



GH Research Ltd. Announces Completion of Phase 1 Clinical Study with GH001 (5-Methoxy-N,N-Dimethyltryptamine) in Healthy Volunteers and Updates on Further Progress

November 19, 2020

DUBLIN, Nov. 19, 2020 /PRNewswire/ -- GH Research Limited ("GH Research" or "the Company") today announced the successful completion of a Phase 1 clinical study with GH001 in healthy volunteers. The Company is currently recruiting for a Phase 1/2 clinical study with GH001 in patients with Treatment-Resistant Depression.

GH Research is a privately-held, clinical-stage biopharmaceutical company, founded in 2018, developing novel therapies for the management of mental diseases. The Company is focused on developing medicines utilizing 5-Methoxy-*N,N*-Dimethyltryptamine ("5-MeO-DMT"), a psychoactive substance from the tryptamine class.

The Company's lead product, GH001, is an innovative drug product for 5-MeO-DMT administration via a proprietary inhalation approach. GH001 has the potential to offer an ultra-rapid clearance of symptoms with long-term sustained remission after a single administration session. In the completed Phase 1 healthy volunteer study (GH001-HV-101), GH001 was safe and well-tolerated at the investigated dose levels. A dose range and an individualized dosing regimen for use in patients were defined. GH001 is currently being investigated in a Phase 1/2 trial (GH001-MDD-102) in patients with Treatment-Resistant Depression.

"GH Research is executing an accelerated clinical development program with GH001 in patients with Treatment-Resistant Depression. GH001 has the potential to establish a new paradigm in the treatment of a range of mental diseases," said Florian Schönharting, Chairman of the Board of Directors of GH Research.

Spike Loy, Managing Director at BVF Partners L.P. ("BVF"), a San Francisco-based private investment firm, and a Director of the Company, added, "BVF is excited to be involved with GH Research and it is a privilege to help bring this promising and differentiated program to patients."

The Company plans to clinically investigate GH001 in additional indications. GH002, an innovative injectable formulation of 5-MeO-DMT, is expected to enter the clinic in 2021.

About GH001

GH001 is an innovative drug product for 5-Methoxy-*N,N*-Dimethyltryptamine (5-MeO-DMT) administration via a proprietary inhalation approach. A healthy volunteer study with GH001 (GH001-HV-101) has been completed, establishing the safety of the inhalation approach and the appropriate GH001 dose range for further clinical studies. A Phase 1/2 study with GH001 in patients with Treatment-Resistant Depression is ongoing (GH001-MDD-102).

About GH Research Ltd.

GH Research Ltd. is a privately-held clinical-stage biopharmaceutical company, founded in 2018, developing novel therapies for the management of mental diseases. The Company's focus is on innovative ultra-rapid and long-acting therapies for people living with mental illness. The Company's lead product, GH001, has the potential to offer ultra-rapid and deep remissions in depression. For more information, see www.ghres.com.

About BVF Partners L.P.

BVF Partners L.P. is a San Francisco-based private investment partnership specializing in fundamentally-driven public biotechnology investments. Since its inception in 1993, BVF has strived to build concentrated, long-term investments in small-cap biotechnology companies while performing rigorous diligence and ongoing monitoring of its investments. BVF is committed to working with its portfolio companies as partners in their successes.

GH Research Ltd. Forward Looking Statements

This press release contains forward-looking statements, all of which are qualified in their entirety by this cautionary statement. Any statements contained herein that do not describe historical facts are forward-looking statements that are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcomes, timing and performance to differ materially from those expressed or implied by such statements. These factors, risks and uncertainties include, but are not limited to: the costs and uncertainties associated with the Company's research and development efforts; the inherent uncertainties associated with the conduct, timing and results of preclinical and clinical studies of the Company's product candidates; the Company's ability to obtain, maintain, enforce and defend issued patents; and the adequacy of the Company's capital resources and availability of additional funding. Except as otherwise noted, these forward-looking statements speak only as of the date of this press release, and the Company undertakes no obligation to update or revise any of such statements to reflect events or circumstances occurring after this press release. Readers are cautioned not to place undue reliance on the forward-looking statements contained in this press release.

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