# 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 December 2021.

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	$\boxtimes$	Form 40-F			
ndicate by ch	eck mark if the registrant is su	bmitting the For	m 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): $\Box$			
ndicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):						

On December 6, 2021, GH Research PLC (the "Company") reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression ("TRD"). A copy the press release is attached hereto as Exhibit 99.1.

In connection with the release of these results, on December 6, 2021, the Company made available on its website an updated corporate presentation. A copy of the corporate presentation is attached hereto as Exhibit 99.2.

The fact that this 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 presentation is being provided as of December 6, 2021 and the Company does not undertake any obligation to update the presentation in the future nor to update forward-looking statements to reflect subsequent actual results.

### **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.

**GH Research PLC** 

Date: December 6, 2021

By: /s/ Julie Ryan

Name: Julie Ryan

Title: Group Finance Director

### **EXHIBIT INDEX**

Exhibit No. Description

99.1 Press release dated December 6, 2021
99.2 Corporate Presentation for December 2021



# GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression

- Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD
  - 7 of 8 patients (87.5%) were in remission (MADRS  $\leq$ 10) at day 7 after dosing (p<0.0001)
- Secondary endpoints met
  - Mean change from baseline in MADRS at day 7 after dosing was -24.4 points (-76%) (p<0.0001)
  - GH001 was well tolerated and no serious adverse events were reported
- In addition, we announce positive preliminary safety results from a Phase 1 clinical pharmacology trial of GH001 in 46 healthy volunteers with 30-day follow-up supporting the safety profile of GH001 beyond day 7.

**Dublin, Ireland, December 6, 2021** – GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD) (GH001-TRD-102).

The primary endpoint of the Phase 2 part of the trial was met with 7 of 8 patients (87.5%) in remission (Montgomery–Åsberg Depression Rating Scale (MADRS)  $\leq$ 10) at day 7 after dosing (p<0.0001). According to FDA Guidance for Industry, a 7-day endpoint is an appropriate primary efficacy endpoint for rapid-acting antidepressants.

The Phase 2 part of the clinical trial recruited 8 patients. The median age was 34 years. The median baseline severity of depression by MADRS was 32.

Patients followed a proprietary GH001 individualized dosing regimen administered on a single day with up to three increasing doses of GH001 (6 mg, 12 mg and 18 mg). The second and third doses were only administered in the event that the patient did not achieve a peak experience<sup>1</sup> (PE) at the previously administered dose. Based on this trial design, 6 patients received 6 mg and 12 mg doses of GH001 and 2 patients received 6 mg, 12 mg and 18 mg doses of GH001. 7 patients were able to achieve a PE at their final dose, and at this final dose the mean PE total score was 90.4.

Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with 5 in remission as early as 2 hours after dosing. The single patient who did not achieve a remission at day 7, also improved on day 7 versus baseline. 6 of the 7 patients in remission had achieved a PE at their final dose. The mean MADRS change from baseline for all 8 patients at day 7 was -24.4 points (-76%) (p<0.0001).

Compared with the single dose results in the previously reported Phase 1 part of the trial (12 mg, n=4; 18 mg, n=4), the proprietary GH001 individualized dosing regimen increased the rate of MADRS remission at day 7, increased the mean MADRS absolute change from baseline at day 7, increased the rate of PE, and increased the mean PE score achieved.

In accordance with the trial protocol, a study safety group (SSG) was established, including external experts, to evaluate the safety data for the clinical trial. All patients completed all planned visits. No serious adverse events (SAE) were reported. 7 of 8 patients (87.5%) experienced at least one adverse drug reaction (ADR), all of which were mild (81%) or moderate (19%) in intensity, and all of which resolved spontaneously. The ADRs reported were: headache, sensory disturbance (each in 3 patients), anxiety, flashback, nausea (each in 2 patients), muscle discomfort, abdominal discomfort, paresthesia, depressive symptom (each in 1 patient). Based on the full safety results of the trial, the SSG concluded that no unexpected or severe adverse effects and no clinically significant changes were observed in any of the safety laboratory analyses, vital signs, psychiatric safety assessments or measures of cognitive function and that no signal for suicidal ideation or behavior was observed.



#### Safety Results from Phase 1 Clinical Pharmacology Trial in Healthy Volunteers

In addition, we also reported positive preliminary safety results from a Phase 1 clinical pharmacology trial in healthy volunteers (GH001-HV-103).

This trial enrolled 46 healthy volunteers with 30-day safety follow-up. The trial investigated three different single doses of GH001 in a double-blind, placebo-controlled design (6 mg (n=8), 12 mg (n=8), 18 mg (n=8), placebo (n=2 in each dose group)) and a proprietary GH001 individualized dosing regimen with intra-subject dose escalation within a single day in an open-label, non-randomized design in two groups with two different intervals between doses (1 hour (n=8), 2 hours (n=8)).

All subjects completed all planned visits. No SAEs were reported. 11 of 24 subjects (45.8%) who received GH001 in the single-dose part and 0 of 6 subjects (0%) who received placebo in the single-dose part experienced at least one ADR. In the multiple-dose part, 7 of 16 subjects (43.8%) who received GH001 experienced at least one ADR. All ADRs were mild and all ADRs resolved spontaneously. In the single-dose part, the ADRs reported were: headache (in four participants), tachycardia, crying (each in two participants), chest discomfort, dizziness, dry mouth, dyskinesia, fatigue, hypoesthesia oral, retching, somnolence, tremor (each in one participant). In the multiple dose part, the ADRs reported were: fatigue (in three participants), headache (in two participants), abnormal dreams, paresthesia oral, crying, tension (each in one participant). No clinically relevant changes were observed for vital parameters, peak expiratory flow rate, safety laboratory analyses, ECG and psychiatric safety assessments.

The preliminary results of this 30-day trial support the safety profile of GH001 single doses and the proprietary GH001 individualized dosing regimen with intra-subject dose escalation within a single day. Final source data verification, the pharmacokinetic analyses and analyses of various secondary endpoints are still ongoing. The full results from this trial are intended to support the selection of the optimal dosing interval for the individualized dosing regimen in future studies of GH001.

<sup>1</sup>The occurrence of peak experiences (PE) is assessed using a proprietary visual analogue scale (PE scale), which averages answers scored by the patient from 0 to 100 for three parameters of the experience: intensity, feelings of loss of control and profoundness. A PE is defined as a total score of at least 75 on this scale.



#### **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 5-MeO-DMT therapies for the treatment of patients with treatment-resistant depression (TRD).

#### **About GH001**

Our lead product candidate, GH001, is formulated for 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. 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.

### **Forward-Looking Statements**

This press release contains statements that are, or may 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, 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 document speak only as of the date of this press release. 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: GHRS)** 

December 2021

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### **Disclaimer Regarding Forward-Looking Statements**

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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.

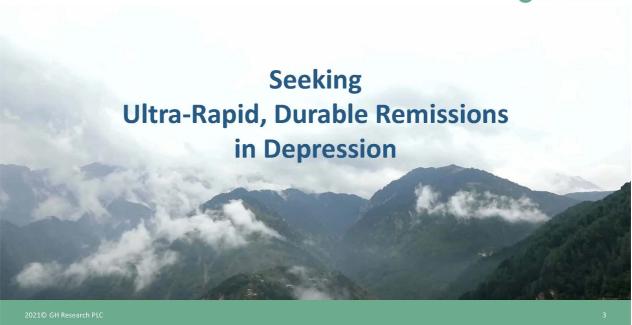
This presentation contains forward-looking statements, all of which are qualified in their entirety by this cautionary statement. Many of the forward-looking statements contained herein can be identified by the use of forward-looking words such as "may", "anticipate", "believe", "could', "expect", "should", "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 uncertainities that may cause actual results, outcomes, timing and performance to differ materially from those expressed or implied by such statements. These factors, risks and uncertainities include, but are not limited to: the costs and uncertainities associated with GH Research's research and development efforts; the inherent uncertainities 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 and availability of additional funding, 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

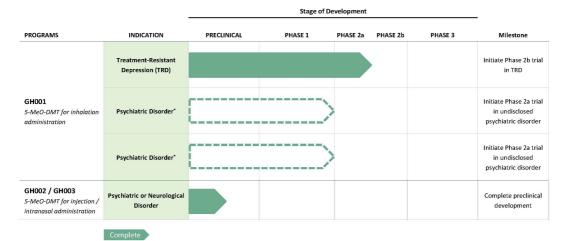
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# **Pipeline**



"In light of our completed Phase 1 clinical trial of GH001 in healthy volunteers and our completed Phase 1/2 trial in TRD, we plan to request clearance from European regulatory authorities to begin Phase 2a clinical trials in potients with two additions undisclosed psychiatric disorders

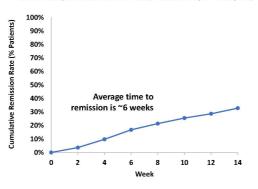
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### The Problem for Patients with Depression

### **Established Therapies are Slow-Acting**

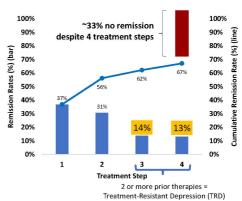
(STAR\*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)



Adapted from Trivedi et al., Am J Psychiatry 2006 and Rush et al., Am J Psychiatry 2006

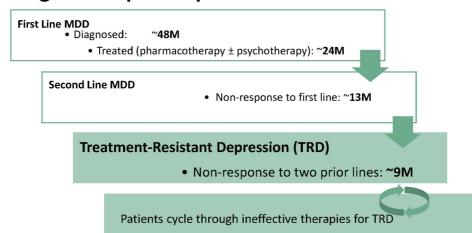
### ... Remission Rates in TRD < 15%

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





### Large and Open Depression Market EU and US



Company estimates based on this (five/www.nimh.nih.gov/heebth/statistics/maja-degression.strint; Wittchen et al., The size and burden of mental disorders and other disorders of the brain in Europe 2010, European Neuropsychopharmocology (2011); Ruch et al., Acute an Longer-Term Outcomes in Degressed Outpatients Requiring One or Several Treatment Steps ASTAR\*O Report, Am J Psychiatry 2006
MOD. Maior Depressive Disorder

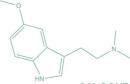
MOD. Maior Depressive Disorder

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### 5-MeO-DMT and GH001

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



5-MeO-DMT

- GH001 (5-MeO-DMT administration via a proprietary inhalation approach)
  - Intraday individualized dosing regimen for maximization of ultra-rapid remissions
  - Single visit initial treatment, with no structured psychotherapy
  - Potential for convenient and infrequent retreatment

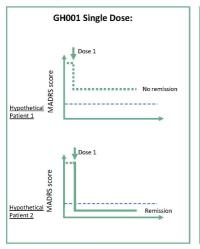


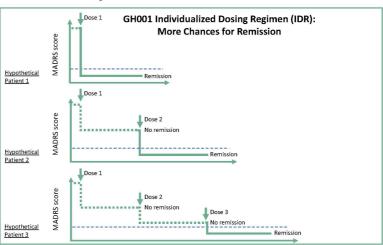
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# GH001 – Individualized Dosing Regimen (IDR) Designed to Achieve Ultra-Rapid and Durable Remissions





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

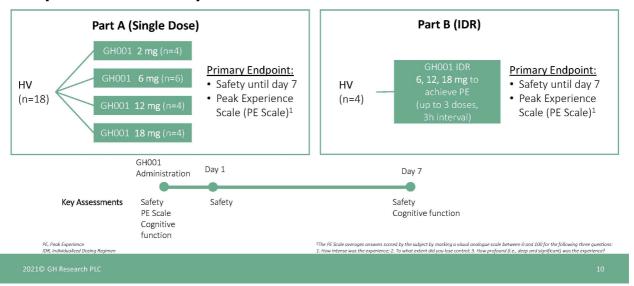
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Clinicaltrials any ID NCTM64083

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





## 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

		Part B (IDR)			
ADRs	2 mg (N=4)	6 mg (N=6)	12 mg (N=4)	18 mg (N=4)	IDR1 (N=4)
MedDRA Preferred Term	n	n	n	n	n
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				

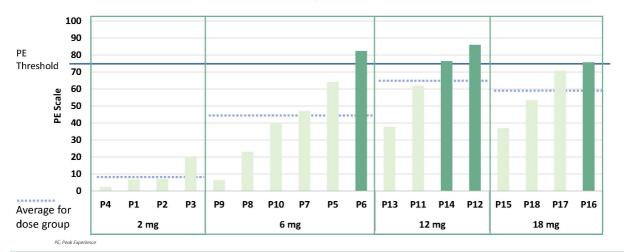
Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing IDR. Individualized Dosina Realmen

<sup>1</sup>6 mg (N=1); 6-12 mg (N=2); 6-12-18 mg (N=1)

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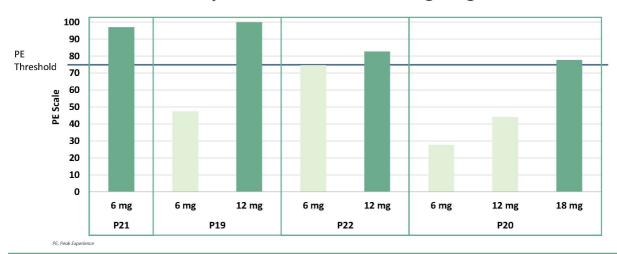
# Part A - Peak Experience (PE) Dose-Effects and Inter-Person Variability



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# Part B – Peak Experience (PE) Effect of Intraday Individualized Dosing Regimen



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

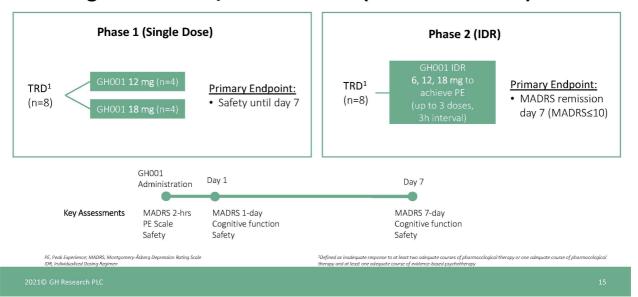
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Clinicaltrials any IO NCT0469860

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





### 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, vital signs, 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"

400-	Phase 1 (Si	Phase 2 (IDR) IDR¹ (N=8)	
ADRs	12 mg (N=4) 18 mg (N=4)		
MedDRA Preferred Term	n	n	n
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

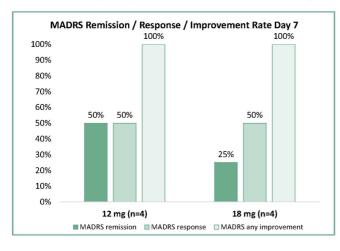
Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing IDR. Individualized Dosina Renimen: G-SSRS, Columbia-Suicide Severity Ratina Scale

<sup>1</sup>6-12 mg (N=6); 6-12-18 mg (N=2)

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## 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

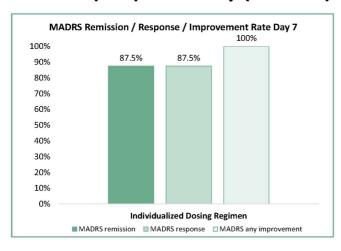
PE, Peak Experience; MADRS, Montgomery-Asberg Depression Rating Scale

MADRS remission = MADRS of \$10: MADRS resonage = Reduction of \$50% from baseline in MADRS

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## Phase 2 (IDR) – Efficacy (MADRS)



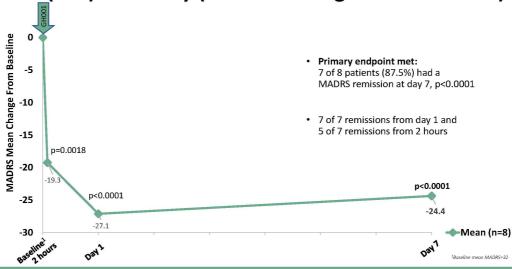
- Primary endpoint met:
   7 of 8 patients (87.5%) had a
   MADRS remission at day 7, p<0.0001</li>
- 7 of 8 patients had a PE and 6 of those had a MADRS remission at day 7

PE, Peak Experience; MADRS, Montgomery–Asberg Depression Rating Scale MADRS remission = MADRS of ≤10; MADRS response = Reduction of ≥50% from baseline in MADRS

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



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# 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%)	-12.8 (-41%)
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 Dosina Regimen

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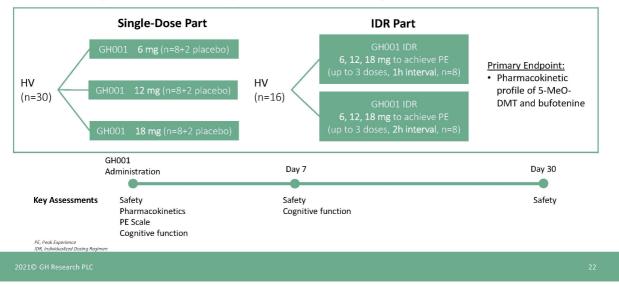
# Phase 1 Clinical Pharmacology Trial in Healthy Volunteers GH001-HV-103

(Recently completed, preliminary safety data available)

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





# Single Dose and IDR – Safety

#### Preliminary<sup>1</sup> 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 assessment, and psychiatric safety assessments, including the C-SSRS

	Single-dose				IDR	
ADRs	6 mg (N=8)	12 mg (N=8)	18 mg (N=8)	Placebo (N=6)	1h interval (N=8) <sup>2</sup>	2h interval (N=8) <sup>3</sup>
MedDRA Preferred Term	n	n	n	n	n	n
Abnormal dreams						1
Chest discomfort		1				
Crying			2		1	
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			

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

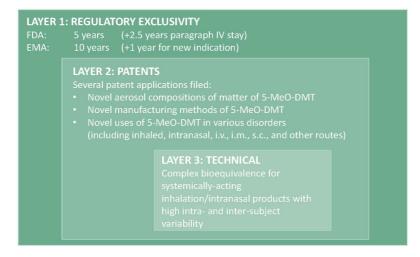
108. Individualized Dosing Regimen: G-SSRS. Columbia-Suicide Severity Rating Scale: Final source data writication, pharmacokinetic analyses of various secondary endocints are still analyses.

<sup>2</sup>6 mg (N=1), 6-12 mg (N=3); 6-12-18 mg (N=4) <sup>3</sup>6-12 mg (N=3); 6-12-18 mg (N=3)

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### **Three-Layer Protection Strategy**



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### **Board of Directors & Management**



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### **Core Development Team**



**Markus Breuer** Dipl. Chem. Dr. rer. nat. Patent Attorney, Co-founder breuer friedrich hahner



Aaron Cameron BSc, MSc, MBA VP, Technical Development Mylan GITERUM

MSD



Conor Burke BSc, PhD, MBA VP, Strategic Innovation



Peter Fitzpatrick Mallinckrodt JABIL

Scientific



Viktoria McDonald BE, MEM BSc (Hors), ERT BSc, MBS
Director, Device Development Director, Nonclinical Development Director, Quality Management



Aoife Soraghan









Padraig O'Grady BSc, PhD Clinical Project Manager SANOFI DGOD



**Fiona Ryan** BPharm, MSc, PhD Clinical Project Manager O Hearthor SOLVETRIN THERAPEUTICS

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Avril Feeney BSc, MSc CMC Project Manager Janssen T III Mylan



Inês Amaro MPharm, PhD CMC Project Manager

SUBLIMITY @ITERUM
Therapeutics Mylan\*



Alma Winther Sørensen BSc, MSc Corporate Project Manager



### **Scientific Advisors**



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



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

The professor of Psychiatry and Human Behavior,
Brown University
BROWN

BROWN





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



Michael Bauer
Prof. Dr. rer. nat. Dr. med.
Prof. Dr. med.
Chair, Department of Psychiatry and Psychotherapy, Head, Center for Affective Neuroscience, Technische Universität Dresden

Westernamen Carl Gestar Claus.
Charité, Berlin
CHARITÉ





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



# **Anticipated Milestones**

#### • GH001

- Request a pre-IND meeting with the FDA and a Scientific Advice meeting with the EMA in Q1 2022
- Pending outcome of the meetings, initiate randomized, controlled Phase 2b trial in TRD
- Request regulatory clearance for two Phase 2a trials in two additional psychiatric disorders in Q1 2022

#### GH002 and GH003

• Complete preclinical work and initiate Phase 1 trial in Healthy Volunteers

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