GH Research Announces Grant of European Patent Covering all Mebufotenin (5-MeO-DMT) and Mebufotenin Salt Products For Use in the Treatment of Major Depressive Disorder and Treatment-Resistant Depression

January 18, 2024

DUBLIN, Ireland, Jan. 18, 2024 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today announced that it recently received a communication from the European Patent Office (EPO) that it has been granted a patent with claims directed to mebufotenin (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in treating patients diagnosed with major depressive disorder (MDD) and treatment-resistant forms of MDD, such as treatment-resistant depression (TRD).

The newly granted patent, EP3927337, which will have an effective date of February 14, 2024, and an expiry date of no earlier than 2040, is expected to cover all mebufotenin (5-MeO-DMT) and mebufotenin salt products for use in the treatment of MDD and TRD, including but not limited to products administered through pulmonary inhalation, intravenous and intranasal routes. It is therefore expected to effectively fortify the company's position at the forefront of novel rapid-acting antidepressant treatments. Similar patent applications are pending on behalf of the company in the US and in over thirty other jurisdictions, aiming to provide broad coverage in all key geographies for the therapeutic use of mebufotenin (5-MeO-DMT) in MDD and TRD.

The present grant represents the first of many expected milestones for GH Research's intellectual property (IP) portfolio as the company continues to advance its additional more than 25 unique international patent applications, that relate to various further aspects of mebufotenin (5-MeO-DMT) therapies, including use for treatment of various disorders via inhaled, nasal, buccal, sublingual, intravenous, intramuscular or subcutaneous routes; novel aerosol compositions of matter; novel manufacturing methods for preparation and purification; novel salt forms; and novel delivery device-related features.

Theis Terwey, CEO and Co-founder of GH Research said: "We are committed to providing highly effective new therapies to patients in mental health care who are underserved by existing treatments. Having a strong IP portfolio helps us with this mission, and it is satisfying to have the EPO endorse the strength of our IP. We believe the EPO's grant of this patent, in view of various third-party observations submitted during the examination process, reflects the fact that our IP portfolio is characterized by early priority dates and is underpinned by the earliest clinical data on the use of mebufotenin to treat mental illness. We feel well placed to progress the rest of our patent portfolio through the examination process in Europe, the US and beyond, and are looking forward to exploring additional opportunities with mebufotenin through continuous research and development."

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 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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