GH Research Provides Updates and Guidance on its Clinical Development Program for GH001 in Treatment-Resistant Depression

September 29, 2023

DUBLIN, Ireland, Sept. 29, 2023 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today provided updates and guidance on its clinical development program for GH001, its proprietary inhalable mebufotenin (5-MeO-DMT) product candidate, in treatment-resistant depression (TRD).

Development Strategy

As previously announced, following successful completion of our Phase 1/2 trial of GH001 in patients with TRD (GH001-TRD-102), we are recruiting for a European multi-center, randomized, double-blind, placebo-controlled Phase 2b trial of GH001 in patients with TRD (GH001-TRD-201), where GH001 is administered using an externally-sourced inhalation device. Separately, we submitted, in the third quarter of 2023, an Investigational New Drug Application (IND) for GH001 with the U.S. Food and Drug Administration (FDA), with the purpose to initiate a Phase 1 healthy volunteer clinical pharmacology trial, where GH001 is administered using our proprietary aerosol delivery device (GH001-HV-106). The trial, subject to regulatory clearance from the FDA, is designed to support bridging to the clinical data generated with the externally-sourced inhalation device we currently use in our European Phase 2b trial such that we can initiate, subject to data and regulatory clearance, a subsequent global Phase 3 pivotal program using our proprietary device.

Update and Guidance on European Phase 2b Clinical Trial of GH001 in Patients with TRD

Our multi-center, randomized, double-blind, placebo-controlled Phase 2b trial of GH001 in patients with TRD (GH001-TRD-201) is now approved in seven European countries and is expected to recruit approximately 80 patients across approximately 20 sites. The primary objective of the trial is 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 is 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. With 14 sites initiated and additional site initiations scheduled, we are now in a position to provide guidance on completion of the double-blind phase of this trial, which is expected to occur in the third quarter of 2024, with top-line data available in the third or the fourth quarter of 2024.

Update on IND for GH001

We recently submitted an IND for GH001 with the FDA. At the end of the 30-day review period, the FDA advised that it had placed our IND on clinical hold due to "21 CFR 312.42(b)(1)(iv): Insufficient information to assess risks to human subjects". The FDA indicated that a letter with additional details will be issued within 30 days. We are awaiting that follow-up letter from the FDA and look forward to working with them to resolve any outstanding concerns. We plan to provide an update in our next earnings release in November 2023.

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/A filed with the U.S. Securities and Exchange Commission for the year ended December 31, 2022 is available at www.ghres.com and shareholders may receive a hard copy free of charge upon request.

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 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 in patients with TRD and in two Phase 2a proof-of-concept trials in patients with bipolar II disorder and a current depressive episode and in patients with postpartum depression.

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, 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, including the FDA's communication plans related to the clinical hold on the GH001 IND, our plans and expectations for discussions with the FDA and the outcomes of such discussions, 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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