
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 September, 2024.

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

On September 3, 2024, GH Research PLC (the "Company") issued a press release announcing the appointment of Dr. Velichka "Villy" Valcheva to Chief Executive Officer. A copy of the press release is attached hereto as Exhibit 99.1.

On September 3, 2024, the Company made available an updated investor presentation on its website. A copy of the investor presentation is attached hereto as Exhibit 99.2.

The fact that this press release and presentation are being made available and furnished herewith should not be deemed an admission as to the materiality of any information contained in the materials. The information contained in the press release and presentation is being provided as of September 3, 2024, and the Company does not undertake any obligation to update the press release and presentation in the future or to update forward-looking statements to reflect subsequent actual results.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated September 3, 2024
99.2	Investor Presentation for September 2024

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: September 3, 2024

GH Research PLC

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

GH Research Announces Appointment of Dr. Velichka “Villy” Valcheva to Chief Executive Officer

DUBLIN, Ireland, September 03, 2024 - GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today announced the promotion of Dr. Velichka “Villy” Valcheva, MD, MSc. to Chief Executive Officer of the Company. Dr. Valcheva succeeds PD Dr. med. Theis Terwey, co-founder of GH Research.

Dr. Valcheva has more than 20 years of experience in various leadership roles in the pharmaceutical and biotech industries. Dr. Valcheva joined the company in August 2023 and has served as the Company’s Chief Medical Officer since February 2024 having leadership responsibility, among other things, for the execution of the Company’s clinical development programs. She joined us from Albireo, where, in her position as VP and Head of Medical Affairs International, she played a pivotal role in the company’s late-stage development, scientific communication, regulatory approvals by the U.S. Food and Drug Administration and EMA as well as gaining market access in multiple markets of the rare disease medicine Bylvay. Dr. Valcheva holds a Masters in Pharmaceutical Medicine from Trinity College Dublin, Ireland as well as a Dr. Med. from University of Medicine – Plovdiv, Bulgaria.

Florian Schönharting, Chairman of the Board of Directors, GH Research, said: “We are very pleased to promote Dr. Valcheva to Chief Executive Officer. As Chief Medical Officer, she has proven her operating and execution skills, and she has the experience base and track record to lead GH Research through its next stage of development to achieve our goal of providing effective therapies for patients suffering from depression. I would also like to thank Theis for his dedication, passionate commitment and scientific rigor applied to our mission since we founded the Company together.”

Dr. Valcheva, Chief Executive Officer, GH Research, added: “Since joining GH Research last year, I have worked tirelessly to realize the potential of our product candidates to help patients with depression. As we’re screening the remaining patients for our phase 2b trial in treatment-resistant depression, we’re on track for completion of enrolment in September this year. Additionally, our phase 1 healthy volunteer study using our proprietary device is now actively enrolling in the UK. I’m excited to lead the company through the next phase of development. The foundation that Theis has laid will always be a part of GH Research.”

“Taking part in the founding of GH Research and leading it in its mission has been a great honor for me and I look forward to seeing the company continue to advance its cause,” said departing CEO, Dr. Terwey.

About GH Research PLC

GH Research PLC is a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. GH Research PLC's initial focus is on developing its novel and proprietary mebufotenin (5-MeO-DMT) therapies for the treatment of patients with treatment-resistant depression (TRD).

GH Research PLC's annual report on Form 20-F filed with the U.S. Securities and Exchange Commission for the year ended December 31, 2023 is available at www.ghres.com and shareholders may receive a hard copy free of charge upon request.

Forward-Looking Statements

This press release contains statements that are, or may be deemed to be, forward-looking statements. All statements other than statements of historical fact included in this press release, including statements regarding our future results of operations and financial position, business strategy, product candidates, medical devices required to deliver these product candidates, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals and their effects on our business strategy, including our plans and expectations related to addressing the clinical hold on the GH001 IND, research and development costs, cash runway, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. Forward-looking statements appear in a number of places in this press release and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those described in our filings with the U.S. Securities and Exchange Commission. No assurance can be given that such future results will be achieved. Such forward-looking statements contained in this press release speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update these forward-looking statements contained in this press release to reflect any change in our expectations or any change in events, conditions, or circumstances on which such statements are based unless required to do so by applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Investor Relations:

Julie Ryan
GH Research PLC
investors@ghres.com



Corporate Presentation

GH Research PLC (NASDAQ: GHR)

September 2024

Disclaimer Regarding Forward-Looking Statements



This presentation has been prepared by GH Research PLC ("GH Research") for informational purposes only and not for any other purpose. Nothing contained in this presentation is, or should be construed as, a recommendation, promise or representation by the presenter or GH Research or any director, employee, agent, or adviser of GH Research. This presentation does not purport to be all-inclusive or to contain all of the information you may desire.

This presentation does not constitute an offer to sell or the solicitation of an offer to buy securities, nor shall there be any sale of securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

This presentation contains forward-looking statements, all of which are qualified in their entirety by this cautionary statement. Many of the forward-looking statements contained herein can be identified by the use of forward-looking words such as "may", "anticipate", "believe", "could", "expect", "should", "plan", "intend", "estimate", "will", "potential" and "ongoing", among others, although not all forward-looking statements contain these identifying words.

Any statements contained herein that do not describe historical facts are forward-looking statements that are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcomes, timing and performance to differ materially from those expressed or implied by such statements. These factors, risks and uncertainties include, but are not limited to: the costs and uncertainties associated with GH Research's research and development efforts; the inherent uncertainties associated with the conduct, timing and results of nonclinical and clinical studies of GH Research's product candidates; GH Research's expectations related to the clinical hold on the GH001 IND, including plans and expectations for progressing any nonclinical programs and any other work to lift the clinical hold and the timing required to lift such clinical hold; GH Research's ability to obtain, maintain, enforce and defend issued patents; the adequacy of GH Research's capital resources, the availability of additional funding and GH Research's cash runway; and other factors, risks and uncertainties described in GH Research's filings with the U.S. Securities and Exchange Commission.

Except as otherwise noted, these forward-looking statements speak only as of the date of this presentation, and GH Research undertakes no obligation to update or revise any of such statements to reflect events or circumstances occurring after this presentation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond GH Research's control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in any such forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. GH Research cautions you not to place undue reliance on the forward-looking statements contained in this presentation.



Seeking Ultra-Rapid, Durable Remissions in Depression

Pipeline



Stage of Development

PROGRAMS	INDICATION	PRECLINICAL	PHASE 1	PHASE 2a	PHASE 2b	PHASE 3	CURRENT STATUS	MILESTONES
GH001 <i>Mebutofenin (5-MeO-DMT) for inhalation administration</i>	Treatment-Resistant Depression (TRD)						Phase 2b RDBPC & Phase 1 PK trial with proprietary device ongoing	Phase 2b DB phase completion in Q3
GH002 <i>Mebutofenin (5-MeO-DMT) for i.v. administration</i>	Psychiatric or Neurological Disorder						Phase 1 HV trial completed	Update on next steps
GH003 <i>Mebutofenin (5-MeO-DMT) for nasal administration</i>	Psychiatric or Neurological Disorder						Pre-clinical development	Complete preclinical development
OTHER INDICATIONS								
GH001	Postpartum Depression (PPD)						Phase 2a POC	Completion in Q4
GH001	Bipolar II Disorder* (BDII)						Phase 2a POC	Guidance to be communicated

*Bipolar II disorder with a current major depressive episode
5-MeO-DMT, 5-Methoxy-N,N-Dimethyltryptamine; i.v., intravenous; RDBPC, Randomized, Double-Blind, Placebo-Controlled; POC, Proof-of-Concept; HV, Healthy Volunteer

Complete

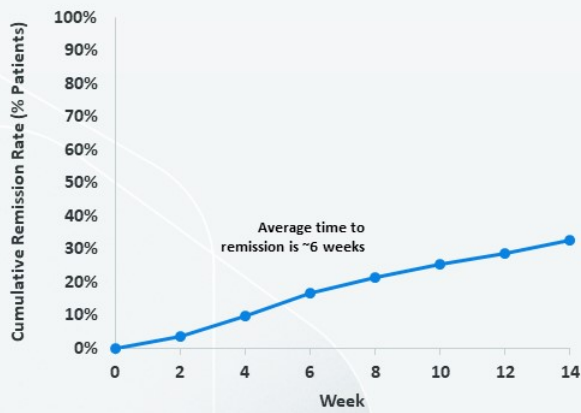
Ongoing



The Problem for Patients with Depression

Established Therapies are **Slow-Acting**

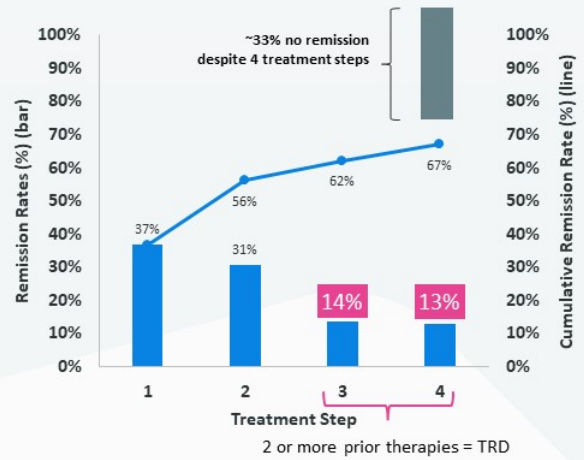
(STAR*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)



Adapted from Trivedi et al., *Am J Psychiatry* 2006 and Rush et al., *Am J Psychiatry* 2006
TRD, Treatment-Resistant Depression

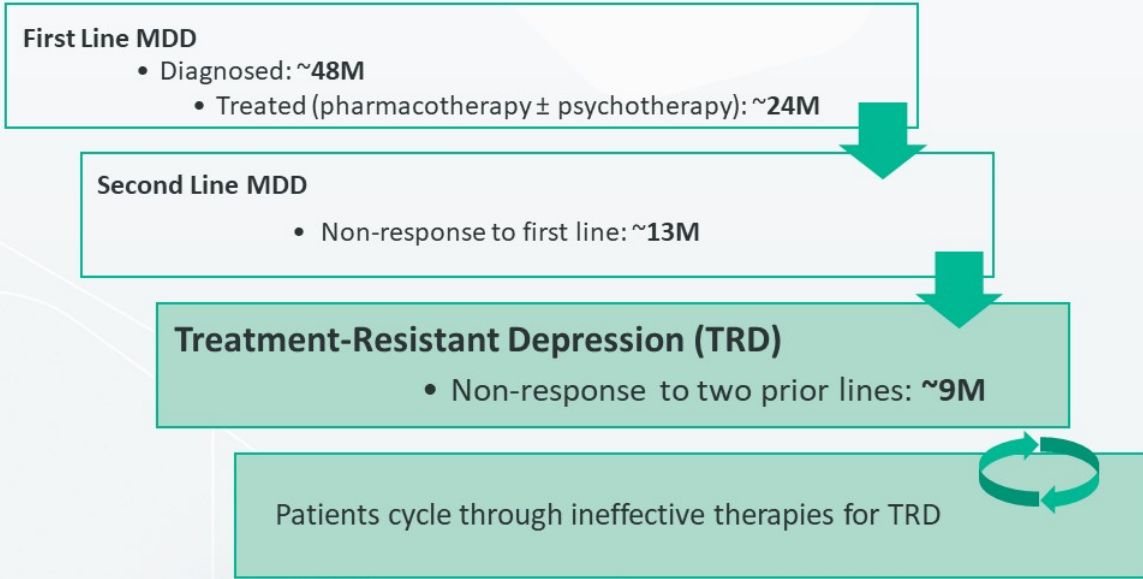
... Remission Rates in TRD < 15%

(STAR*D study, Remission Rates Treatment Steps 1 to 4)



2024 © GH Research PLC

Large and Open Depression Market in the EU and US



Company estimates based on: <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>; Wittchen et al., The size and burden of mental disorders and other disorders of the brain in Europe 2010. *European Neuropsychopharmacology* (2011); Rush et al., Acute and Long-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR*D Report. *Am J Psychiatry* 2006
MDD, Major Depressive Disorder

2024 © GH Research PLC

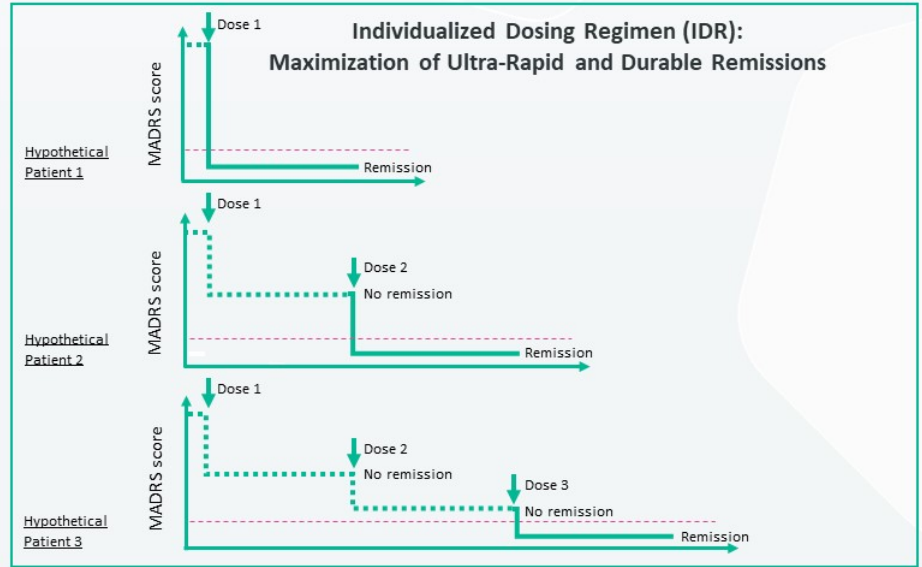
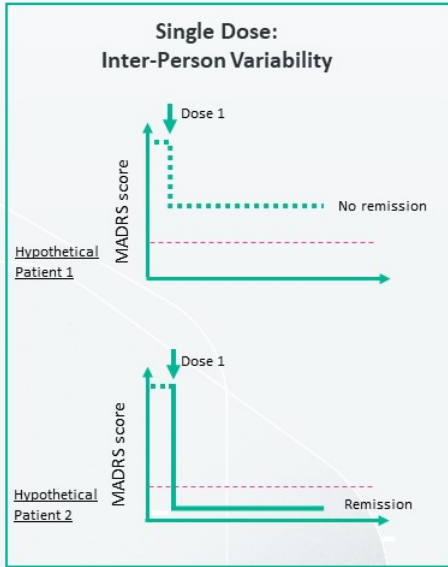
GH001 & GH002



API	Mebufotenin (5-MeO-DMT)
Pharmacology	5-HT1A/5-HT2A agonist
Route	Pulmonary inhalation (GH001) or IV administration (GH002)
Psychoactive effect	Ultra-rapid onset (within seconds) and short duration (<30 min)
Dose	Individualized dosing regimen (IDR) of 1 to 3 doses in a single visit
Visit duration	1 to 3-hours, no additional visits for psychotherapy or structured psychological support



Individualized Dosing Regimen (IDR) for Maximization of Ultra-Rapid and Durable Remissions



MADRS, Montgomery-Åsberg Depression Rating Scale



Phase 1 Trial of GH001 in Healthy Volunteers GH001-HV-101

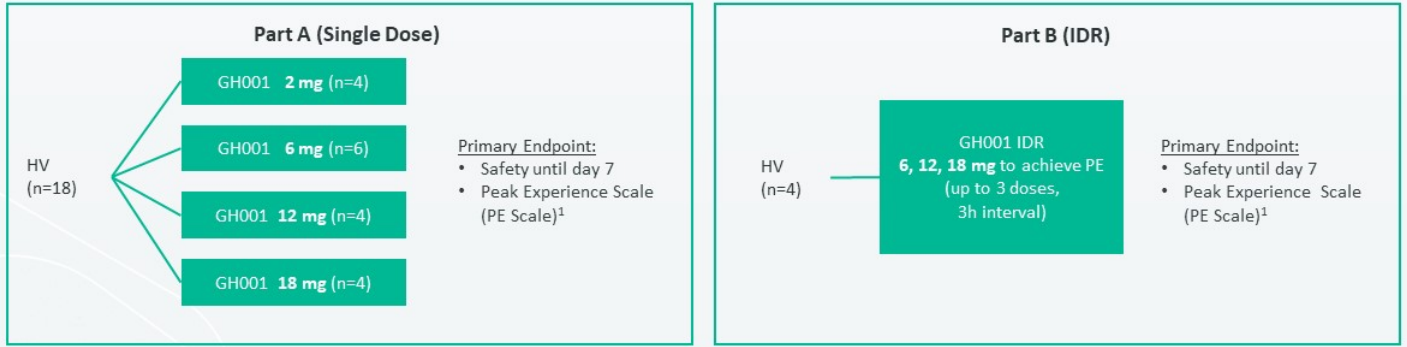
(Completed)

Clinicaltrials.gov ID: NCT04640831

2024 © GH Research PLC

9

Design of Phase 1 Trial of GH001 in Healthy Volunteers (GH001-HV-101)



HV, Healthy Volunteer; PE, Peak Experience; IDR, Individualized Dosing Regimen

2024 © GH Research PLC

¹The PE Scale averages answers scored by the subject by marking a visual analogue scale between 0 and 100 for the following three questions:
1. How intense was the experience; 2. To what extent did you lose control;
3. How profound (i.e., deep and significant) was the experience? 10

Part A (Single Dose) and Part B (IDR) – Safety



Study Safety Group review

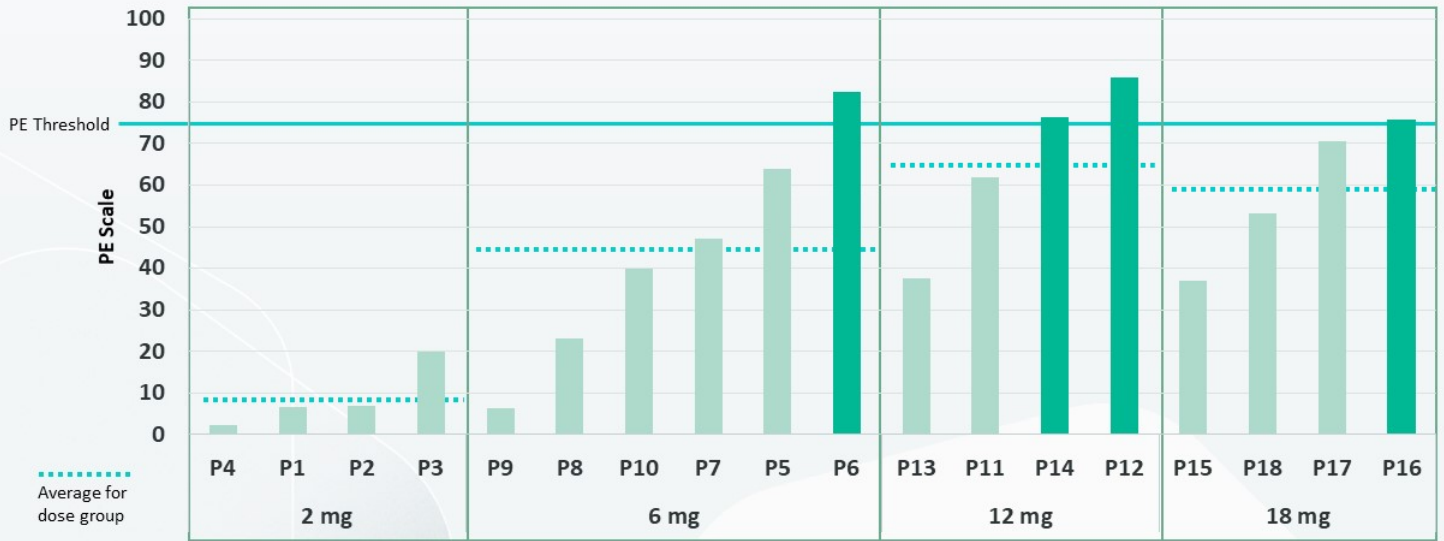
- No SAEs
- All ADRs mild, except two moderate (*)
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically relevant changes in safety laboratory analyses, psychiatric symptom scales or measures of cognitive function

ADRs	Part A (Single Dose)				Part B (IDR)
	2 mg (n=4)	6 mg (n=6)	12 mg (n=4)	18 mg (n=4)	IDR ¹ (n=4)
MedDRA Preferred Term	Number of Events				
Abnormal dreams				1	
Anxiety		1	1		
Clumsiness		1			
Confusional state		1			
Euphoric mood		1			
Fatigue				1	1*
Feeling hot		1			
Flashback				1	
Hallucination				1	
Head discomfort					1
Headache		2		1	1
Heart rate increased			1*		
Hyperacusis				1	
Insomnia				1	
Mental fatigue				1	
Nausea	2	1		1	2
Vision blurred	1				

SAE, Serious Adverse Event; ADR, Adverse Drug Reaction, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing; IDR, Individualized Dosing Regimen

* 6 mg (n=1); 6-12 mg (n=2); 6-12-18 mg (n=1)

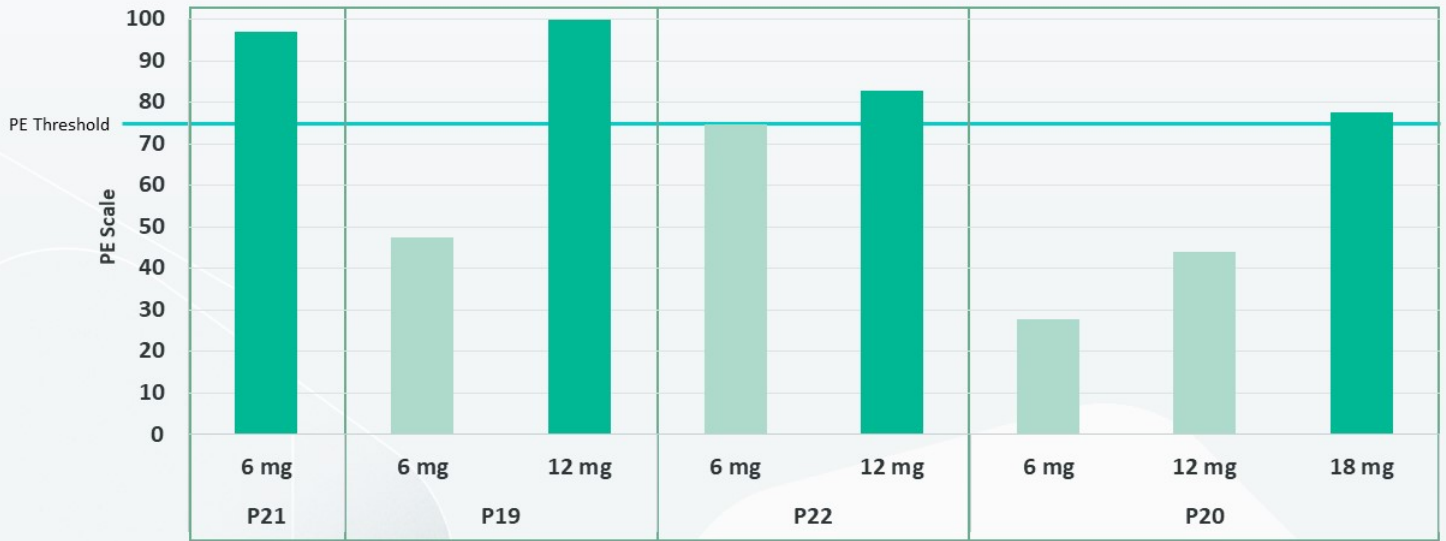
Part A – Peak Experience (PE) Dose-Effects and Inter-Person Variability



PE, Peak Experience

Part B – Peak Experience (PE)

Effect of Intraday Individualized Dosing Regimen (IDR)



PE, Peak Experience



Phase 1/2 Trial of GH001 in Treatment-Resistant Depression GH001-TRD-102

(Completed)

Clinicaltrials.gov ID: NCT04698603

2024 © GH Research PLC

14

Design of Phase 1/2 Trial of GH001 in TRD (GH001-TRD-102)



TRD, Treatment-Resistant Depression; PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; IDR, Individualized Dosing Regimen; H, Hour; D, Day

¹Defined as inadequate response to at least two adequate courses of pharmacological therapy or one adequate course of pharmacological therapy and at least one adequate course of evidence-based psychotherapy

Phase 1 (Single Dose) and Phase 2 (IDR) – Safety



Study Safety Group review

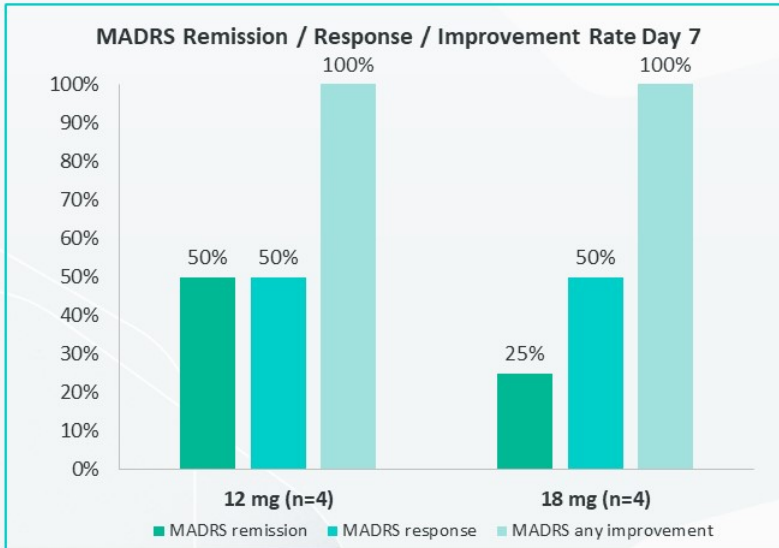
- No SAEs
- All ADRs mild, except three moderate (*)
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically relevant changes in safety laboratory analyses, psychiatric safety assessments or measures of cognitive function
- No safety signal relating to suicidal ideation or suicidal behavior, based on C-SSRS and MADRS subscore item “suicidal thoughts”

ADRs	Phase 1 (Single Dose)		Phase 2 (IDR)
	12 mg (n=4)	18 mg (n=4)	IDR ¹ (n=8)
MedDRA Preferred Term	Number of Events		
Abdominal discomfort			1
Anxiety			2
Depressive symptom			1*
Dizziness	1		
Feeling abnormal	1	1	
Flashback	1	1	2
Headache	2	1	3
Muscle discomfort			1
Muscle spasms		1	
Nausea			2*
Paresthesia			1
Sensory disturbance			3

SAE, Serious Adverse Event; ADR, Adverse Drug Reaction, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing; IDR, Individualized Dosing Regimen; C-SSRS, Columbia-Suicide Severity Rating Scale; MADRS, Montgomery-Åsberg Depression Rating Scale

¹6-12 mg (n=6); 6-12-18 mg (n=2)

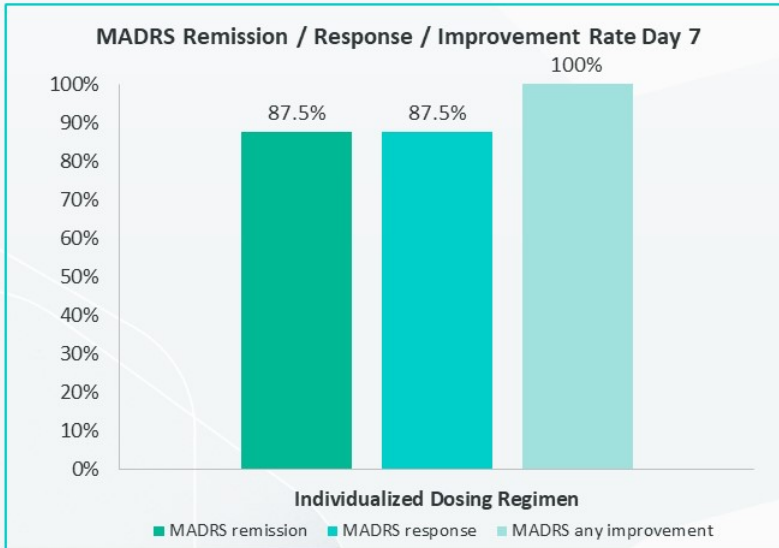
Phase 1 (Single Dose) – Efficacy (MADRS)



- 2 of 4 (50%) in the 12 mg group and 1 of 4 (25%) in the 18 mg group had a MADRS remission at day 7
- 2 of 8 patients had a PE and both had a MADRS remission at day 7

PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale
MADRS remission = MADRS of ≤10; MADRS response = Reduction of ≥50% from baseline in MADRS; MADRS any improvement = any reduction from baseline in MADRS

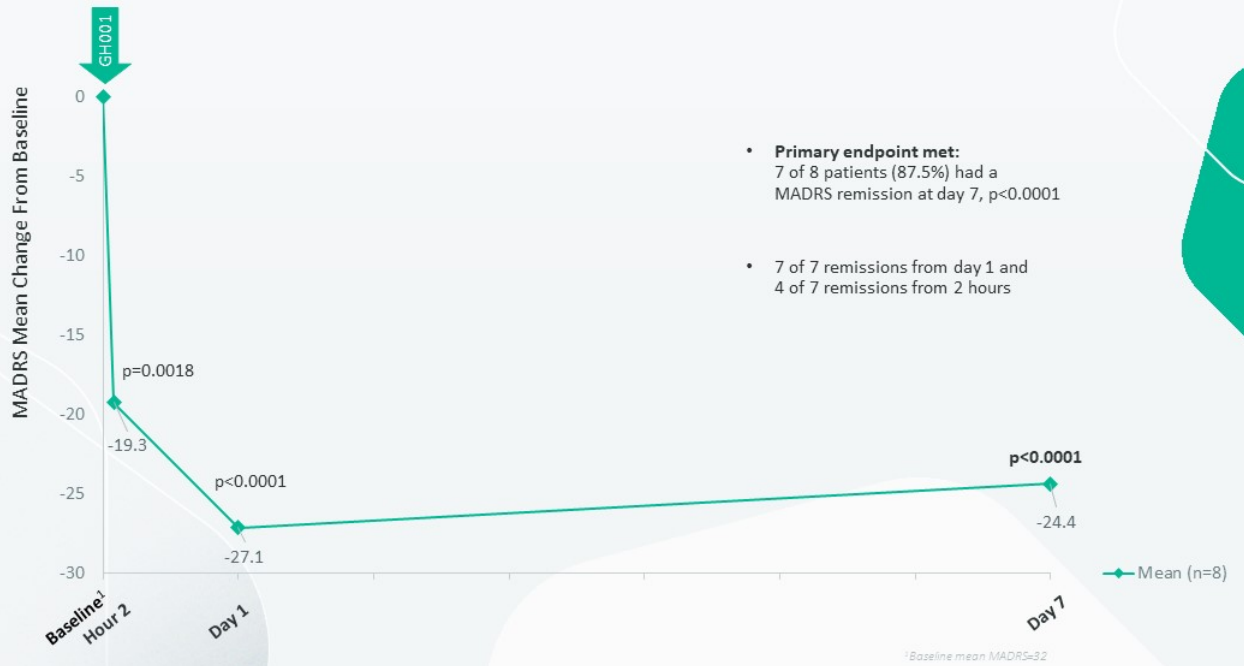
Phase 2 (IDR) – Efficacy (MADRS)



- **Primary endpoint met:**
7 of 8 patients (87.5%) had a MADRS remission at day 7, $p < 0.0001$
- 7 of 8 patients had a PE and 6 of those had a MADRS remission at day 7

PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale
MADRS remission = MADRS of ≤ 10 ; MADRS response = Reduction of 250% from baseline in MADRS; MADRS any improvement = any reduction from baseline in MADRS

Phase 2 (IDR) – Efficacy (MADRS Change from Baseline)



- **Primary endpoint met:**
7 of 8 patients (87.5%) had a MADRS remission at day 7, $p<0.0001$
- 7 of 7 remissions from day 1 and 4 of 7 remissions from 2 hours

MADRS and PE – Observed Improved Outcome in Phase 2 (IDR) vs Phase 1 (Single Dose)



	Phase 2 (IDR)	Phase 1 (Single Dose) 12 mg	Phase 1 (Single Dose) 18 mg
MADRS Remission Rate Day 7	87.5% (7 of 8)	50% (2 of 4)	25% (1 of 4)
Mean MADRS Change Day 7	-24.4 (-76%)	-21.0 (-65%)	-12.5 (-40%)
Rate of PE	87.5% (7 of 8)	50% (2 of 4)	0% (0 of 4)
Mean PE Score	90.4 (at final dose)	58.2	59.1

PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale;
IDR, Individualized Dosing Regimen

2024 © GH Research PLC

20



Phase 2b Trial in Treatment-Resistant Depression GH001-TRD-201

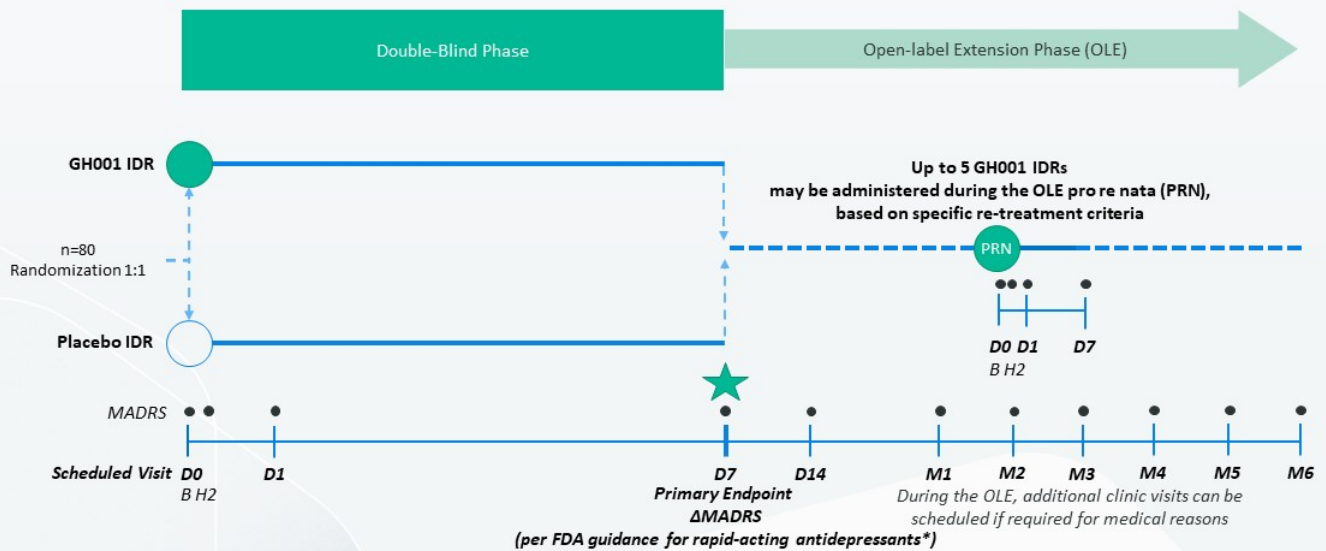
(Initiated)

EudraCT Number: 2022-000574-26

2024 © GH Research PLC

21

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



The bold solid lines indicate the fixed duration of 7 days (± 1 day) after an IDR with visits on D0, D1 and D7. The bold dotted line indicates the variable duration until a potential GH001 IDR in the OLE. The GH001 IDR consists of up to 3 increasing doses (6, 12, 18 mg) and the Placebo IDR consists of up to three placebo doses, to achieve a peak experience, given at a 1H interval. As in previously completed trials, the GH001-TRD-201 trial will be conducted under the supervision of a healthcare provider, but without any planned psychotherapeutic interventions before, during, or after dosing. IDR, Individualized Dosing Regimen; PRN, pro re nata (as needed); B, Baseline; H, Hour; D, Day; M, Month. *FDA draft guidance for industry "Major Depressive Disorder: Developing Drugs for Treatment".

Three-Layer Protection Strategy



LAYER 1: REGULATORY EXCLUSIVITY

FDA: 5 years (+2.5 years paragraph IV stay)
EMA: 10 years (+1 year for new indication)

LAYER 2: PATENTS

Granted patents and patent applications relating to mebufotenin (5-MeO-DMT), including:

- Novel uses in various disorders (including inhaled, nasal, buccal, sublingual, i.v., i.m., s.c. routes)
- Novel aerosol compositions of matter
- Novel manufacturing methods and novel salt forms
- Novel device-related aspects

LAYER 3: TECHNICAL

Complex bioequivalence for systemically-acting inhalation/intranasal products with high intra- and inter-subject variability

Board of Directors & Executive Management



Florian Schönharting
MSc
Chairman of the Board, Co-founder



Michael Forer
BA, LLB
Vice-Chairman of the Board



Dermot Hanley
BSc, MBA
Board Member



Duncan Moore
MPhil, PhD
Board Member



Velichka (Villy) Valcheva
MD, MSc
Chief Executive Officer



Julie Ryan
FCA, MAcc, BComm
VP, Finance



Aaron Cameron
MSc, MBA
Chief Operating Officer



Magnus Halle
BSc
Managing Director, Ireland, Co-founder



Scientific Advisors



Madhukar Trivedi
M.D.
Professor of Psychiatry,
UT Southwestern Medical Center




Michael Thase
M.D.
Professor of Psychiatry, Perelman School of Medicine
University of Pennsylvania




Mark Zimmerman
M.D.
Professor of Psychiatry and Human Behavior,
Brown University




Eduard Vieta
Prof. Dr.
Head, Psychiatry Unit,
Hospital Clínic de Barcelona




Michael Bauer
Prof. Dr. rer. nat. Dr. med.
Chair, Department of Psychiatry and Psychotherapy,
Technische Universität Dresden




Malek Bajbouj
Prof. Dr. med.
Head, Center for Affective Neuroscience,
Charité, Berlin




Johannes Ramaekers
Prof. Dr.
Professor, Faculty of Psychology
and Neuroscience of Maastricht University


Anticipated Milestones and Financial Overview



GH001

- Complete double-blind phase of European Phase 2b trial in TRD in Q3 2024; complete open-label extension phase in Q1 2025
- Complete Phase 2a trial in PPD in Q4 2024;
- Complete nonclinical studies and prepare device design verification information to support response to clinical hold on U.S. IND for GH001 administered using our proprietary aerosol delivery
- Complete Phase 1 clinical pharmacology trial with proprietary aerosol delivery device in Europe

GH002

- Complete review of next development steps

GH003

- Complete preclinical development

Financial Overview

- Cash, cash equivalents, other financial assets and marketable securities were \$204.5 million as of June 30, 2024
- We believe existing cash, cash equivalents, other financial assets and marketable securities will be sufficient to fund operating expenses and capital expenditure requirements into 2026



Appendix

Additional Completed Trials



Phase 1 Clinical Pharmacology Trial of GH001 in Healthy Volunteers GH001-HV-103

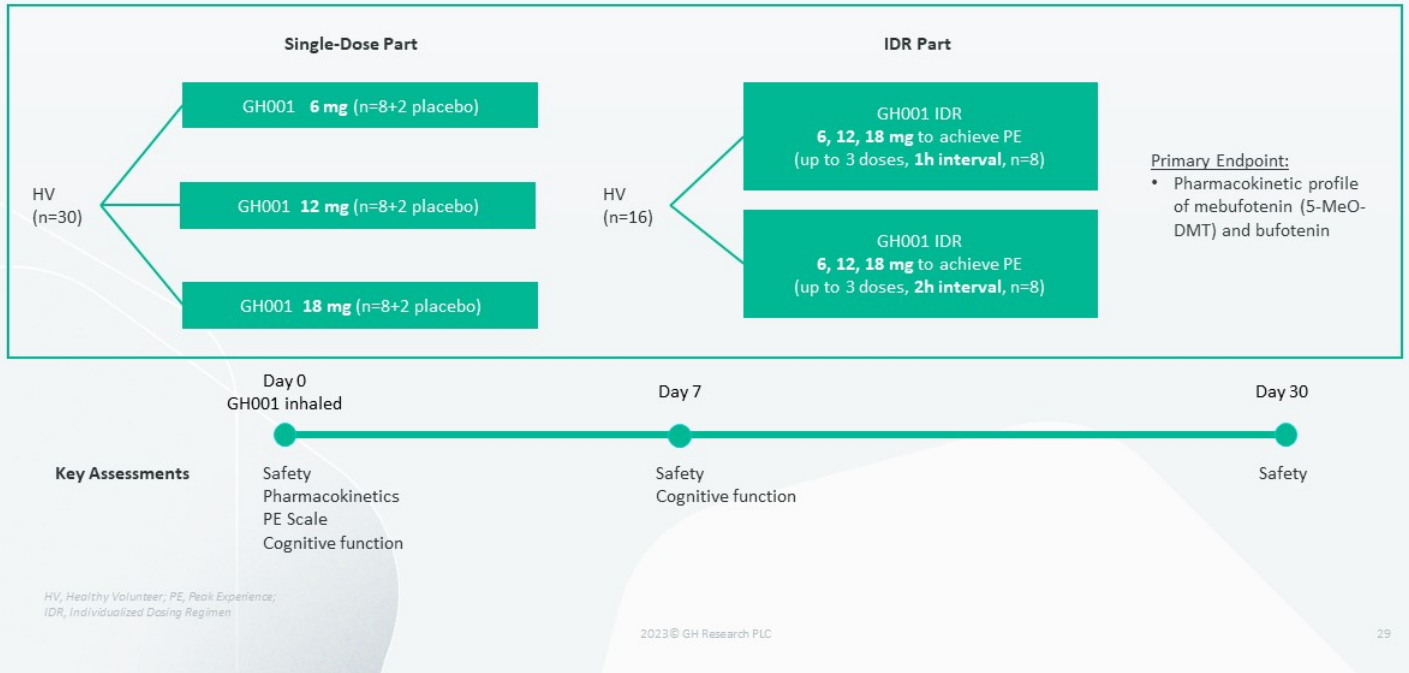
(Completed)

Clinicaltrials.gov ID: NCT05163891

2024 © GH Research PLC

28

Design of Phase 1 Clinical Pharmacology Trial of GH001 in Healthy Volunteers (GH001-HV-103)



Single Dose and IDR – Safety and Further Results



Safety Review

- No SAEs
- All ADRs mild
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically relevant changes in ECG, safety laboratory analyses, peak flow, cognitive function or psychiatric symptom scales, including the C-SSRS

Further Results

- Pharmacokinetic analyses and psychoactive effect assessments (PE Scale) support that an interval down to 1 hour between individual doses of the IDR is feasible for future clinical trials

ADRs	Single-dose				IDR	
	6 mg (n=8)	12 mg (n=8)	18 mg (n=8)	Placebo (n=6)	1h interval (n=8) ¹	2h interval (n=8) ²
MedDRA Preferred Term	Number of Events					
Abnormal dreams						1
Chest discomfort		1				
Crying			2		2	
Dizziness			1			
Dry mouth	1					
Dyskinesia			1			
Fatigue		1			2	1
Headache	3		1		1	1
Hypoesthesia oral		1				
Paresthesia oral						1
Retching			1			
Somnolence		1				
Tachycardia			2			
Tension						1
Tremor			1			

SAE, Serious Adverse Event; ADR, Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing; IDR, Individualized Dosing Regimen; C-SSRS, Columbia-Suicide Severity Rating Scale; PE, Peak Experience

¹6 mg (n=1), 6-12 mg (n=3); 6-12-18 mg (n=4)
²6-12 mg (n=3); 6-12-18 mg (n=5)



Phase 1 Clinical Pharmacology Trial of GH002 in Healthy Volunteers GH002-HV-105

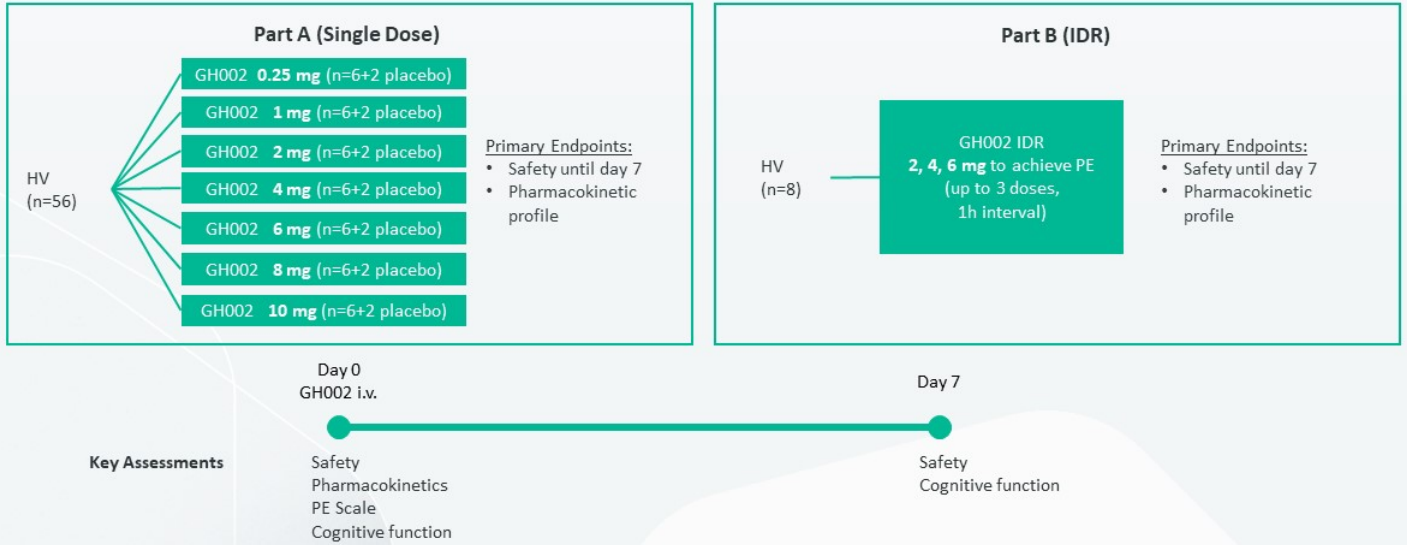
(Completed)

Clinicaltrials.gov ID: NCT05753956

2024 © GH Research PLC

31

Design of Phase 2 Trial of GH002 in Healthy Volunteers (GH002-HV-105)



HV, Healthy Volunteer; PE, Peak Experience; IDR, Individualized Dosing Regimen

Single Dose and IDR – Safety and Further Results



Safety review

- No SAEs
- All ADRs mild, except one moderate (*)
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH002
- No clinically relevant changes in ECG and safety laboratory analyses
- No clinically relevant changes in psychiatric symptoms scales, except for changes associated with the ADRs of emotional distress and poor quality sleep

Further Results

- Potent psychoactive effects (PsE) with ultra-rapid onset and short duration were observed. The pharmacokinetic profile correlated with the ultra-rapid profile of the PsE.

ADRs	Single Dose							IDR	
	0.25 mg (n=6)	1 mg (n=6)	2 mg (n=6)	4 mg (n=6)	6 mg (n=6)	8 mg (n=6)	10 mg (n=6)	Placebo (n=14) ¹	1h interval (n=8) ²
MedDRA Preferred Term	Number of Events								
Abnormal dreams							1		
Body temperature increased			1						
Chest discomfort				1					
Cold sweat				1					
Dizziness			2	1		1			
Dyspnoea									1
Emotional distress			1			1*			
Fatigue			2		1	1	1		
Grunting							2		
Headache					1			1	2
Head discomfort				1		1			1
Muscle spasms							2		
Muscle twitching							1		
Nausea	1	1		2		1			2
Neck pain							1		
Pain in extremity							2		
Poor quality sleep							1		
Sleep disorder							1		
Vomiting		1				1	1		1

¹ n=2 subjects received placebo in each dose group

² 2 mg (n=4), 2-4 mg (n=2), 2-4-6 mg (n=2)

SAE, Serious Adverse Event; ADR, Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing; IDR, Individualized Dosing Regimen



Seeking Ultra-Rapid, Durable Remissions in Depression