UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of May, 2025.

Commission File Number: 001-40530

GH Research PLC

(Exact name of registrant as specified in its charter)

Joshua Dawson House
Dawson Street
Dublin 2
D02 RY95
Ireland
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

GH Research PLC (the "Company") will attend the American Society of Clinical Psychopharmacology ("ASCP") Annual Meeting, which is scheduled to take place from May 27-30, 2025 in Scottsdale, Arizona (the "Congress").

The Company will present posters during the Congress.

A copy of the poster to be delivered in conjunction with the Pharmaceutical Pipeline Presentation session, presented by Michael E. Thase, is attached hereto as Exhibit 99.1.

A copy of the poster to be presented by Wiesław J. Cubała to be delivered during Poster Session II is attached hereto as Exhibit 99.2.

A copy of the poster to be presented by Claus Bo Svendsen to be delivered during Poster Session II is attached hereto as Exhibit 99.3.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Poster presented by Michael E. Thase with Title: Safety and Efficacy of GH001 in Treatment-Resistant Depression: Results From a Phase 2b, Double-Blind, Randomized Controlled Trial
99.2	Poster presented by Wiesław J. Cubała, with Title: Safety and Tolerability of GH001 in Treatment-Resistant Depression: Results From a Phase 2b, Double-Blind, Randomized, Controlled Trial
99.3	Poster presented by Claus Bo Svendsen with Title: Results of a Phase 2a Clinical Trial of Inhaled Mebufotenin (GH001) in Patients With Postpartum Depression

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 21, 2025

GH Research PLC

By: /s/ Julie Ryan
Name: Julie Ryan
Title: Vice President, Finance

Safety and Efficacy of GH001 in Treatment-Resistant Depression: Results From a Phase 2b, Double-Blind, Randomized Controlled Tri

Michael E. Thase,[1,2]* Bernhard T. Baune,[3] Narcís Cardoner,[4] Rosa Maria Dueñas Herrero,[5] Luboš Janů,[6] John R. Kelly,[7] Shane J. McInerney,[8] Alexander Nawka,[9] Tomáš Páleníček,[10] Andreas Reif,[11] Víctor Pérez Sola,[12-15] Madhukar H. Trivedi,[16] Velichka Valcheva,[17] Eduard Vieta,[18] Wiesław J. Cubała[19]

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Background

- Treatment-resistant depression (TRD) affects approximately 30% of patients treated for major depressive disorder (MDD)[1]
- Current therapies for TRD are limited and there is a large unmet need for treatments that offer rapid and sustained effects
- Mebufotenin (5-methoxy-N,N-dimethyltryptamine [5-MeO-DMT]) is a non-selective serotonin (5-HT) agonist with high affinity for several receptor subtypes, including the 5-HT$_{1A}$ receptor[2]
- GH001 is a synthetic form of mebufotenin for pulmonary inhalation[3,4]
- Early-stage trials in healthy volunteers and patients with TRD suggest that GH001 is well tolerated and may have the potential to induce an ultra-rapid remission in depressive symptoms[3,4]

Objective

- The aim of this double-blind, placebo-controlled trial was to investigate the safety and efficacy of GH001 in patients with TRD

References

1. Kubitz N, et al. *PLoS One*. 2013;8(10):e76882.
2. Shen H, et al. *Curr Drug Metab*. 2010;11(8):659-66.
3. Reckweg J, et al. *Front Pharmacol*. 2021;12:760671.
4. Reckweg JT, et al. *Front Psychiatry*. 2023;14:1133414.

Acknowledgments

This trial was sponsored by GH Research. The sponsor would like to thank the participants in the trial. The sponsor would also like to thank the investigators who conducted this trial. Under the guidance of the authors, medical writing and editorial support were provided by Brian Brennan, PhD, and Claire Sweeney, PhD, of GH Research, and Jane Phillips, PhD, of OPEN Health. Primary analysis of the trial was conducted by the contract research organization Worldwide Clinical Trials. Additional analyses were conducted by Rachael Macisaac, PhD, of GH Research.

Disclosures

MET: Grants – Acadia, Alkermes, Axsome, Intra-Cellular Therapies, Janssen, National Institute of Mental Health, Otsuka, Patient-Centered Outcomes Research Institute (PCORI), and Takeda. Advisory Boards – Autobahn Therapeutics, Axsome, Clexio Biosciences, Gerson Lehrman Group, GH Research, Lundbeck, Janssen, Johnson & Johnson, Luye Pharma, Merck, Object Pharma, Otsuka, Pfizer, Sage, Seelos Therapeutics, Sunovion, and Takeda. Royalties – American Psychiatric Association Foundation, Guilford Publications, Herald House, Wolters Kluwer, and W W Norton & Company. **BTB:** Consultant – National Health and Medical Research Council (Australia). Honoraria – Angelini, AstraZeneca, Biogen, BMS, Boehringer Ingelheim, Johnson & Johnson, LivaNova, Lundbeck, Medscape, Otsuka, Pfizer, Roche, Servier, Sumitomo Pharma, Sunovion, Teva, and Wyeth. Advisory boards – Biogen, Boehringer Ingelheim, Janssen-Cilag, LivaNova, Lundbeck, Medscape, Novartis, Otsuka, and Teva. Research grants from private industries or nonprofit funds – AstraZeneca, BMBF (Germany), BMG (Germany), DFG (Germany), ERA PerMed, Fay Fuller Foundation, Horizon Europe (European Union), James & Diana Ramsay Foundation (Adelaide), Johnson & Johnson, Lundbeck, La Marató de TV3, National Health and Medical Research Council (Australia), Sanofi-Synthélabo, and Wellcome Trust (UK). **NC:** Grants – Spanish Ministry of Health, Spanish Ministry of Science and Innovation (CIBERSAM), Strategic Plan for Health Research and Innovation (PERIS) 2016–2020, Recercaixa, and La Marató de TV3. Honoraria – Adamed, Elsevier, Exeltis, Janssen, Lundbeck, Pfizer, and Servier. Advisory Boards – Angelini, Esteve, Janssen, Lundbeck, Novartis, Pfizer, and Viatris. Lectures/Meetings – Janssen, Lundbeck, and Pfizer. **BMDH:** Principal investigator – Beckley Psytech and GH Research. Subinvestigator – Compass. **LI:** Principal investigator – GH Research. **JRK:** Principal investigator – Compass, GH Research, and Transcend Therapeutics. Consultant – Clerkenwell Health. Grant funding – Health Research Board (ILP-POR-2022-030, DIFA-2023-005, KTA-2024-002). **SJM:** Principal investigator – GH Research and Transcend Therapeutics. Honoraria – Janssen and Lundbeck. **AN:** Principal investigator – GH Research. **TP:** Principal investigator – Compass, GH Research, MAPS, and Ketabon. Shares – Psychedelická klinika s.r.o., Společnost pro podporu neurovědního výzkumu s.r.o., and AVI-X Aviation Experts s.r.o. Founder – PSYRES (Psychedelic Research Foundation). Consultant – CB21 Pharma and GH Research. **AJR:** Honoraria for lectures and/or advisory boards – AbbVie, Boehringer Ingelheim, Cyclerion, Compass, GH Research, Janssen, LivaNova, Medice, MSD, Newron, Sage/Biogen, and Shire/Takeda. Research grants – Medice and Janssen. **VPS:** Consultant, honoraria, or grants – AB-Biotics, AstraZeneca, Bristol Myers Squibb, CIBERSAM, FIS-ISCIII, Janssen Cilag, Lundbeck, Medtronic, Otsuka, and Servier. **MHT:** Advisory boards – Alto Neuroscience and Base Point Health Management. Consultant – Axsome, Biogen, Daiichi Sankyo, GH Research, Legion Health, Neurocrine Biosciences, Otsuka Pharmaceutical Europe, Otsuka Pharmaceutical Development & Commercialization, Otsuka Pharmaceutical, PureTech, and Takeda. Advisor – Cerebral Therapeutics, Circular Genomics, and Seaport Therapeutics. Scientific advisor – GreenLight VitalSign6. Board of Directors – Charities2Love. **VV:** Employee and stock option holder of GH Research. **EV:** Grants – AB-Biotics, AbbVie, Almirall, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Celon, Cephalon, Dainippon Sumitomo Pharma, Elan, Ferrer, GH Research, GlaxoSmithKline, Janssen, Lilly, Lundbeck, Orion, Otsuka, Pfizer, Sanofi Aventis, Servier, Sunovion, and Takeda. Honoraria – Abbott, AbbVie, Angelini, AstraZeneca, Bristol Myers Squibb, Cambridge University Press, Elsevier, Farmindustria, Ferrer, Galenica, GlaxoSmithKline, Janssen, Johnson & Johnson, Lilly, Lundbeck, Oxford University Press, Otsuka, Pfizer, Sanofi Aventis, and Viatris. Advisory boards – AbbVie, Angelini, AstraZeneca, Biogen, Biohaven, Bristol Myers Squibb, Celon, Compass, Ferrer, GH Research, Gedeon Richter, HMNC, Idorsia, Janssen, Johnson & Johnson, Jazz, Lilly, Lundbeck, Merck Sharp & Dohme, Novartis, Organon, Otsuka, Pfizer, Roche, Sage, Sanofi Aventis, Servier, Shire, Sunovion, Takeda, and Teva. **WJC:** Grants – Acadia, Angelini, Beckley Psytech, GH Research, HMNC Brain Health, Intra-Cellular Therapies, Janssen, MSD, Neumora, Novartis, Otsuka, Recognify Life Sciences. Honoraria – Angelini, GH Research, Janssen, and Novartis. Advisory boards – Douglas Pharmaceuticals, GH Research, Janssen, MSD, and Novartis (relationships reported within the last three years).

Presented at the American Society of Clinical Psychopharmacology Annual Meeting | Scottsdale, AZ, USA | May 27–30, 2025

Methods

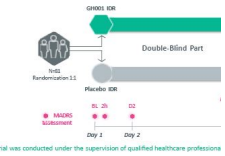
Trial Design

- This Phase 2b multicenter trial consisted of two parts (Figure 1):
  - Double-blind part (described here): a randomized, double-blind, placebo-controlled trial with follow-up to 7 days postdose. Patients were randomized in a 1:1 ratio to receive an individualized dosing regimen (IDR) of up to three escalating doses of GH001 (6, 12, and 18 mg) or placebo on a single day; there was a 1-hour interval between doses
  - Open-label extension (OLE): a 6-month trial with up to five GH001 re-treatments administered depending on the patient's clinical status
- Patients were required to meet the trial criteria for TRD as assessed by a trial psychiatrist:
  - Recurrent or single MDD episode without psychotic features, with current episode of ≤2 years
  - Current major depressive episode based upon the Massachusetts General Hospital – Structured Assessment for Evaluation of Risk (MGH-SAFER) criteria interview
  - 17-item Hamilton Depression Rating Scale (HAM-D-17) total score ≥20
  - Nonresponse to ≥2 and ≤5 oral antidepressant treatments

Assessments

- The primary endpoint of the double-blind part of this trial was mean change in Montgomery–Åsberg Depression Rating Scale (MADRS) from baseline to Day 8, as assessed by a blinded rater
- Secondary endpoints included change in global disease severity as assessed by the Clinical Global Impression – Severity (CGI-S) Scale, anxiety as assessed by the Hamilton Anxiety Rating Scale (HAM-A), and quality of life as assessed by the Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF)
- Treatment-emergent adverse events (TEAEs) were assessed throughout the trial

Figure 1. Clinical Trial Schematic



This trial was conducted under the supervision of qualified healthcare professiona

*Patients also attended assessment visits on Day 2 (phone call) and Day 8 after each re-treatment.
BL = Baseline; D = Day; h = Hour; IDR = Individualized dosing regimen; MADRS = Montgomery–Åsberg Depression F

Results

Double-Blind Part

- A total of 81 patients with TRD were enrolled in the double-blind part (GH001 IDR, n=40; placebo IDR, n=41; Table 1)

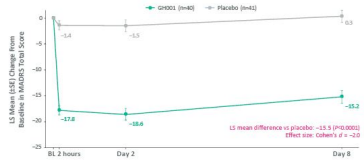
Table 1. Patient Disposition and Characteristics in the Double-Blind Part

		GH001 (n=40)	Placebo (n=41)
Patient Disposition			
Completed double-blind part, n (%)		40 (100)	41 (100)
Patient Demographics			
Age, years, mean (SD)		41.6 (11.4)	43.9 (10.9)
Female, n (%)		24 (60.0)	22 (53.7)
Race, White, n (%)		40 (100)	41 (100)
BMI, kg/m², mean (SD)		24.8 (4.3)	27.5 (6.3)
Previously used any psychedelic (lifetime), n (%)		4 (10.0)	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)
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)
Patients Receiving IDR Doses[a]			
First dose (6 mg GH001 or one placebo dose), n (%)		9 (22.5)	0 (0)
Second dose (6+12 mg GH001 or two placebo doses), n (%)		21 (52.5)	0 (0)
Third dose (6+12+18 mg GH001 or three placebo doses), n (%)		10 (25.0)	41 (100)
Duration of PsE[b]			
6 mg (or placebo first dose), minutes, median (range)		9.0 (2–35)	0 (0–15)
12 mg (or placebo second dose), minutes, median (range)		14.0 (4–50)	0 (0–5)
18 mg (or placebo third dose), minutes, median (range)		11.5 (8–50)	0 (0–7)

[a]Up to three doses of GH001 or placebo were administered to each patient. [b]Includes all patients who received respective dose of GH001 or placebo, irrespective of total dose.
BMI = Body mass index; HAM-D-17 = 17-item Hamilton Depression Rating Scale; IDR = Individualized dosing regimen; MADRS = Montgomery–Åsberg Depression Rating Scale; MDE = Major depressive episode; PsE = Psychoactive effects; SD = Standard deviation.

- Change in MADRS total score from baseline to Day 8 was significantly greater with GH001 than with placebo (Figure 2)
  - Statistically significant reductions were also observed in the GH001 group at 2 hours postdose and on Day 2

Figure 2. Primary Endpoint*: Change in MADRS Total Score From Baseline to Day 8



*FDA Guidance notes that efficacy with rapid-acting antidepressants generally should be demonstrated within 1 week, supporting a primary efficacy endpoint within this timeframe.
BL = Baseline; FDA = Food and Drug Administration; LS = least squares; MADRS = Montgomery–Åsberg Depression Rating Scale; SE = Standard error.

- On Day 8, remission (MADRS total score ≤10) and response (MADRS total score ≥50% reduction) were achieved in 57.5% and 60.0% of patients treated with GH001, respectively, compared with 0% in the placebo groups (Figure 3)

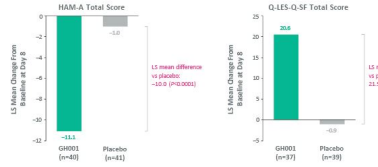
Figure 3. Percentage of Patients With Remission or Response Through Day 8 After Administration of GH001 IDR or Placebo IDR

Remission: MADRS total score ≤10 | Response: ≥50% reduction from baseline in MADRS total score

IDR = Individualized dosing regimen; MADRS = Montgomery–Åsberg Depression Rating Scale; NNT = Number needed to treat.

- GH001 led to improvements in anxiety and quality of life vs placebo (Figure 4)

Figure 4. Change From Baseline in HAM-A Total Score and Q-LES-Q-SF Total Score at Day 8



HAM-A = Hamilton Anxiety Rating Scale; LS = least squares; Q-LES-Q-SF = Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form.

- Greater improvements from baseline in global illness severity were also observed with GH001 vs placebo (Figure 5)

Figure 5. CGI-S Scores at Baseline and Day 8

Percentages are for each baseline category within treatment.
CGI-S = Clinical Global Impression – Severity; LS = least squares; SE = Standard error.

Safety and Tolerability of GH001 in Treatment-Resistant De
Double-Blind, Randomized, Contro

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Background

- Treatment-resistant depression (TRD) is a chronic condition affecting approximately 30% of patients with major depressive disorder[1]
- There are currently only two pharmacotherapies approved for the treatment of TRD, highlighting the unmet need for additional safe and effective treatments[2]
- Early-phase clinical trials of GH001, a synthetic form of mebufotenin for pulmonary inhalation, in healthy volunteers and patients with TRD demonstrated it is well tolerated with an acceptable safety profile[3,4]
- This trial evaluated the safety and tolerability of GH001 in patients with TRD in a randomized, double-blind, placebo-controlled setting

Objective

- The objective of this analysis is to present safety and tolerablility data for GH001 from the double-blind part of a Phase 2b trial in which GH001 was administered as an individualized dosing regimen (IDR) to patients with TRD

References

1. Kubitz N, et al. *PLoS One*. 2013;8:e76882. **2.** Jha MK, Mathew SJ. *Am J Psychiatry*. 2023;180:190-9.
3. Reckweg J, et al. *Front Pharmacol*. 2021;12:760671. **4.** Reckweg JT, et al. *Front Psychiatry*. 2023;14:1133414.

Acknowledgments

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Disclosures

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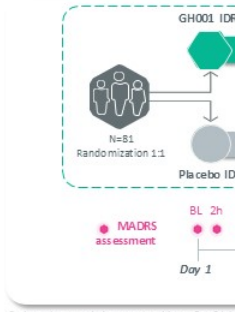
Presented at the American Society of Clinical Psychopharmacology Annual Meeting | Scottsdale, AZ, USA | May 27–30, 2025

Methods

- This two-part, Phase 2b trial (NCT05800860) enrolled patients with TRD (Figure 1)
  - The double-blind part (presented here) was a 7-day part in which patients were randomized 1:1 to receive an IDR of up to three escalating doses of GH001 (6, 12, and 18 mg) or placebo IDR on a single day
  - Patients in the 6-month open-label extension received up to five GH001 re-treatments depending on their clinical status (data not presented here)
- This trial was conducted under the supervision of qualified healthcare professionals, providing psychological support per standard of care, but without any planned psychotherapeutic intervention before, during, or after dosing
- Safety assessments (up to Day 8) included treatment-emergent adverse events (TEAEs), vital signs, electrocardiogram (ECG), laboratory assessments, and safety assessment tools (Columbia-Suicide Severity Rating Scale [C-SSRS], Brief Psychiatric Rating Scale positive symptoms subscale [BPRS+], Clinician-Administered Dissociative States Scale [CADSS], Modified Observer's Assessment of Alertness and Sedation [MOAA/S] scale, and Clinical Assessment of Discharge Readiness [CADR])

Figure 1. Clinical Trial Schematic



[a]Patients also attended assessment visits on Day 2 (ph
BL = Baseline; D = Day; h = Hour; IDR = Individualized

Results From the Double-Blind Part

- In the double-blind part of this trial, 81 patients with TRD were enrolled; 40 and 41 patients were randomized to receive GH001 or placebo, respectively
  - The mean (SD) age was 42.8 (11.2) years; 56.8% of the patients were female
- There were no serious or severe TEAEs reported (Table 1)
- TEAEs were observed in 29/40 (72.5%) patients who received GH001 and 3/41 (7.3%) patients who received placebo (Table 1)
  - The maximum severity of TEAEs observed in patients who received GH001 was mild in 14/29 patients and moderate in 15/29 patients
  - No TEAE resulted in study drug withdrawal or early withdrawal from the trial in either treament group in the double-blind part
- No TEAEs of flashbacks were reported

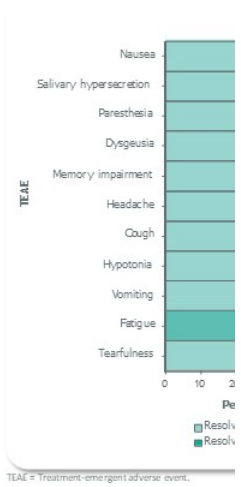
Table 1. Overall Summary of Safety in the Double-Blind Part

Patients, n (%)	GH001 (n=40)	Placebo (n=41)
Any TEAE	29 (72.5)	3 (7.3)
Maximum severity of TEAEs		
Mild	14 (35.0)	2 (4.9)
Moderate	15 (37.5)	1 (2.4)
Severe	0	0
Treatment-related TEAEs	29 (72.5)	1 (2.4)
Serious TEAE	0	0
AESIs	8 (20.0)	0
Death	0	0
TEAEs occurring in >5% of patients in either group		
Nausea	17 (42.5)	0
Salivary hypersecretion	8 (20.0)	0
Paresthesia	8 (20.0)	0
Headache	3 (7.5)	1 (2.4)
Dysgeusia	3 (7.5)	0

AESI = Adverse event of special interest; TEAE = Treatment-emergent adverse event.

- Of the 81 total TEAEs in the double-blind part, 80.2% of events resolved within 1 hour, 8.6% resolved within 24 hours, 7.4% resolved within 72 hours, and 1.2% resolved within 1 week
  - Of the TEAEs reported at least twice in patients receiving GH001, most resolved within 1 hour of dosing (Figure 2)

Figure 2. Duration of TEAEs Repor the Double-Blind Part



TEAE = Treatment-emergent adverse event.

- There were no TEAEs related to changes in blood pressure or he
- There was no evidence of treat behavior (assessed by the C-SSR or dissociation at discharge (ass
- By 1 hour postdose, no sedation and 97.4% of patients were disc ready following dosing, but after determined to be discharge-rea

Results of a Phase 2a Clinical Trial of Inhaled M in Patients With Postpartum Dep

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Background

- Postpartum depression (PPD) is a common perinatal complication that can have serious consequences for the well-being of the mother and the long-term development of the child[1,2]
- Epidemiologic studies estimate the global prevalence rate of PPD to be as high as 20%,[3] with up to 13% of diagnosed patients still experiencing symptoms two years after giving birth[4]
- Current treatment options for PPD have slow onset of action, low remission rates, and/or high treatment burden[5]; therefore, novel treatment methods are needed
- Mebufotenin (5-methoxy-N,N-dimethyltryptamine [5-MeO-DMT]) is a potent psychedelic drug that acts as a non-selective serotonin agonist with highest affinity for the 5-HT$_{1A}$ receptor subtype[6]
- Early-phase clinical trials of mebufotenin administered via pulmonary inhalation (GH001) demonstrated that GH001 has an acceptable safety profile and is well tolerated, with an ultra-rapid onset of therapeutic benefits[7,8]
- The trial presented here is the first in which mebufotenin was administered to patients diagnosed with PPD

Objective

- To investigate the potential antidepressant effects and safety of GH001 in adult, female patients with PPD

Methods

- This Phase 2a, proof-of-concept, open-label trial (NCT05804708) enrolled women aged 18–45 years who met the Mini-International Neuropsychiatric Interview diagnostic criteria for major depressive disorder with peripartum onset and who had outpatient status
- Patients were required to have received no other antidepressant therapy for 14 days prior to dosing and have a Montgomery–Åsberg Depression Rating Scale (MADRS) total score of ≥28, reflecting moderate to severe depressive symptoms
- Patients must have either ceased lactating at screening or, if still lactating or actively breastfeeding, must have agreed to temporarily cease breastfeeding from just prior to dosing through 24 hours after the last dose
- Patients were administered an individualized dosing regimen (IDR) of up to three escalating doses of GH001 (6, 12, and 18 mg) with a 1-hour interval between doses on a single day (Figure 1)
- Criteria for administration of the second and third doses as part of the IDR were based on patients' subjectively reported psychoactive effects and the safety and tolerability at the previous dose level
- This trial was conducted under the supervis
  providing psychological support per standar
  psychotherapeutic intervention before, duri
- The primary endpoint was change in MADF
  from baseline in MADRS total score at 2 ho
  (MADRS total score ≤10) were assessed as
- Safety and tolerability were assessed throu
  included the following parameters: treatm
  as assessed by the Modified Observer's Ass
  psychiatric symptoms as assessed by the B
  suicidality as assessed by the Columbia-Su
- Discharge readiness was assessed by the Cli
- *P* values were calculated using one-sample
  of α=0.025, and the study was adequately
  difference

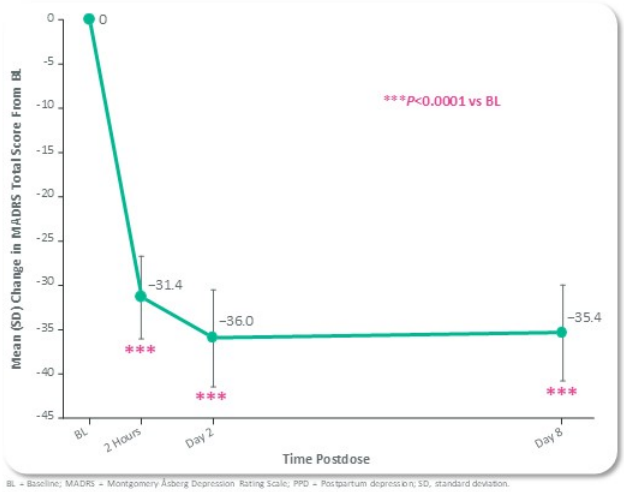
Results

- This trial enrolled 10 patients diagnosed with PPD with a mean (SD) age of 32 (5.2) years
- The mean (SD) duration of the current depressive episode was 30.9 (12.9) weeks, and the mean (SD) parity was 2 (0.94)
- One patient (10.0%) had received pharmacotherapy for the current depressive episode, and six patients (60.0%) had received pharmacotherapy for prior major depressive episodes
- The mean (SD) baseline MADRS total score was 36.7 (4.8)

Efficacy

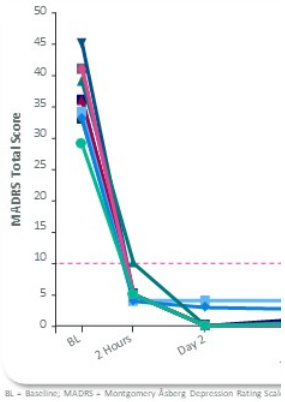
- The primary endpoint was achieved, with a significant reduction from baseline to Day 8 of −35.4 points (96.3%) in MADRS total score with GH001 treatment (*P*<0.0001; Figure 2)
- Significant reductions in MADRS total score were also observed at 2 hours postdose and on Day 2 (*P*<0.0001 for both time points)
- All 10 patients demonstrated nearly identical and consistent reductions in MADRS total score at 2 hours postdose, on Day 2, and Day 8 (Figure 3)
- All patients (100%) achieved remission at Day 8, as well as at 2 hours postdose and on Day 2

Figure 2. Mean Change in MADRS Total Score From Baseline in Patients With PPD Treated With GH001



BL = Baseline; MADRS = Montgomery Åsberg Depression Rating Scale; PPD = Postpartum depression; SD, standard deviation.

Figure 3. MADRS Total Scores for Individua



BL = Baseline; MADRS = Montgomery Åsberg Depression Rating Scale

Safety

- TEAEs were observed in 8/10 patients (80.
  one patient reported a TEAE as moderate i
- Headache was the most commonly reporte
  a single patient each
- No TEAEs of flashbacks were reported
- There were no serious TEAEs or severe TEA
- There was a clinically significant reduction i
- There was no clinically relevant worsening
  CADR, C-SSRS, and MOAA/S scales)
- Based on the CADR, all patients were deeme

Conclusions

- In this trial evaluating the safety and ant
  was observed on Day 8 postdose
- Significant reductions in MADRS total sc
- GH001 administered via inhalation dem

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