GH Research Announces Acceptance of Pharmaceutical Pipeline Presentation and Late-Breaking Posters at the American Society of Clinical Psychopharmacology 2025 Annual Meeting

May 15, 2025

DUBLIN, May 15, 2025 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the lives of patients by developing a practice-changing treatment in depression, today announced the acceptance of a Pharmaceutical Pipeline Presentation at the American Society of Clinical Psychopharmacology Annual Meeting (ASCP) in Arizona, United States from May 27 – 30, where Professor Michael E. Thase, MD, Professor of Psychiatry, Perelman School of Medicine, University of Pennsylvania will present clinical data from a randomized, double-blind, placebo-controlled Phase 2b clinical trial with GH001 in patients with treatment-resistant depression (TRD) (GH001-TRD-201).

"*The findings from this double-blind, placebo-controlled Phase 2b trial are truly exciting and - if replicated in larger trials - could prove to be a transformative leap in our efforts to help people with treatment-resistant depression. In clinical research there's a hierarchy of evidence and this well-controlled trial delivers robust evidence of the treatment's efficacy and safety. These findings build on prior successes studying drugs formerly pigeonholed as "psychedelics" and bring us closer to offering real hope to patients who have exhausted other options,*" said Professor Michael E. Thase, MD, Professor of Psychiatry, Perelman School of Medicine, University of Pennsylvania.

Additionally, two late-breaking posters have been accepted presenting safety and tolerability data from the double-blind part of the Phase 2b trial in TRD as well as data from a proof-of-concept trial with GH001 in postpartum depression.

"*The acceptance of a late-breaking poster for the Phase 2a proof-of-concept trial in postpartum depression highlights the importance of these results. GH001 was well tolerated with no serious adverse events reported. Postpartum depression remains a critical unmet need, often leaving women feeling isolated and overwhelmed during what should be a time of joy. With all ten participants in remission at Day 8, this proof-of-concept trial represents a new beacon of hope, offering the potential for effective treatment that could transform lives,*" said Dr William Gann, Sheffield Health and Social Care NHS FT (UK).

Finally, a poster has been accepted at the International Society for Bipolar Disorders (ISBD) Annual Conference in Chiba, Japan from September 17 – 19, where PD Dr. med. Philipp Ritter, MD, PhD will present the results of a Phase 2a clinical trial of GH001 in patients with bipolar II disorder and a current major depressive episode.

"Bipolar II disorder is often more chronic in its depressive course than bipolar I disorder and remains particularly difficult to treat. Available therapies frequently require weeks before clinically meaningful antidepressant effects emerge. In this proof-of-concept study, a single-day individualized dosing regimen of inhaled GH001 was well-tolerated, with no treatment-emergent serious adverse events and no signs of emerging mania. GH001 produced a 52% mean reduction in depressive symptoms by Day 8, suggesting both rapid onset and substantial efficacy, supporting GH001's potential as a therapeutic candidate to induce rapid improvement of bipolar II depression," said PD Dr. med. habil. Philipp Ritter, MBBS, University Hospital Carl Gustav Carus, Technische Universität Dresden, Dresden, Germany.

Abstract Details:

Pharmaceutical Pipeline Presentation (ASCP)

Presentation Title: Safety and Efficacy of GH001 in Treatment-Resistant Depression: Results from a Phase 2b, Double-Blind, Randomized Controlled Trial

Presenting Author: Michael E. Thase, Department of Psychiatry, University of Pennsylvania, Philadelphia, PA, USA

Date and Time: May 27 from 3.30pm MST

Late-breaking Poster (ASCP)

Poster Title: Safety and Tolerability of GH001 in Treatment-Resistant Depression: Results from a Phase 2b, Double-Blind, Randomized, Controlled Trial

Presenting Author: Wiesław J. Cubała, Department of Psychiatry, Faculty of Medicine, Medical University of Gdańsk, Gdańsk, Poland

Date and Time: May 29 from 11.30am to 1.00pm MST

Late-breaking Poster (ASCP)

Poster Title: Results of a Phase 2a Clinical Trial of Inhaled Mebufotenin (GH001) in Patients with Postpartum Depression

Presenting Author: Claus Bo Svendsen, GH Research, Dublin, Ireland

Date and Time: May 29 from 11.30am to 1.00pm MST

Poster (ASCP)

Poster Title: Results from Early-Stage Trials of Inhaled Mebufotenin (GH001) in Healthy Volunteers and Patients with Treatment-Resistant Depression

Presenting Author: Kelly Doolin, GH Research, Dublin, Ireland

Date and Time: May 29 from 11.30am to 1.00pm MST

Poster (ISBD)

Poster Title: Results of a Phase 2a Clinical Trial of Inhaled Mebufotenin (GH001) in Patients with Bipolar II Disorder and a Current Major Depressive Episode

Presenting Author: Philipp Ritter, Department of Psychiatry and Psychotherapy, Faculty of Medicine at the University Hospital Carl Gustav Carus, TU-Dresden, 01307, Dresden, Germany

About GH Research PLC

GH Research PLC is a clinical-stage biopharmaceutical company dedicated to transforming the lives of patients by developing a practice-changing treatment in depression. GH Research PLC's initial focus is on developing its novel and proprietary mebufotenin therapies for the treatment of patients with treatment-resistant depression (TRD).

About GH001

Our lead product candidate, GH001, is formulated for mebufotenin administration via a proprietary inhalation approach. Based on the observed clinical activity in our Phase 2b GH001-TRD-201 trial, where the primary endpoint was met with a MADRS reduction from baseline of -15.5 points compared with placebo on Day 8 ($p<0.0001$), we believe that GH001 has potential to change the way TRD is treated today.

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 for discussions with the FDA and the outcomes and resolution of such discussions related to 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.

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