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 March, 2023.

Commission File Number: 001-40530

GH Research PLC

(Exact name of registrant as specified in its charter)

28 Baggot Street Lower
Dublin 2
D02 NX43
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 ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

GH Research PLC (the "Company") provided business updates on March 2, 2023 by way of a press release and an updated corporate presentation. A copy of the press release is attached hereto as Exhibit 99.1 and a copy of the presentation is attached hereto as Exhibit 99.2.

The fact that this press release and presentation is 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 the presentation is being provided as of March 2, 2023 and the Company does not undertake any obligation to update the press release or 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 March 2, 2023
99.2	Corporate Presentation for March 2023

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: March 2, 2023

GH Research PLC

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

Exhibit 99.1

GH Research Reports Full Year 2022 Financial Results and Provides Business Updates

DUBLIN, Ireland., March 2, 2023 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported financial results for the full year ended December 31, 2022 and gave updates on its business.

Business Updates

We are pleased to report that we have recently initiated our multi-center, randomized, double-blind, placebo-controlled Phase 2b trial of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201). GH001 is our proprietary inhalable mebufotenin (5-MeO-DMT) product candidate.

We expect to recruit approximately 80 patients for this trial across several European countries. The primary objective will be to determine the efficacy of our single-day individualized dosing regimen (IDR) of GH001 compared with placebo in improving depressive symptoms as assessed by the mean change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) at the end of the 7-day double-blind phase. The double-blind phase will be followed by a 6-month open-label extension phase where all patients can receive treatment with the GH001 IDR as-needed, based on the patient's clinical status. Further trial design details are described in our updated corporate presentation, which is available in the investor section on our website.

Recent Business Highlights

In January 2023, we reported development progress in respect of our proprietary aerosol delivery device and our expectation that we will submit an IND for GH001, delivered with this proprietary device, in the third quarter of 2023. The IND-opening study is expected to be a Phase 1 clinical pharmacology trial in healthy volunteers (GH001-HV-106), designed to support bridging to the clinical data generated with the third-party device we currently use in our clinical trials.

We also reported, in January 2023, the recent initiation of our randomized, double-blind, placebo-controlled, dose-ranging clinical pharmacology trial of GH002 in healthy volunteers (GH002-HV-105). GH002 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach. We expect to complete this trial in the fourth quarter of 2023.

Furthermore, we reported the recent expansion of our patent portfolio, to include 11 patent families that relate to various aspects of mebufotenin (5-MeO-DMT) use in a therapeutic context, including but not limited to the use of mebufotenin (5-MeO-DMT) for treatment of various disorders when administered by inhalation, or by nasal, buccal, sublingual, intravenous, intramuscular or subcutaneous routes.

We also announced the selection of mebufotenin as the International Nonproprietary Name (INN) for 5-MeO-DMT by the World Health Organization (WHO) Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations.

Full Year 2022 Financial Highlights

Cash position

Cash, cash equivalents and marketable securities were $251.7 million as of December 31, 2022, compared to cash of $276.8 million as of December 31, 2021. Marketable securities are comprised of investment grade bonds. We believe that our existing cash, cash equivalents and marketable securities will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2026.

Research and development expenses

R&D expenses were $20.5 million for the year ended December 31, 2022, compared to $8.6 million for the full year 2021. The increase was primarily due to increased activities relating to our technical development, clinical trials and increased employee expenses to support these activities.

General and administrative expenses

G&A expenses were $10.1 million for the year ended December 31, 2022, compared to $6.5 million for the full year 2021. The increase was primarily due to higher insurance costs, an increase in professional costs as well as increased employee expenses.

Net loss

Net loss was $22.5 million, or $0.432 loss per share, for the year ended December 31, 2022, compared to $9.2 million, or $0.211 loss per share, for the full year 2021.

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).

About GH001

Our lead product candidate, GH001, is formulated for mebufotenin (5-MeO-DMT) administration via a proprietary inhalation approach. With GH001, we have completed two Phase 1 healthy volunteer clinical trials and a Phase 1/2 clinical trial in patients with treatment-resistant depression (TRD). Based on the observed clinical activity, where 87.5% of patients with TRD were brought into an ultra-rapid remission with our GH001 individualized single-day dosing regimen in the Phase 2 part of the trial, we believe that GH001 has potential to change the way TRD is treated today. GH001 is currently in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial of GH001 in treatment-resistant depression (TRD). Across the GH001 program, no serious adverse events have been reported and GH001 was well tolerated at the investigated single dose levels and in the individualized dosing regimen.

About GH002 and GH003

GH002 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach. GH002 is currently in Phase 1 clinical development. GH003 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intranasal administration approach. GH003 is currently in preclinical development. We anticipate developing GH002 and GH003 in subpopulations and confined use scenarios within our focus area of psychiatric and neurological disorders.

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, cash runway, business strategy, product candidates, proprietary medical devices, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals, research and development costs, 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

GH Research

GH RESEARCH PLC

Consolidated Statement of Comprehensive Income (Unaudited)

(in thousands, except share and per share amounts)

	Year ended December 31,	
	2022 $'000	**2021 $'000**
Operating expenses		
Research and development	(20,484)	(8,553)
General and administration	(10,070)	(6,547)
Loss from operations	**(30,554)**	**(15,100)**
Net finance income/(expense)	922	(9)
Foreign exchange gain	7,176	5,907
Total finance income	**8,098**	**5,898**
Loss before tax	**(22,456)**	**(9,202)**
Tax charge/(credit)	—	—
Loss for the year	**(22,456)**	**(9,202)**
Other comprehensive income/(expense)		
Items that may be reclassified to profit or loss		
Fair value movement on marketable securities	558	—
Currency translation adjustment	(7,132)	(6,103)
Total comprehensive loss for the year	**(29,030)**	**(15,305)**
Attributable to owners:		
Loss for the year	(22,456)	(9,202)
Comprehensive loss for the year	(29,030)	(15,305)
Loss per share		
Basic and diluted loss per share (in USD)	(0.432)	(0.211)

GH RESEARCH PLC

Consolidated Balance Sheet (Unaudited)

(in thousands)

	At December 31,	
	2022 $'000	**2021 $'000**
ASSETS		
Current assets		
Cash and cash equivalents	165,955	276,776
Other current assets	2,586	3,066
Total current assets	**168,541**	**279,842**
Non-current assets		
Marketable securities	85,724	—
Property, plant and equipment	97	82
Total non-current assets	**85,821**	**82**
Total assets	**254,362**	**279,924**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	1,868	883
Other current liabilities	2,678	1,866
Total current liabilities	**4,546**	**2,749**
Total liabilities	**4,546**	**2,749**
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,448	291,448
Other reserves	2,595	366
Foreign currency translation reserve	(13,035)	(5,903)
Accumulated deficit	(32,493)	(10,037)
Total equity	**249,816**	**277,175**
Total liabilities and equity	**254,362**	**279,924**

Corporate Presentation

GH Research PLC (NASDAQ: GHRS)

March 2023

Disclaimer Regarding Forward-Looking Statements

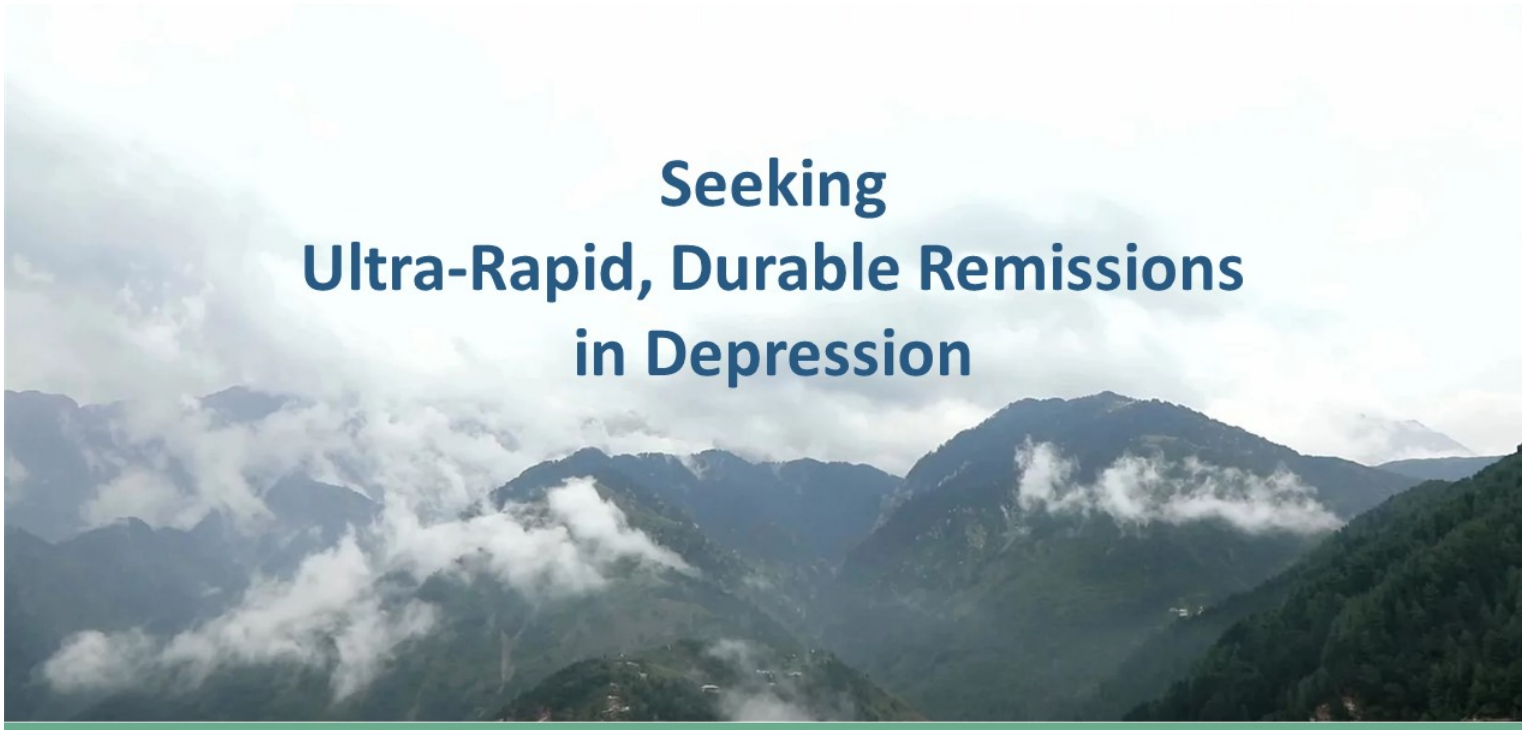
This presentation has been prepared by GH Research PLC ("GH Research") for informational purposes only and not for any other purpose. Nothing contained in this presentation is, or should be construed as, a recommendation, promise or representation by the presenter or GH Research or any director, employee, 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 these 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.

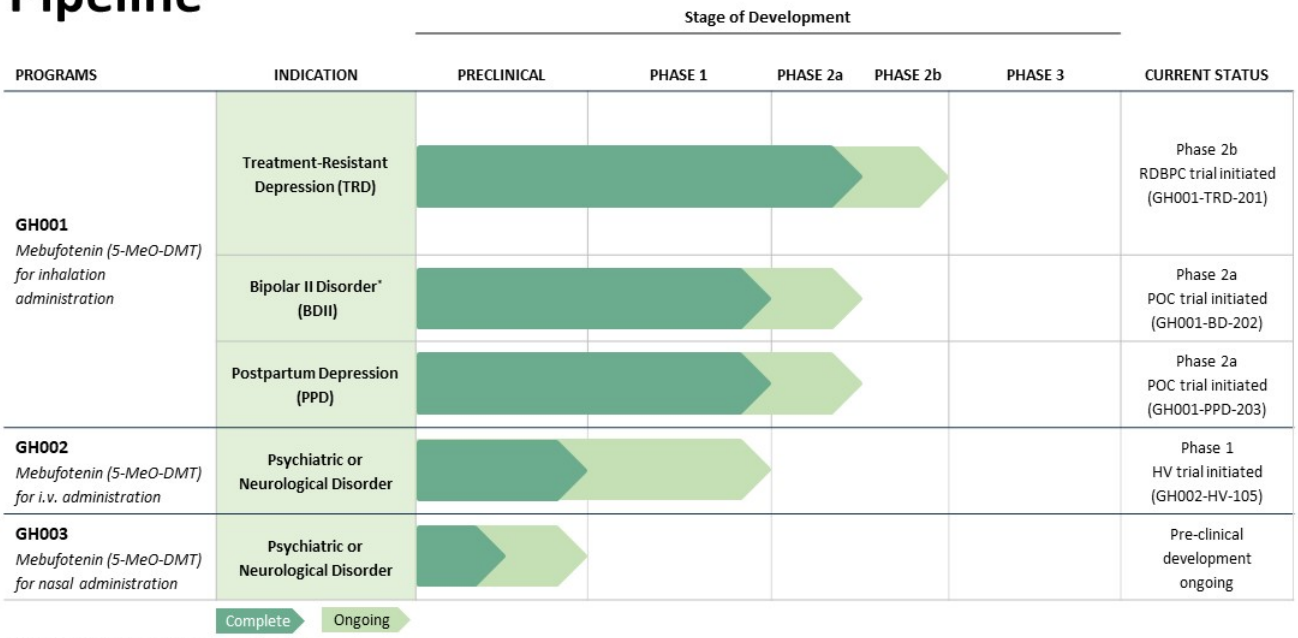
Any statements contained herein that do not describe historical facts are forward-looking statements that are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcomes, timing and performance to differ materially from those 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 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

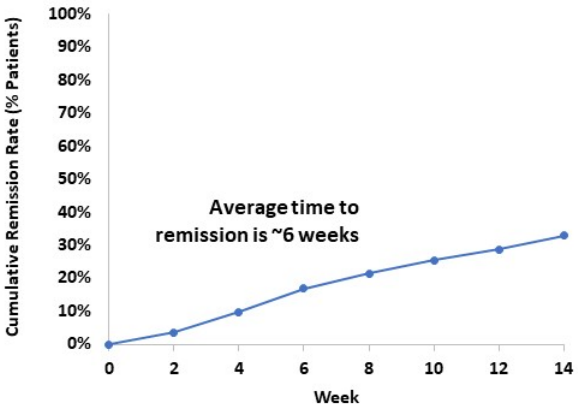


Bipolar II disorder with a current major depressive episode
5-MeO-DMT, 5-Methoxy-N, N-Dimethyltryptamine; i.v., intravenous; RDBPC, Randomized, Double-Blind, Placebo-Controlled; POC, Proof-of-Concept; HV, Healthy Volunteer

The Problem for Patients with Depression

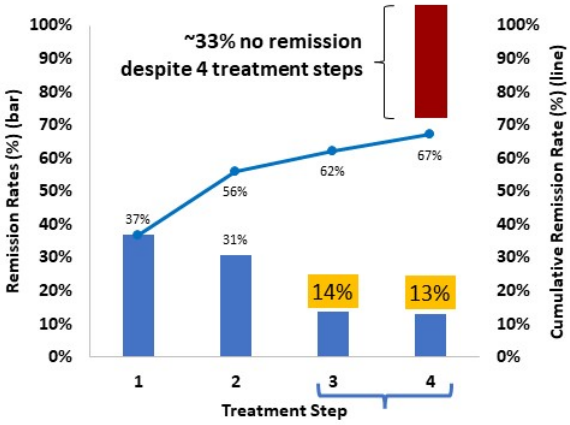
Established Therapies are Slow-Acting

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



... Remission Rates in TRD < 15%

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



2 or more prior therapies = TRD

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

Large and Open Depression Market in the EU and US

First Line MDD
- Diagnosed: **~48M**
- Treated (pharmacotherapy ± psychotherapy): **~24M**

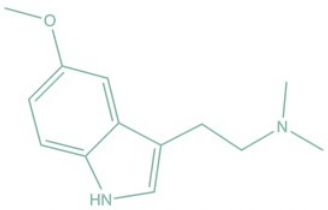
Second Line MDD
- Non-response to first line: **~13M**

Treatment-Resistant Depression (TRD)
- Non-response to two prior lines: **~9M**

Patients cycle through ineffective therapies for TRD

*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 Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR*D Report, Am J Psychiatry 2006*
MDD, Major Depressive Disorder

Mebufotenin (5-MeO-DMT) and GH001



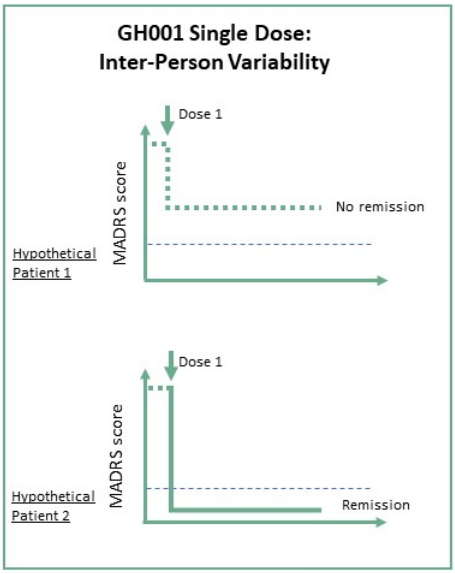
Mebufotenin (5-MeO-DMT)

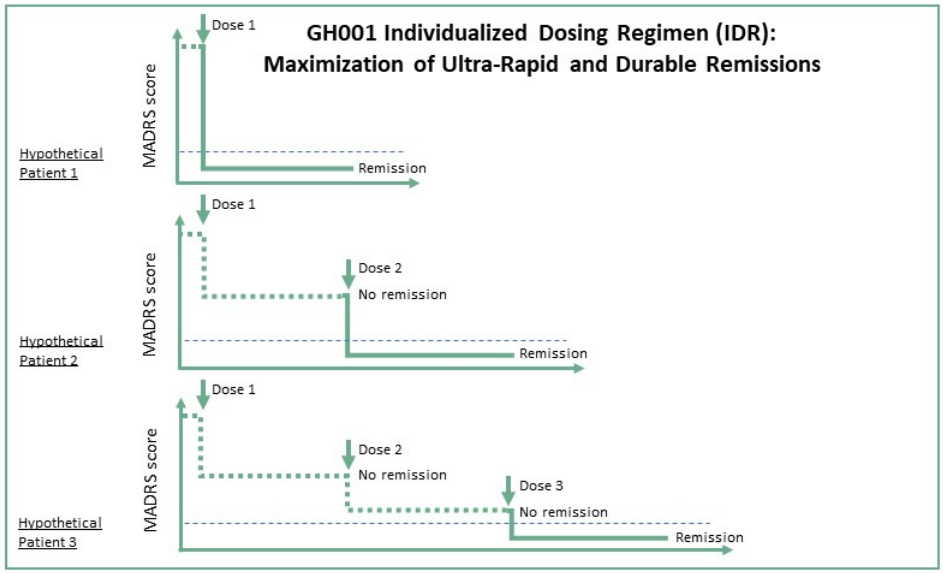
- Mebufotenin (5-Methoxy-N,N-Dimethyltryptamine, 5-MeO-DMT)
  - Naturally-occurring psychoactive substance from tryptamine class
  - **Highly potent** agonist on 5-HT1A and 5-HT2A receptors

- GH001 (Mebufotenin administration via a proprietary pulmonary inhalation approach)
  - **Psychoactive effects with ultra-rapid onset** (within seconds) **and short duration** (5 to 30 min)
  - **High propensity to induce peak experiences (PE), which may be a surrogate marker for therapeutic effects**
  - **Intraday individualized dosing regimen (IDR)** for **maximization of ultra-rapid and durable remissions**
  - **Single visit initial treatment,** with no structured psychotherapy
  - Potential for **convenient and infrequent retreatment**

Foundational IP

GH001 – Individualized Dosing Regimen (IDR) for Maximization of Ultra-Rapid and Durable Remissions





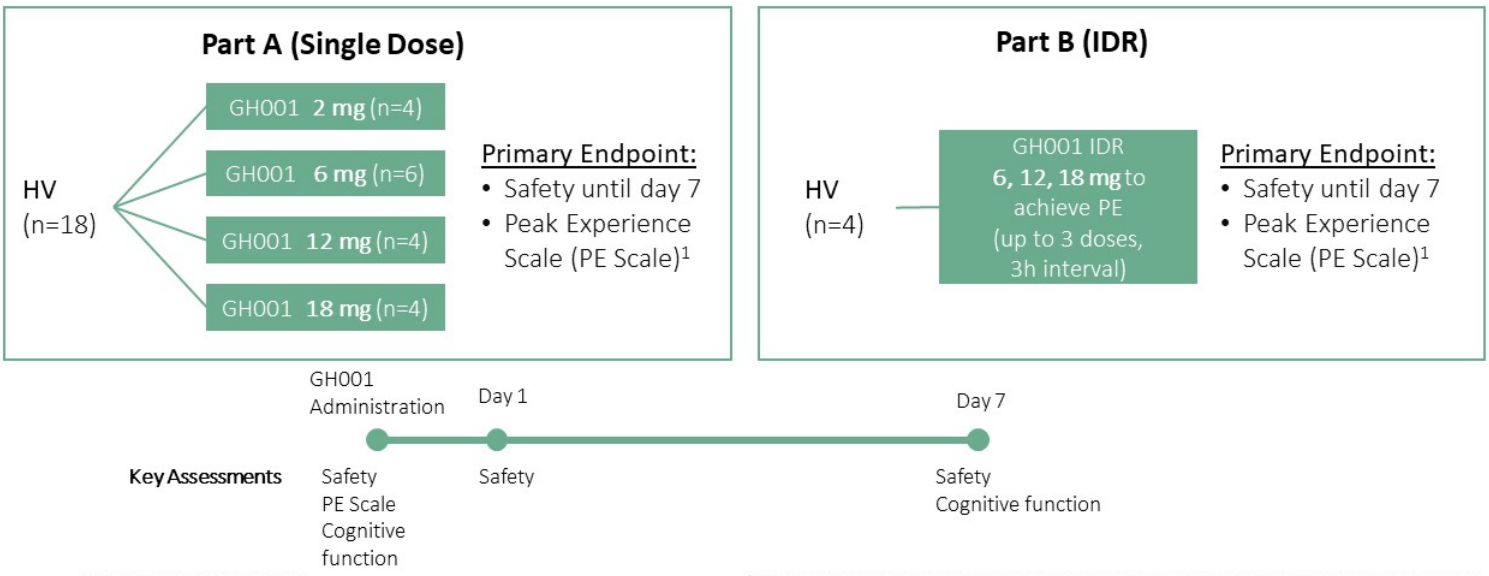
MADRS, Montgomery-Åsberg Depression Rating Scale

Phase 1 Trial in Healthy Volunteers
GH001-HV-101

(Completed)

Clinicaltrials.gov ID: NCT04640831

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



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

[1] The 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?

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

Study Safety Group review

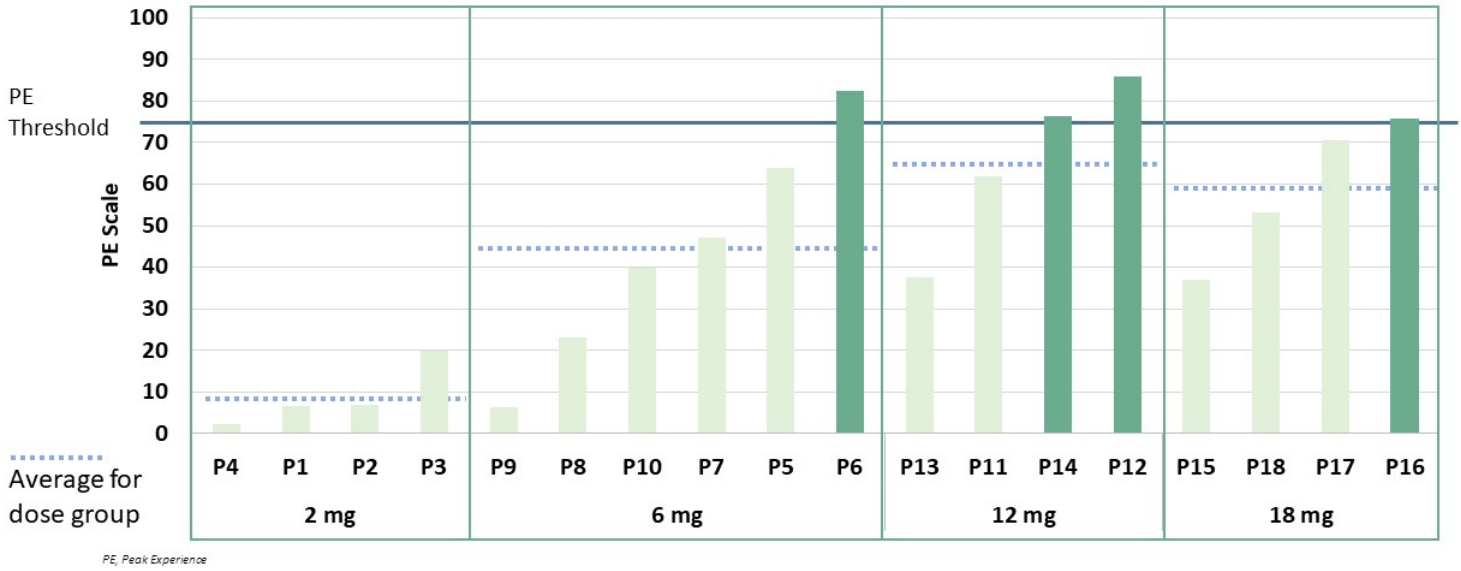
- **No SAEs**
- **All ADRs mild, except two moderate (*)**
- **All ADRs resolved spontaneously**
- **Inhalation well-tolerated**
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
-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

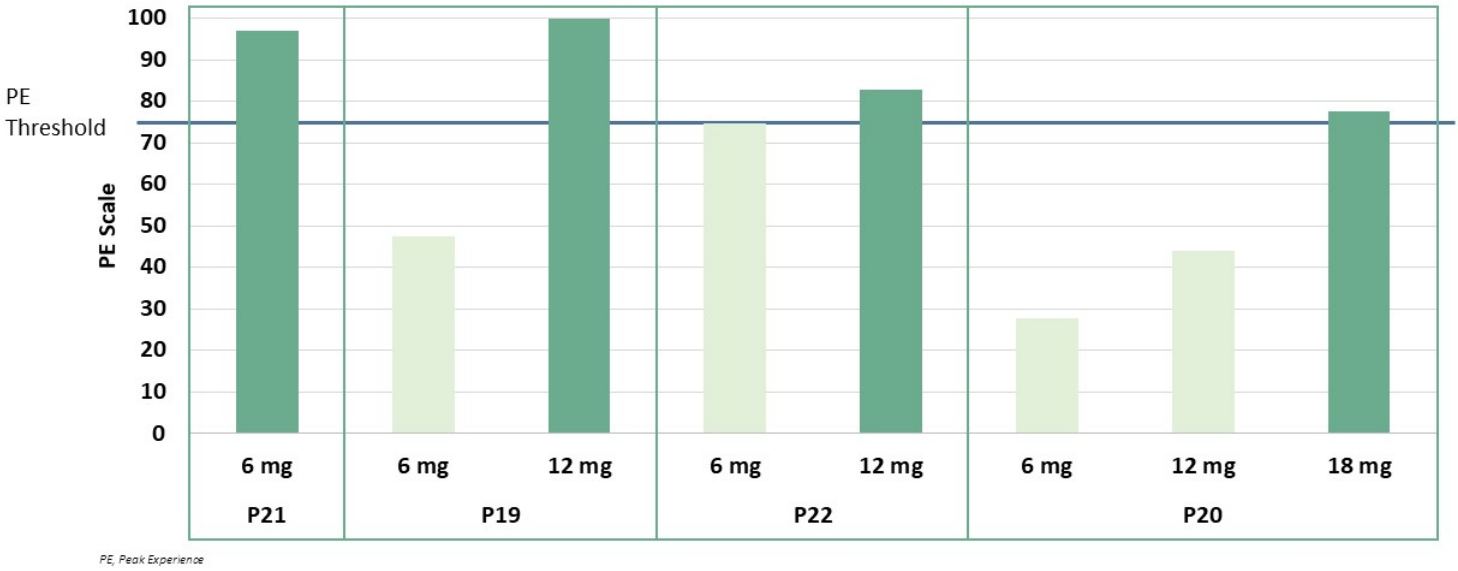
[1] *6 mg (n=1); 6-12 mg (n=2); 6-12-18 mg (n=1)*

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)



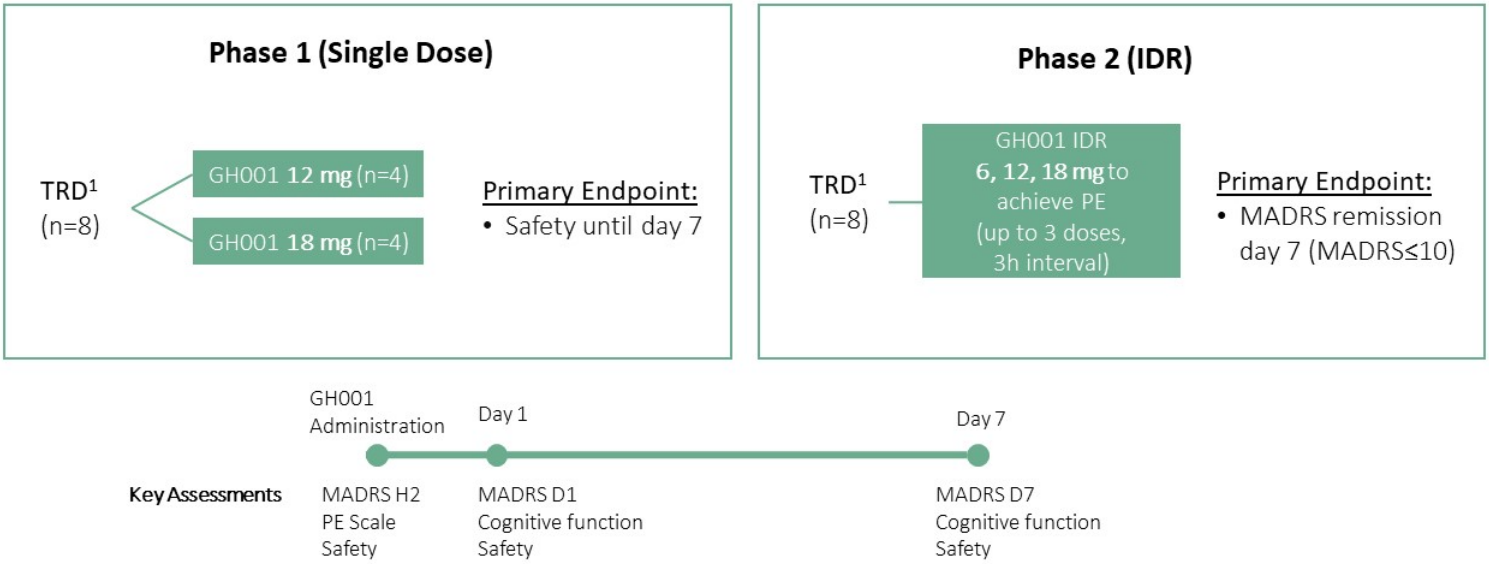
PE, Peak Experience

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

(Completed)

Clinicaltrials.gov ID: NCT04698603

Design of Phase 1/2 Trial 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

[1] Defined 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

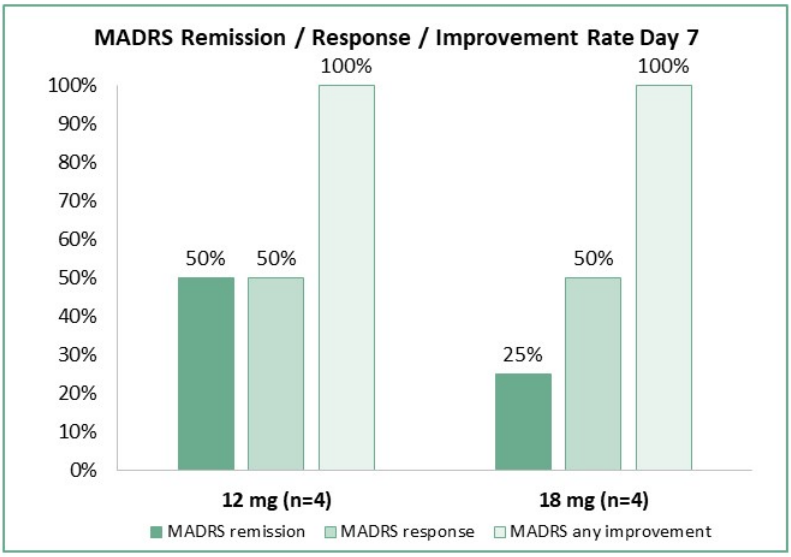
- **No SAEs**
- **All ADRs mild, except three moderate***
- **All ADRs resolved spontaneously**
- **Inhalation well-tolerated**
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant 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

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

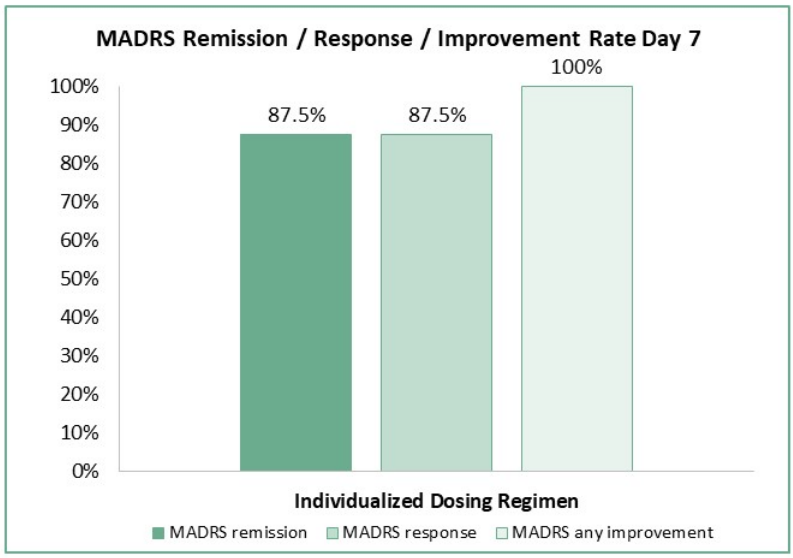
Phase 1 (Single Dose) – Efficacy (MADRS)



- 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.

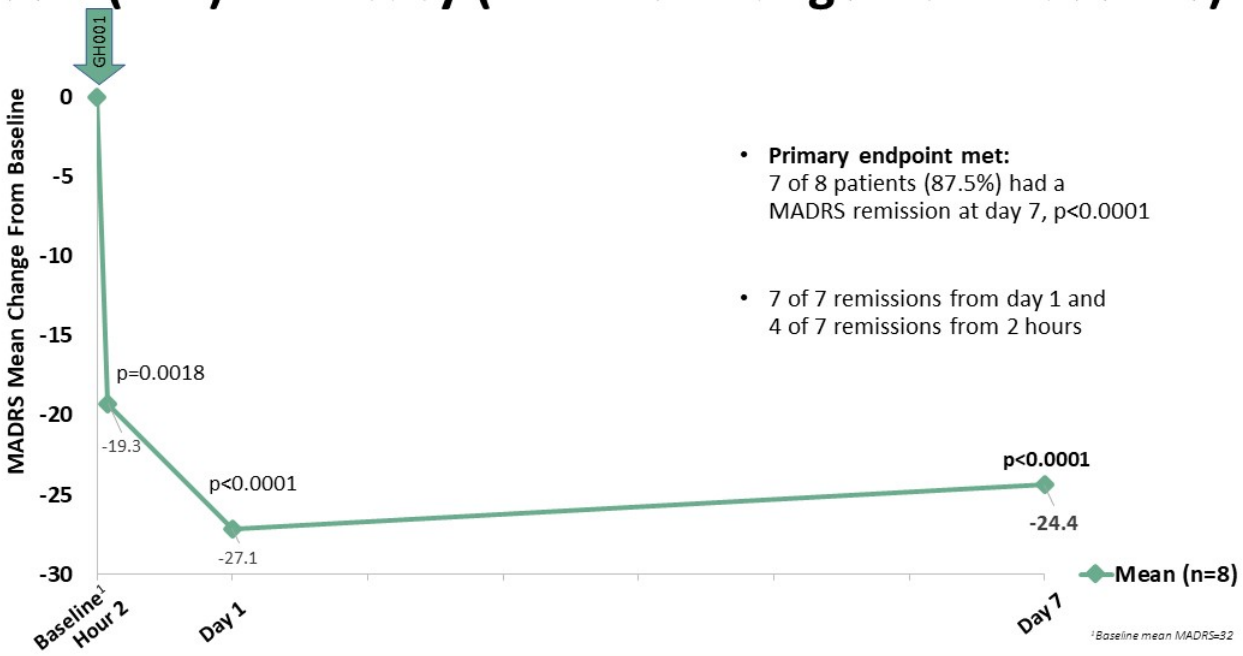
Phase 2 (IDR) – Efficacy (MADRS)



- **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 ≥50% 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

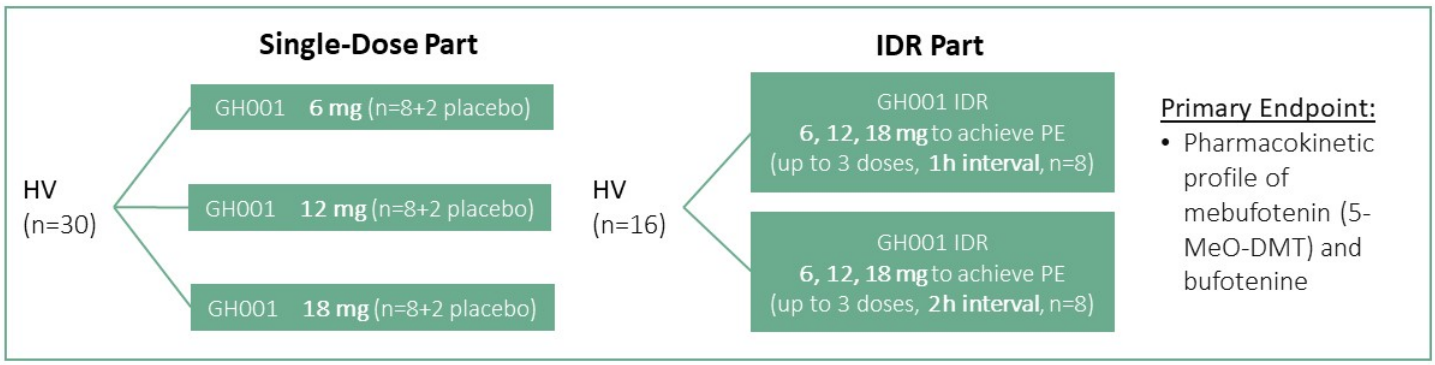
PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; IDR, Individualized Dosing Regimen

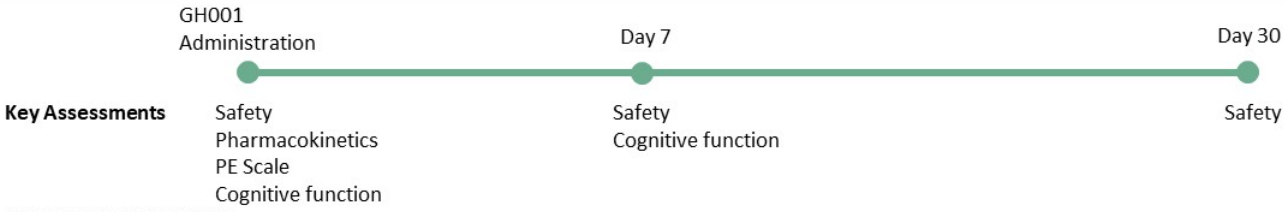
Phase 1 Clinical Pharmacology Trial in Healthy Volunteers GH001-HV-103

(Completed)

Clinicaltrials.gov ID: NCT05163691

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





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**
- **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, psychiatric safety assessments, 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; 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

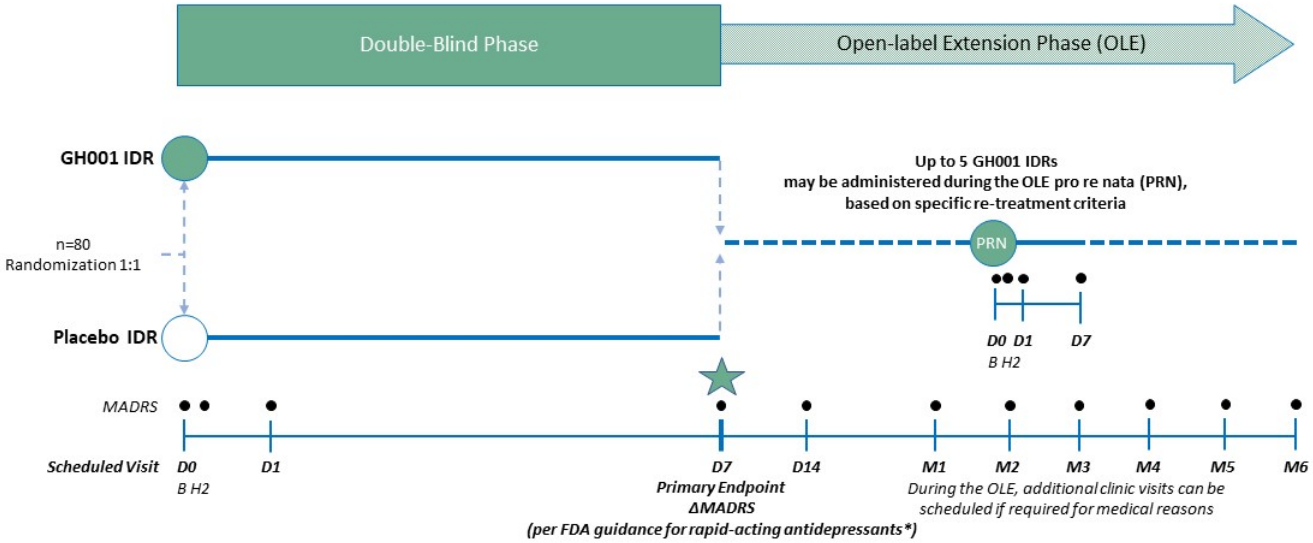
[1] 6 mg (n=1), 6-12 mg (n=3); 6-12-18 mg (n=4)
[2] 6-12 mg (n=3); 6-12-18 mg (n=5)

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

(Initiated)

EudraCT Number: 2022-000574-26

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

11 patent families filed 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

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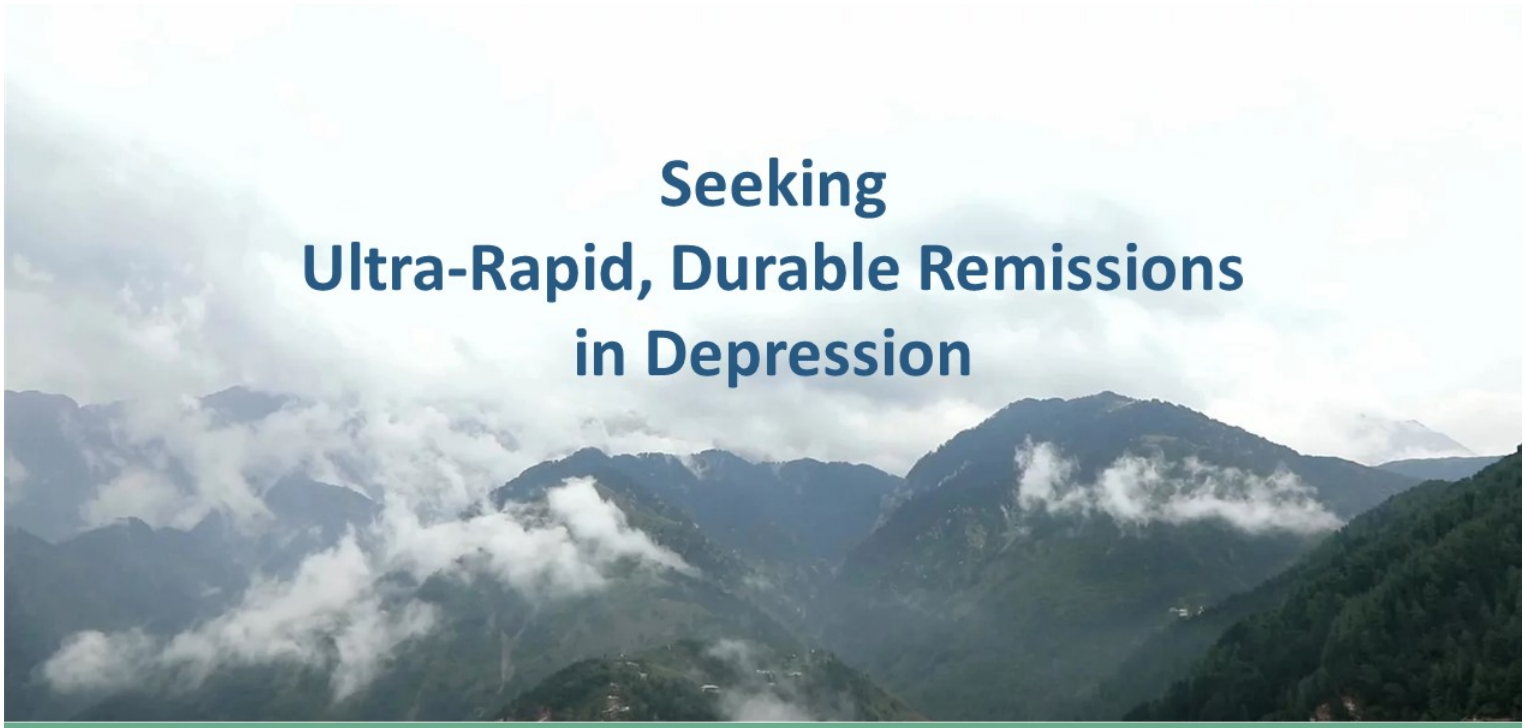
Anticipated Milestones and Financial Overview

- GH001
  - Complete multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in TRD
  - Submit U.S. IND for GH001 with proprietary aerosol delivery device in Q3 2023
  - Complete proof-of-concept Phase 2a trials in BDII and in PPD in Q4 2023
- GH002
  - Complete Phase 1 clinical pharmacology trial in healthy volunteers in Q4 2023
- GH003
  - Complete preclinical development
- Financial Overview
  - Cash, cash equivalents and marketable securities was $251.7 million as of December 31, 2022
  - We believe existing cash, cash equivalents and marketable securities will be sufficient to fund operating expenses and capital expenditure requirements into 2026



Seeking Ultra-Rapid, Durable Remissions in Depression