GH Research Provides Business Updates and Highlights Key Upcoming Milestones

January 9, 2023

- Initial approvals received for Phase 2b trial of GH001 in TRD (GH001-TRD-201), initiation of this trial expected in Q1 2023
- Development of proprietary aerosol delivery device for GH001 progressed, IND submission with this device expected in Q3 2023
- Phase 1 trial of GH002 in healthy volunteers (GH002-HV-105) initiated, completion of this trial expected in Q4 2023
- New patent application filed, expanding patent portfolio to 11 families
- Mebufotenin selected by WHO as International Nonproprietary Name for 5-MeO-DMT

DUBLIN, Ireland, Jan. 09, 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 on its business and highlighted key upcoming milestones.

GH001 for the treatment of TRD

GH001 is our proprietary inhalable mebufotenin (5-MeO-DMT) product candidate. We have recently received initial regulatory and ethical approvals for our planned multi-center, randomized, double-blind, placebo-controlled Phase 2b trial of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201). We continue to expect initiation of this trial in several European countries in the first quarter of 2023. Trial design details are described in our updated corporate presentation, which is available in the investor section on our website.

Proprietary aerosol delivery device for GH001

In 2021, we initiated the development of a proprietary aerosol delivery device for GH001 for use in our pivotal clinical trial program and for commercial use. Based on recent development progress, we now expect to submit an IND for GH001, delivered with this proprietary device, in the third quarter of 2023. The IND-opening study will 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. Due to the progress with our proprietary aerosol delivery device, we no longer plan to submit an IND with this third-party device.

GH002

GH002 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary injectable approach. The previously announced randomized, double-blind, placebo-controlled, dose-ranging clinical pharmacology trial of GH002 in healthy volunteers (GH002-HV-105) has recently been initiated. We expect to complete this trial in the fourth quarter of 2023.

Intellectual property

We have recently filed a new device-related patent application, expanding our patent portfolio to 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.

Other updates

We are pleased to announce 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. From this point forward, we will introduce the nomenclature mebufotenin into our communications.

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 filed with the U.S. Securities and Exchange Commission for the year ended December 31, 2021 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 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 single-day individualized 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. GH001 is expected to enter Phase 2b clinical development in TRD in the first quarter of 2023.

About GH002 and GH003

GH002 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary injectable 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.

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, our cash runway, 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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