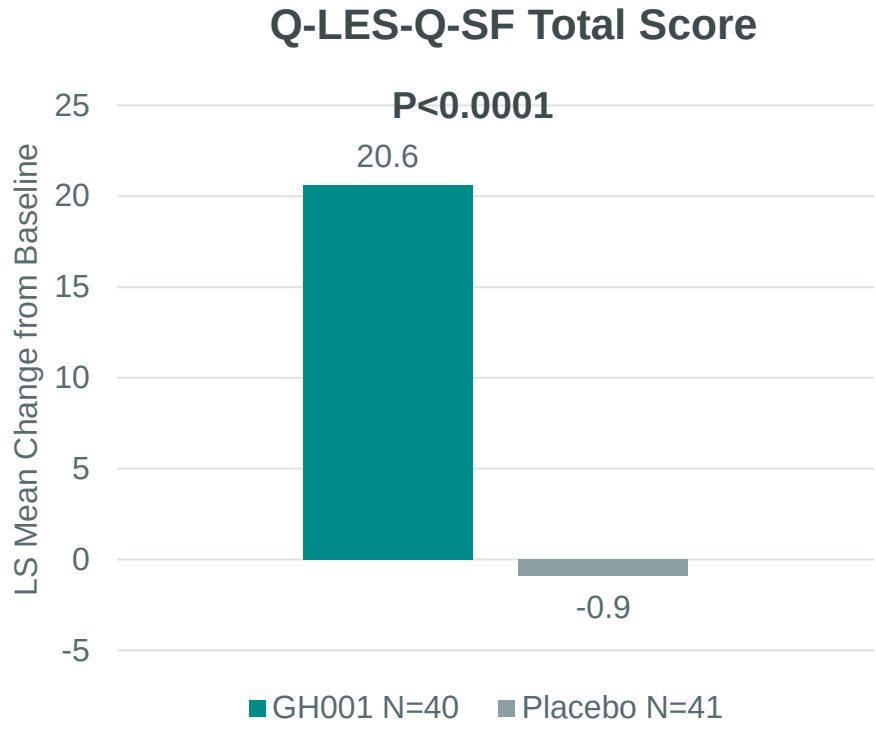


Abbreviations: BL= Baseline; HAM-A = Hamilton Anxiety Rating Scale; LS = Least squares; SD = Standard deviation; SE = Standard error.

Secondary endpoints: GH001 led to Q-LES-Q-SF total score difference of 21.5 on Day 8 compared with placebo (p<0.0001)

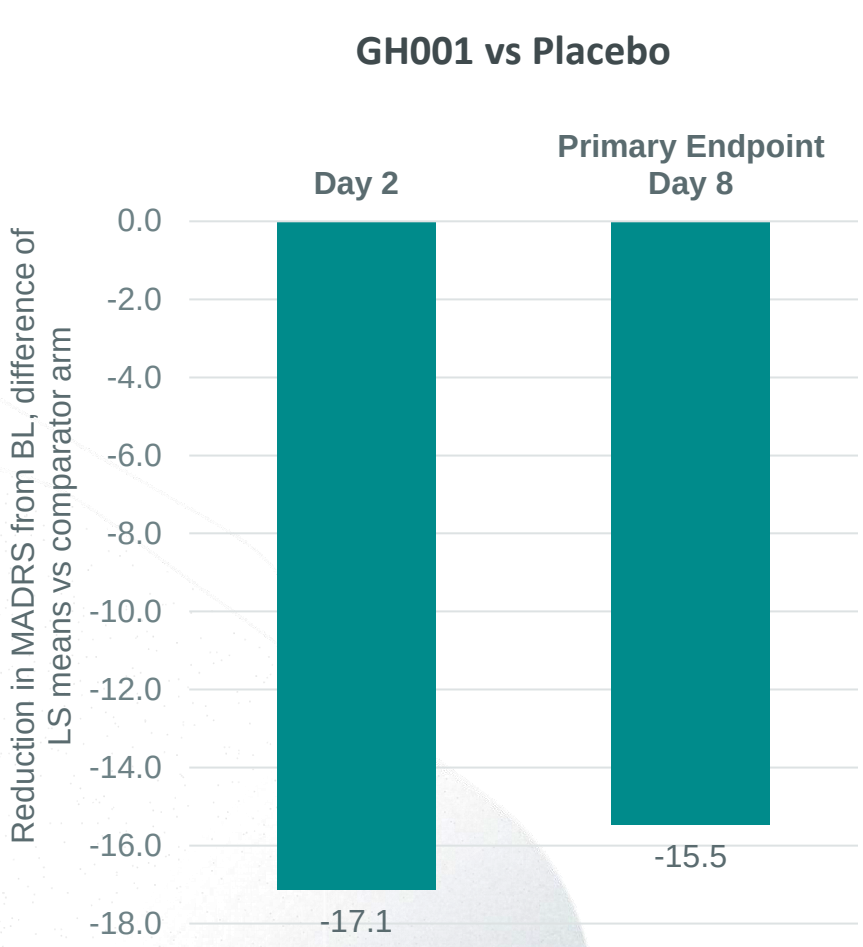
Q-LES-Q-SF measures QoL domains such as physical health, mood, work, household duties, schoolwork, leisure time activities, social and family relations, and overall well-being

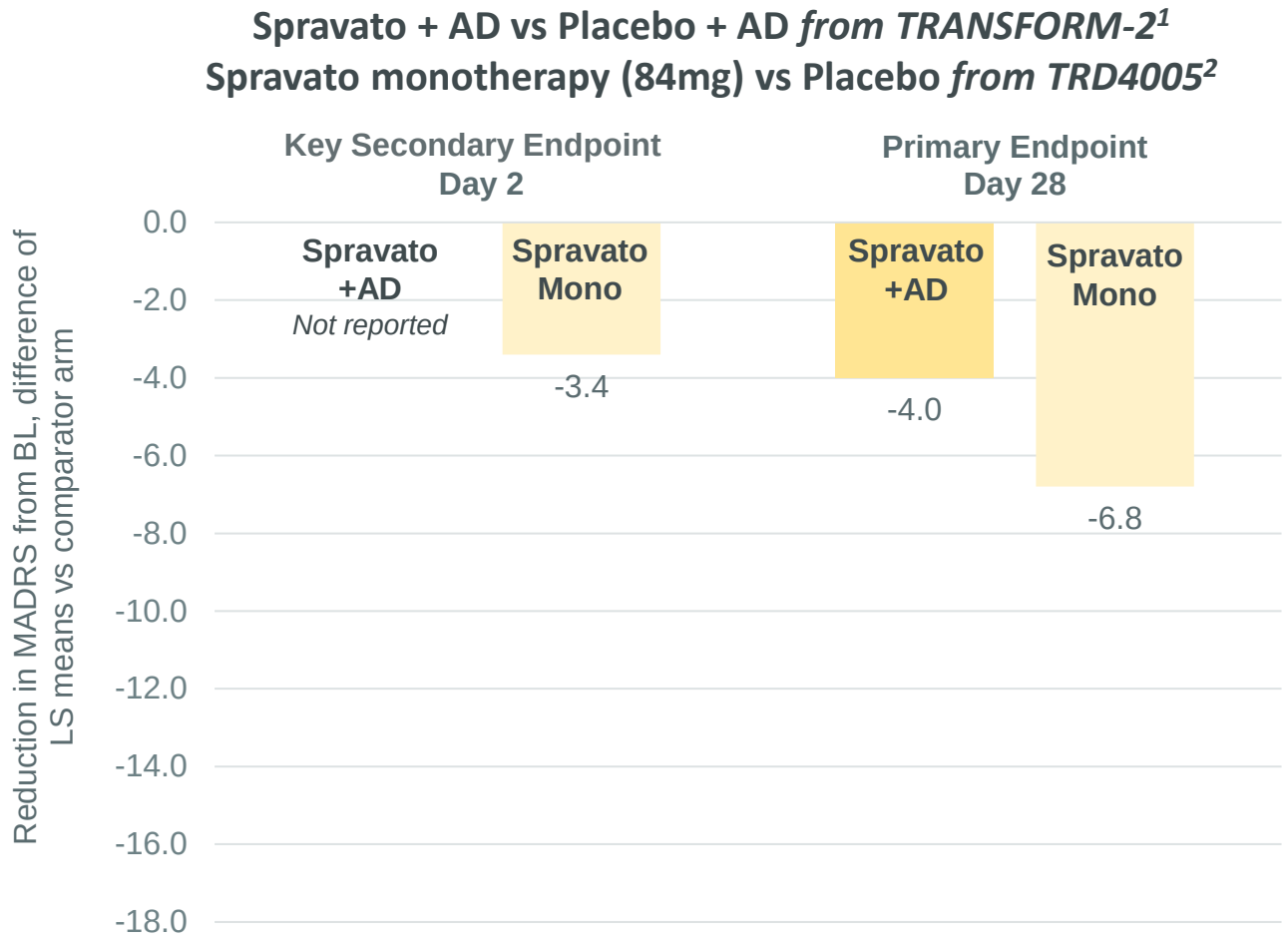
Q-LES-Q-SF Results	GH001 (N=40)	Placebo (N=41)	P value
BL total score, mean (SD)	27.9 (9.0)	25.2 (8.2)	-
Day 8 total score, mean (SD)	47.2 (12.5)	25.5 (8.8)	-
LS mean (SE) change from BL to Day 8	**20.6 (1.8)**	**-0.9 (1.7)**	-
LS mean difference GH001 vs placebo	**21.5 (2.5)**	-	**<0.0001**



Abbreviations: BL = Baseline; LS = Least squares; Q-LES-Q-SF = Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form; QoL = Quality of Life; SD = Standard deviation; SE = Standard error.

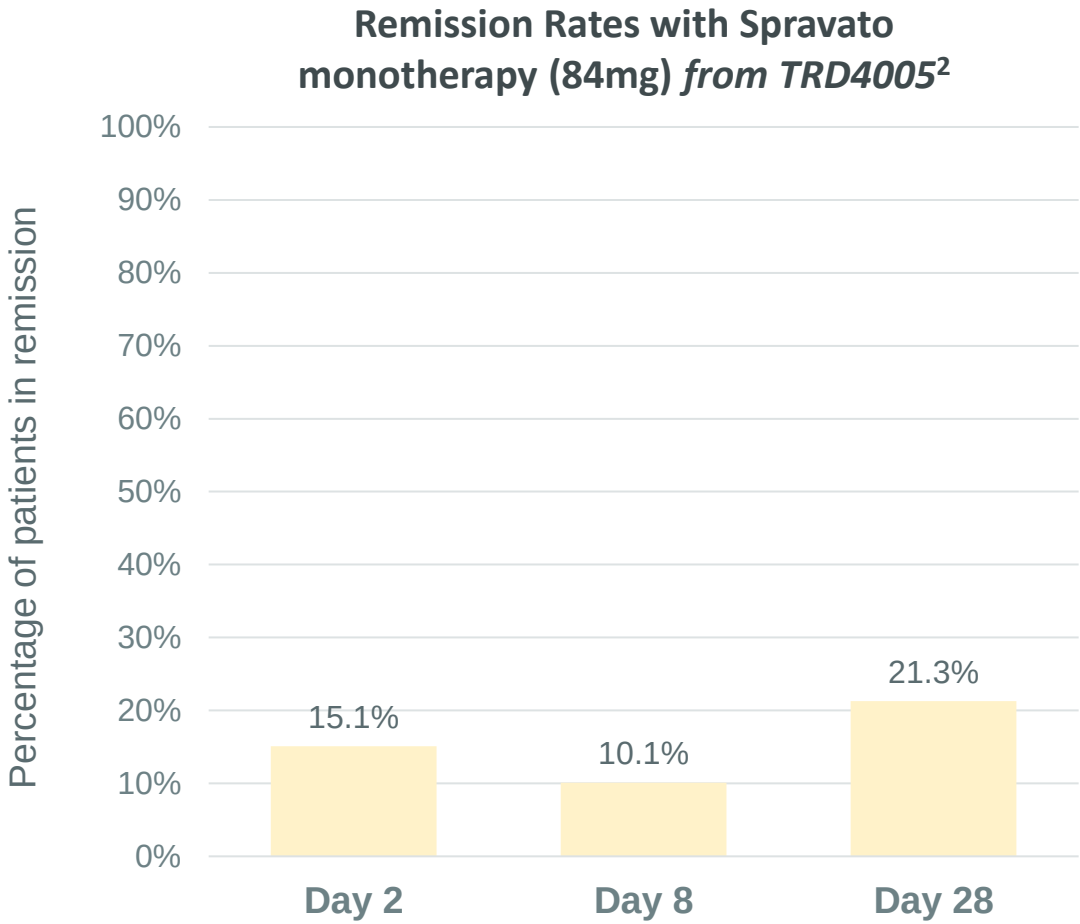
MADRS Total Score Change from Baseline: GH001 and Spravato at D2 and Primary Endpoint (difference from comparator arm)





Note: To-date, no head-to-head comparisons of any other products to any of our product candidates in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable.
Sources: [1]Spravato + AD data from TRANSFORM-2, Popova et al., 2019; [2]Spravato monotherapy data for 84mg dose from TRD4005 trial, presented at ECNP 2024;
Spravato 56mg MADRS total score change from baseline difference of LS means from PBO was -5.1 at Day 28 and -3.8 at Day 2
Abbreviations: AD = Antidepressant; BL = Baseline; D = Day; MADRS = Montgomery-Åsberg Depression Rating Scale; Mono = Monotherapy; LS = Least Squares; vs = Versus

Secondary Endpoints: Remission[1] GH001 Day 2 and Day 8 and Spravato Monotherapy (84mg) Day 2, Day 8 and Day 28



Note: To-date, no head-to-head comparisons of any other products to any of our product candidates in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable.

[1]Remission defined as MADRS total score ≤10 for both GH001 and Spravato

[2]Source: Spravato monotherapy data for 84mg dose from TRD4005 trial, data presented at ECNP 2024;
Spravato 56mg participants in the TRD4005 trial achieved remission rates of 13.1% at Day 2, 7.1% at Day 8 and 14.6% at Day 28 (MADRS ≤10)

Abbreviations: D = Day; MADRS = Montgomery-Åsberg Depression Rating Scale

Overall Summary of Safety

- **GH001 was well tolerated, and no serious adverse events (SAEs) were reported.**
- **All TEAEs were mild or moderate with no severe adverse events.**
- **The most common TEAEs in patients treated with GH001 were nausea, salivary hypersecretion, paresthesia, headache, and dysgeusia.**
- **No TEAEs of flashbacks were reported.**
- **No TEAEs related to vital signs or ECG, or clinically significant changes in blood pressure and heart rate.**
- **No evidence of treatment-emergent suicidal ideation or behaviour, or treatment-emergent BPRS+ symptoms.**
- **No dissociative state symptoms or sedation at discharge, 97.4% of patients discharge ready within 1-hour of the last dose.**

Abbreviations: AE = Adverse event; BPRS+ = Brief Psychiatric Rating Scale positive symptoms; DB = Double-blind; ECG = Electrocardiogram; SAE = Serious adverse event; TEAE = Treatment-emergent adverse event.

Overview of Adverse Events

Overview of Adverse Events: GH001 vs Placebo				
	GH001 N=40		Placebo N=41	
	Pts n (%)	Events n	Pts n (%)	Events n
Any TEAE[1]	29 (72.5)	81	3 (7.3)	7
Max severity of TEAEs[2]				
Mild	14 (35.0)	55	2 (4.9)	6
Moderate	15 (37.5)	26	1 (2.4)	1
Severe	0 (0)	0	0 (0)	0
Treatment-related TEAEs[3]	29 (72.5)	79	1 (2.4)	4
Device-related TEAEs	1 (2.5)	1	0 (0)	0
SAEs[4]	0 (0)	0	0 (0)	0
Treatment-related SAEs[3]	0 (0)	0	0 (0)	0
TEAEs leading to study drug withdrawal	0 (0)	0	0 (0)	0
TEAEs leading to early withdrawal from trial	0 (0)	0	0 (0)	0
AESIs	8 (20.0)	10	0 (0)	0
Death	0 (0)	0	0 (0)	0

Five Most Common TEAEs in Patients Treated with GH001		
MedDRA PT	GH001 N=40	
	Pts n (%)	Events n
Nausea	17 (42.5)	19
Salivary hypersecretion	8 (20)	10
Paresthesia	8 (20)	8
Headache	3 (7.5)	3
Dysgeusia	3 (7.5)	3

No TEAEs of flashbacks reported

[1]TEAE=AE that emerges after the start of study drug dosing having been absent pretreatment, or an AE that worsens in severity relative to a pretreatment onset
[2] Number of events for mild, moderate and severe TEAEs represents total number of events of each severity
[3]Treatment-related TEAE/SAE is any TEAE/SAE that is possibly or probably related to the study drug
[4]SAE=any untoward medical occurrence of effect at any dose that a) results in death, b) is life threatening, c) requires inpatient hospitalization or prolongation of hospitalization, d) results in persistent or significant disability or incapacity, e) is a congenital anomaly or birth defect, f) any other important medical event
Abbreviations: AESI = Adverse event of special interest; Pts = Patients; SAE = Serious adverse event; TEAE = Treatment-emergent adverse event; MedDRA = Medical dictionary for regulatory activities; PT = Preferred term;

Columbia-Suicide Severity Rating Scale[1] (C-SSRS)

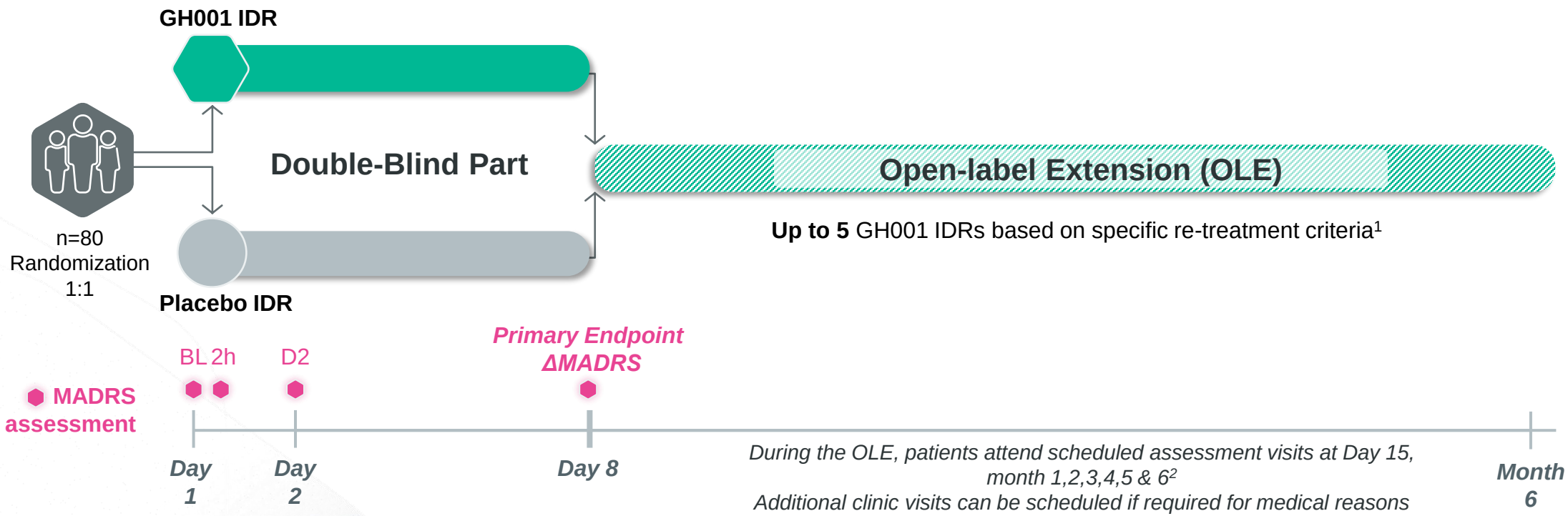
	GH001, N=40 n (%)	Placebo, N=41 n (%)
Past 12 months		
Suicidal ideation (1-3)	8 (20)	11 (26.8)
Suicidal ideation with intent (4-5)	0 (0)	0 (0)
Suicidal behaviour (6-9)	0 (0)	0 (0)
Baseline		
Suicidal ideation (1-3)	7 (17.5)	7 (17.1)
Suicidal ideation with intent (4-5)	0 (0)	0 (0)
Suicidal behaviour (6-9)	0 (0)	0 (0)
Discharge on Day 1		
Suicidal ideation (1-3)	0 (0)	4 (9.8)
Suicidal ideation with intent (4-5)	0 (0)	0 (0)
Suicidal behaviour (6-9)	0 (0)	0 (0)
At Day 2		
Suicidal ideation (1-3)	1 (2.5)	6 (14.6)
Suicidal ideation with intent (4-5)	0 (0)	0 (0)
Suicidal behaviour (6-9)	0 (0)	0 (0)
At Day 8		
Suicidal ideation (1-3)	4 (10)	7 (17.1)
Suicidal ideation with intent (4-5)	0 (0)	0 (0)
Suicidal behaviour (6-9)	0 (0)	0 (0)

[1] *C-SSRS is comprised of 5 questions assessing suicidal ideation, and 4 questions assessing suicidal behaviour with sub-questions assessing severity.*

Open-Label Extension

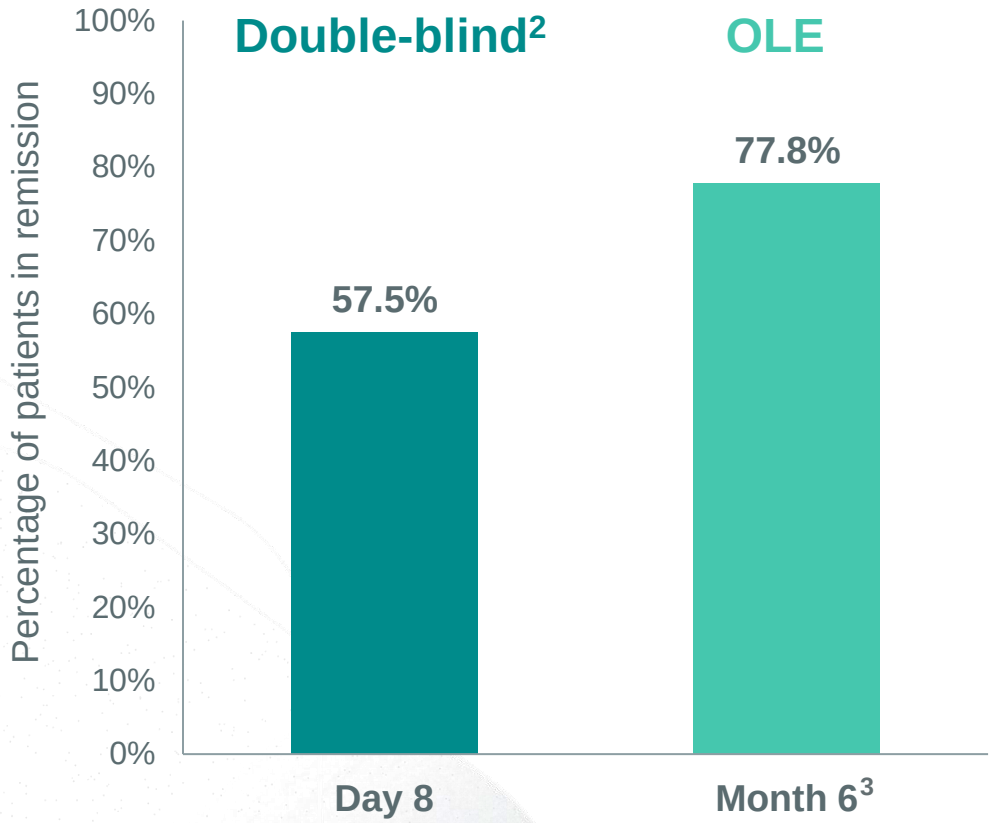
Data as of January 22, 2025

Phase 2b Trial of GH001 in Patients with TRD: Design (GH001-TRD-201)



[1]*Re-treatment criteria include the severity of depression and the effectiveness, tolerability, and number of previous IDRs. The patient meets one of the following criteria: i. has MADRS >18; or ii. has MADRS >10 and ≤18 and MADRS ≤10 has not been observed at D8 of the prior treatment or at any visit since then; or iii. has MADRS >10 and ≤18 and MADRS >18 has been observed since the most recent observation of MADRS ≤10*
[2]*Patients also attended assessment visits on Day 2 and Day 8 after each re-treatment*
As in previously completed trials, the GH001-TRD-201 trial is conducted under the supervision of a healthcare provider, but without any planned psychotherapeutic interventions before, during, or after dosing.
Sources: 1) NCT05800860. (2024). A Trial of GH001 in Patients With Treatment-Resistant Depression. ClinicalTrials.gov. Accessed August 23, 2024.
Abbreviations: BL = Baseline; D = Day; h = Hour; IDR = Individualized dosing regimen; MADRS = Montgomery–Åsberg Depression Rating Scale; OLE = Open-label extension; TRD = Treatment-resistant depression.

77.8% Remission Rate at 6 Months in OLE Completers[1] (n=54)



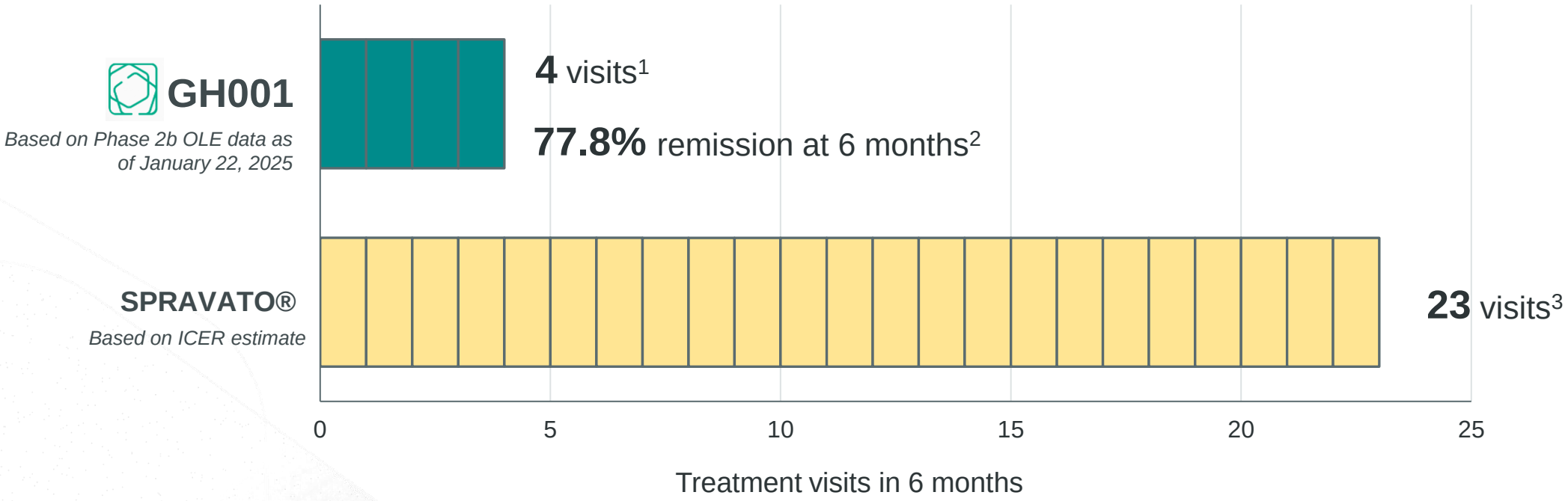
OLE status (January 22, 2025): 9 patients ongoing, 54 completed, 18 early terminations (comparable to other antidepressant trials[4]; n=1 due to AE)

From the patients who completed the OLE:

- **77.8%** (n=42) of patients were in remission[5] at 6 months (81.5% responders)[6]
- Completers (n=54) had a mean MADRS total score of **8.6 at 6 months**
- **63.0%** (n=34) received **1-4 treatments** with GH001
- As of January 22, 2025, **no serious adverse events (SAEs) have been reported** throughout the OLE. *Note: safety analysis has not yet been completed for the OLE*

[1] Patients who completed the 6-month OLE follow-up per protocol (patients who terminated early are excluded)
[2] Includes n=40 patients who received GH001 in double blind part of trial
[3] 6 Months' or 'Month 6' (end of trial) was at approximately 6 months post-study start (mean 168 days from Day 1 of double-blind period)
[4] For example, Spravato ESCAPE-TRD trial = 23.2% discontinued, 4.2% due to AEs; Spravato TRANSFORM-2 trial = 15.5% withdrawn, 7.8% due to AEs (note: no head-to-head comparisons have been made in any clinical trials that have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable).
[5] Remission defined as a patient with a MADRS total score ≤10
[6] Response defined as a patient with ≥50% reduction from baseline in total MADRS score
Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension; AE = Adverse Event.

83% fewer treatment visits with GH001 than with Spravato



Note: To-date, no head-to-head comparisons of any other products to any of our product candidates in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable

[1] 4 GH001 visits deduced from mean total number of treatments received by OLE completers over the 6-month time period of the TRD-201 trial (data as of January 22, 2025)

[2] '6 Months' (end of trial) was at approximately 6 months post-study start (mean 168 days from Day 1 of Double-Blind period)

[3] SPRAVATO®: Assumes 23 treatment visits, as per standard initiation protocol of 8 & 4 sessions in months 1 & 2, respectively, and ICER assumed maintenance treatment frequency of 2.86 treatments per month for months 3-6 (1,2,3).

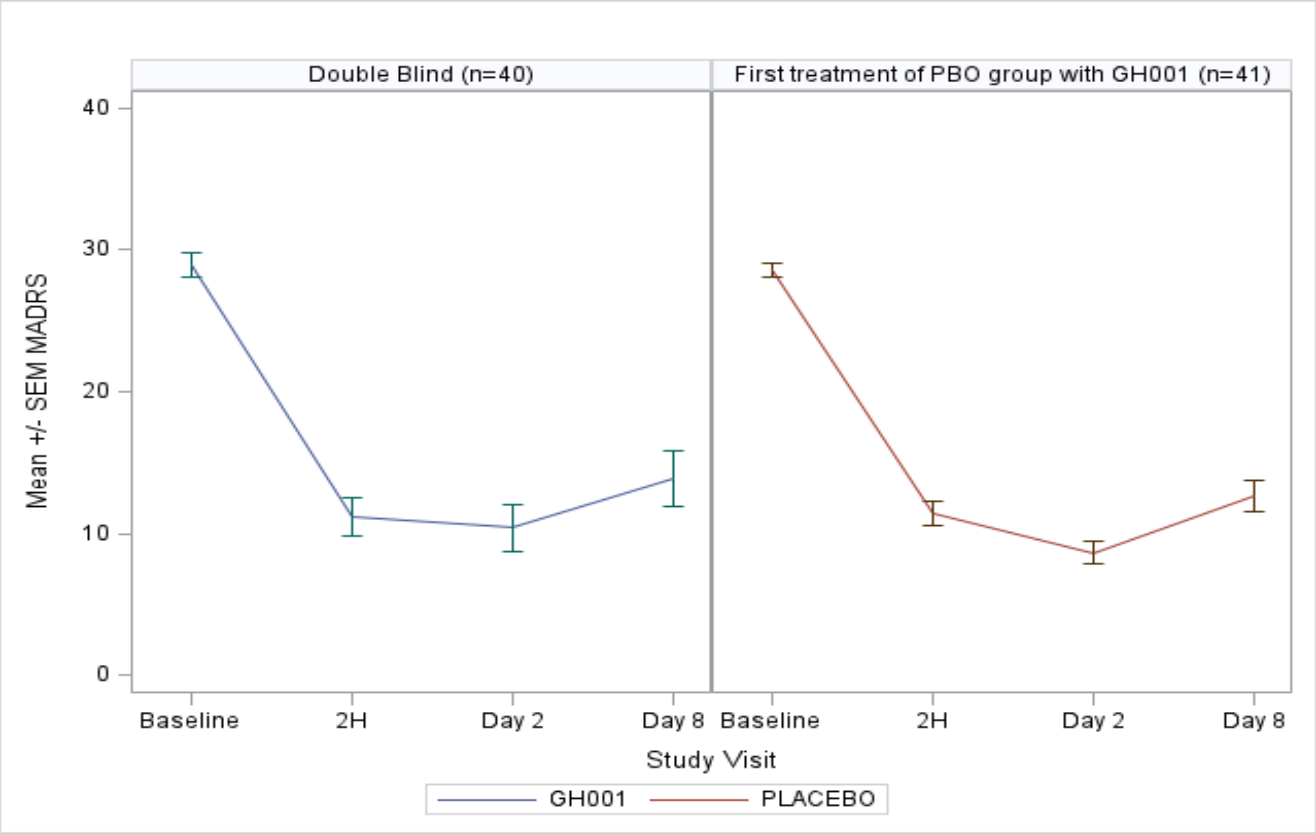
Remission defined as MADRS ≤10; Spravato 32-Week remission rates from ESCAPE-TRD trial were 49.1% remission at 32 weeks (55.0% with LOCF method) (4).

Abbreviations: ICER = Institute for Clinical and Economic Review; LOCF = Last Observation Carried Forward.

Sources: 1) Johnson & Johnson Spravato Access, Coding and Reimbursement Guide; 2) ICER Spravato Final Evidence Report; 3) Janssenscience.com, Dosage and Administration of Spravato, Duration of Therapy; 4) Reif et al., N Engl J Med 2023

Reduction in MADRS total score with GH001 in DB reproduced in PBO Group with first GH001 treatment in OLE

Mean MADRS Total Score from Baseline to Day 8 by First Active Treatment



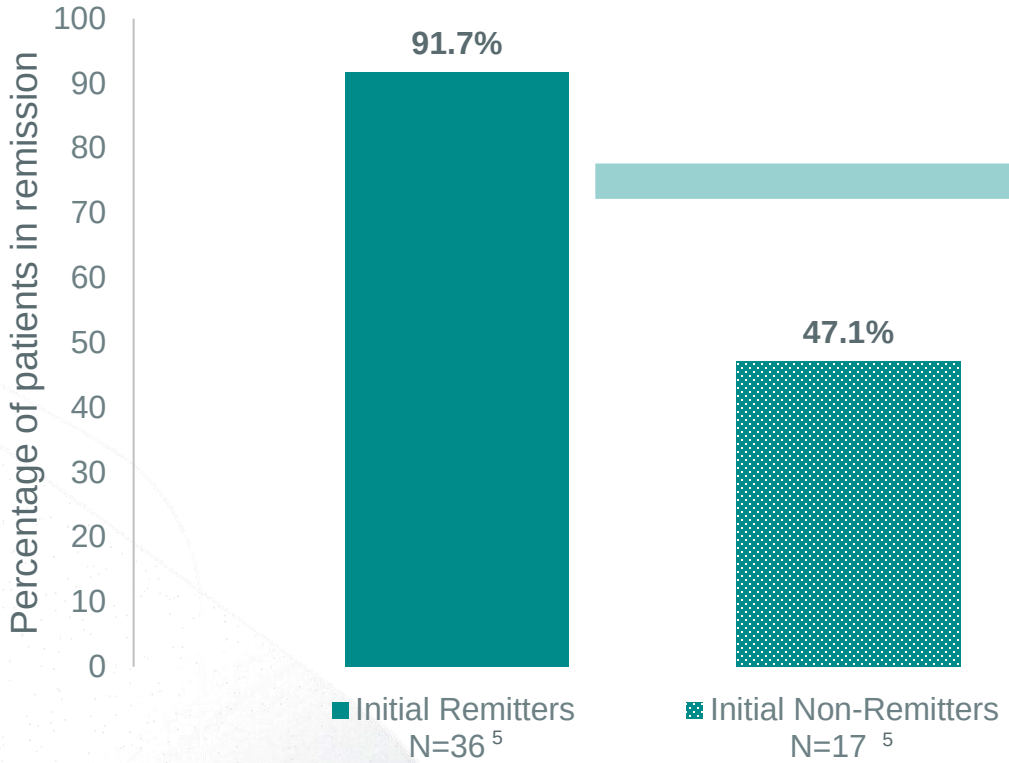
- All patients enrolled in the DB part of the trial directly transitioned into the OLE at the end of the DB period.
- Once a patient completed the Day 8 visit of the DB part, if re-treatment criteria were met, a GH001 treatment could be administered.
- **All patients allocated placebo in the DB part received at least one treatment with GH001 in the OLE.**
- In the OLE, the reduction in MADRS total score in the DB placebo group following first active treatment*, was comparable to the results observed in the GH001 group in the DB part, showing **reproducibility of effects.**

**An active treatment refers to treatment with GH001*

Abbreviations: BL = Baseline; DB = Double blind; MADRS = Montgomery-Åsberg Depression Rating Scale; SEM = Standard error of mean; PBO = Placebo; OLE = Open-Label Extension

Remission on Day 8 / Remission at 6 Months

Remission[1] Rate at 6 Months[2] in OLE Completers[3] by Day 8 First Active Treatment, Remitters / Non-Remitters[4]

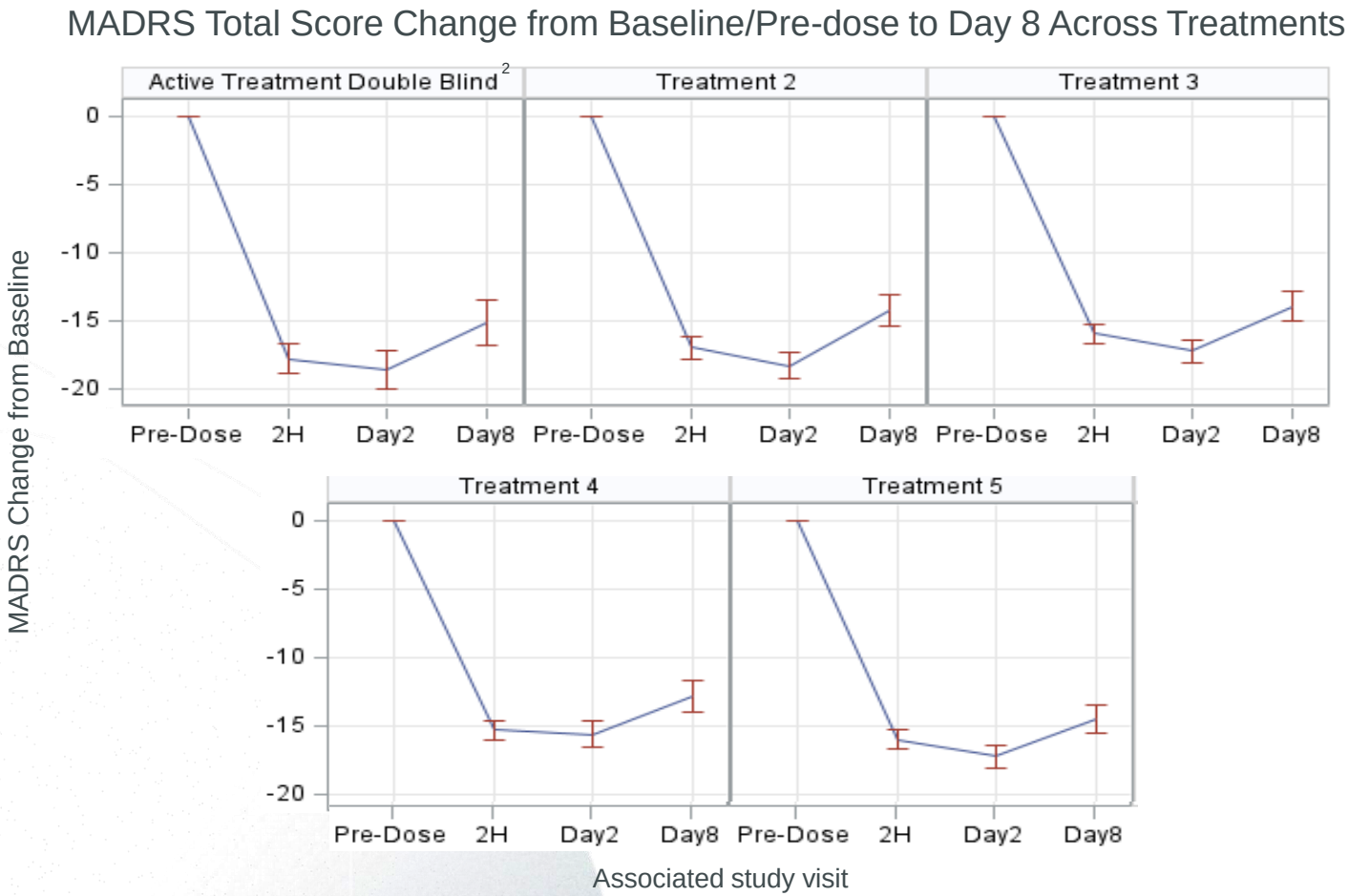


Patients who had remission on Day 8 after their first active treatment had a 91.7% remission rate at 6 Months.

(91.7% of the OLE Completers[3] who had remission[1] at Day 8 after first active treatment[4], also had Remission at 6 Months[2].)

[1] *Remission defined as a patient with a MADRS total score ≤10*
[2] *6 Months' or 'Month 6' (end of trial) was at approximately 6 months post-study start (mean 168 days from Day 1 of double-blind period)*
[3] *Patients who completed the 6-month OLE follow-up per protocol (patients who terminated early are excluded)*
[4] *First active treatment refers to first treatment with GH001 = initial remitters / initial non-remitters*
[5] *N=53 patients in total; 1 OLE completer not evaluable due to missing data at data cut as of January 22, 2025*

MADRS Total Score Change from Baseline/Pre-dose to Day 8 Across Treatments[1] in DB and OLE



OLE data as of January 22, 2025, shows GH001 leads to a **consistent and rapid reduction in MADRS after each GH001 treatment**, as in the DB part

[1] *Treatments 2-5 were administered in the OLE, and all patients were administered GH001*
[2] *Includes patients who received GH001 in the DB period*
Abbreviations: BL = Baseline; DB = Double-blind; MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension

Overall Summary of OLE

- As of January 22, 2025, **9 patients (11.1%) are ongoing** in the trial. **54 patients have completed the full 6-month** follow-up of the OLE.
- Of the 54 patients who completed the OLE:
  - **77.8% of patients were in remission**[1] (MADRS≤10) at the 6 month visit and 81.5% were responders[2]
  - Mean MADRS total score at 6 months[3] was 8.6.
  - **63.0%** (n=34) received **1-4 treatments** with GH001. On this basis, GH001 could reduce the number of administration visits by 83% compared to SPRAVATO®.
  - **91.7%** of the OLE Completers[4] who had Remission at Day 8, also had Remission at 6 months.
- As of January 22, 2025, **no serious adverse events (SAEs) have been reported** throughout the OLE *(OLE ongoing)*.
- Discontinuation rate in the OLE is comparable to other antidepressant trials[5] with 1 patient discontinuation due to an adverse event.

[1] Remission defined as a patient with a MADRS total score ≤10
[2] Response defined as a patient with ≥50% reduction from baseline in total MADRS score
[3] 6 Months' or 'Month 6' (end of trial) was at approximately 6 months post-study start (mean 168 days from Day 1 of double-blind period)
[4] Patients who completed the 6-month OLE follow-up per protocol (patients who terminated early are excluded), N=53 patients in total; 1 OLE completer not evaluable due to missing data at data cut of January 22, 2025
[5] No head-to-head comparisons have been made in any clinical trials that have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable

Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension; SAE = Serious Adverse Event.

CONCLUSION

Double-Blind

- **Primary Endpoint:** GH001 led to MADRS reduction from baseline of -15.5 on Day 8 compared with placebo ($p<0.0001$).
- **Secondary Endpoints:** All secondary endpoints results were consistent with the primary endpoint.
- **Safety:** GH001 was well tolerated, with no serious adverse events (SAEs) reported and no evidence of treatment-emergent suicidal ideation or behaviour.

Open-Label Extension

- **Durability:** GH001 can maintain the patient in remission for a long time with 77.8% of TRD patients in remission at 6 months. This is achieved with relatively infrequent treatment visits and rapid reduction in MADRS after each GH001 re-treatment.
- As of January 22, 2025, **no serious adverse events (SAEs) have been reported** throughout the OLE[1] *(OLE ongoing)*.

[1] Open Label Extension is on-going as of January 22, 2025; Safety conclusion subject to change following this date
Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; TRD = Treatment Resistant Depression, DB = Double Blind; OLE = Open-Label Extension; SAE = Serious Adverse Event.

A Randomized, Double-Blind, Placebo-Controlled, Phase 2b Trial with an Open-Label Extension to Determine the Safety and Efficacy of GH001 in Patients with Treatment-Resistant Depression

GH001-TRD-201

Clinicaltrials.gov ID: NCT05800860