GH Research Announces FDA Lifts Clinical Hold on GH001, Clearing Path for Global Phase 3 Initiation in 2026

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- GH001 cleared by FDA for U.S. clinical investigation, enabling U.S. subject enrollment
- Company to seek FDA alignment on global Phase 3 program replicating Phase 2b design
- Phase 3 initiation targeted for 2026

DUBLIN, Jan. 05, 2026 (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 that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on its Investigational New Drug Application (IND) for GH001.

This clearance enables U.S. subject enrollment and progresses the company toward alignment of its development across major jurisdictions.

“The FDA clearance is a major milestone and positions us to advance GH001 as a potential ultra-rapid and durable treatment option for TRD patients,” said Dr. Velichka Valcheva, Chief Executive Officer. “We continue to expect initiation of our global pivotal program in 2026. We look forward to meeting with the FDA to align on the design for the pivotal Phase 3 program.”

GH001 Phase 2b Profile Highlights from the Previously Reported Phase 2b trial (GH001-TRD-201):

- Primary endpoint met: -15.5 point placebo-adjusted MADRS reduction on Day 8 ($p<0.0001$)
- Ultra-rapid remission (57.5% of patients on Day 8); 73% remission at 6 months with infrequent dosing (~4 treatments on average)
- Short psychoactive experience (median of ~11 minutes)
- No required psychotherapy
- 99% of patients discharge-ready within 1 hour of dosing
- Favorable safety: well-tolerated, no serious treatment-related adverse events

Recent presentations at scientific conferences reinforce GH001's potential for integration into existing interventional psychiatry practices through its convenient administration profile.

Michael E. Thase, MD, Professor of Psychiatry, Perelman School of Medicine at the University of Pennsylvania, said, “The large and rapid antidepressant effect observed with GH001 in the Phase 2b trial, combined with sustained remission through infrequent, short clinic visits, has the potential to be practice-changing for patients with treatment-resistant depression.”

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 the 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 expectations with regard to initiating our global pivotal program, and the expected timing of such initiation, 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.

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