Inside information: Herantis Pharma announces positive topline data from the Phase 1a clinical trial of HER-096, a disease modifying therapeutic developed for Parkinson's disease

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- HER-096 Phase 1a clinical trial met primary and secondary endpoints;
- Subcutaneous single dose injections of HER-096 had overall good safety and tolerability profile in young and older healthy subjects;
- The pharmacokinetic profile showed fast uptake of HER-096 after subcutaneous injection and demonstrated blood-brain barrier (BBB) penetration in humans;
- Management will host a webinar 15:00 pm EEST today (see information on the webinar below).

Herantis Pharma Plc ("Herantis"), a clinical-stage biotechnology company developing disease-modifying therapies for Parkinson's disease, today announced positive results from its Phase 1a clinical trial in healthy subjects. The clinical trial demonstrated favorable safety and tolerability, fast uptake of HER-096, and significant HER-096 concentrations in the cerebrospinal fluid (CSF) after a single subcutaneous injection.

"We are very pleased with the topline results. This trial demonstrated that following subcutaneous administration, HER-096 efficiently penetrates the blood-brain barrier reaching a therapeutic concentration in the human cerebrospinal fluid. It is encouraging to see that the concentration of HER-096 remained at a high level in the cerebrospinal fluid longer than expected. These results in combination with our strong preclinical data, provide a solid basis for further clinical development in Parkinson's disease and in other neurodegenerative diseases. In addition, these data are important for advancing our partnering discussions" said **Antti Vuolanto, CEO of Herantis**. *"I would like to thank the healthy volunteers for their participation in this trial, our partners for their contribution, and the great Herantis team for finalizing the trial ahead of the planned schedule. We are now looking forward to advancing HER-096 into the next phase of clinical development."*

Anders Gersel Pedersen, M.D, Chairman of Herantis Scientific Advisory Board, formerly Director at Eli Lilly and Company, and EVP at Lundbeck, commented: *"The safety and CSF data of HER-096 in the Phase 1a clinical trial combined with the strong preclinical efficacy data are very encouraging and makes HER-096 a very promising clinical-stage disease-modifying drug candidate addressing the unmet clinical need in Parkinson's disease."*

Topline data overview

- Overall good safety and tolerability profile in young and older healthy subjects. As expected, there were mild local injection site adverse events both in the HER-096 and the placebo groups.

- Plasma pharmacokinetic (PK) profile in humans is well aligned with preclinical data. Maximum plasma concentration reached at the highest dose level (300 mg) was approximately 10 000 ng/ml and the plasma half-life was approximately 2 hours in all dose groups in young subjects and 2.5 hours in older subjects. Elimination of HER-096 occurred mainly via renal excretion as predicted by preclinical studies.

- HER-096 concentration in the cerebrospinal fluid (CSF) reached 50 – 100 ng/ml within 4 – 12 hours after a 200 mg subcutaneous dose of HER-096. This is in the predicted pharmacologically active CSF concentration range and is aligned with the preclinical data.

Based on these very encouraging Phase 1a results, Herantis intends to advance HER-096 into a Phase 1b clinical trial in 2024 with the aim to demonstrate safety and tolerability for multiple subcutaneous dosing of HER-096 in Parkinson's disease patients, start other preparations for Phase 2 readiness and explore the potential of HER-096 in other indications.

About the HER-096 Phase 1a clinical trial
The Phase 1a trial was a randomized, double-blinded, placebo-controlled, safety, tolerability, and pharmacokinetic trial of subcutaneous single ascending doses of HER-096.

- In part 1 of the trial, a single subcutaneous dose of HER-096 or placebo was administered to young, healthy, male subjects (20-45 years of age) to assess safety, tolerability, and the pharmacokinetic profile of HER-096 (plasma, urine) in six ascending dose groups, 6 dosed with HER-096 and 2 dosed with placebo in each dose group.

- In the part 2 of the trial, 12 older healthy subjects (50-75 years of age), both males and females, were administered a single dose of HER-096 to assess safety, tolerability, and the pharmacokinetic profile of HER-096 including blood-brain barrier penetration (plasma, urine, CSF).

In total, the trial recruited 60 healthy volunteer subjects. The trial took place at a single site in Finland and was conducted by the contract research organization Clinical Research Services Turku – CRST Oy. The trial is registered at ClinicalTrials.gov with an ID NCT05915247.

Webinar (in English) will be held today at 15:00 EEST / 14:00 CEST

Link to the webinar: Register here

Please join the webinar a few minutes in advance. You need a Zoom account to register for this event. Questions can be submitted throughout the webcast event.

Following the webcast, a recording will be available on Herantis Pharma's website: https://herantis.com/news-events/video-presentations/

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About Herantis Pharma Plc
Herantis Pharma Plc is a clinical-stage biotechnology company developing disease modifying therapies for Parkinson's disease. Herantis' lead product HER-096, is an advanced small synthetic chemical peptidomimetic molecule developed based on the active site of the CDNF protein. It combines the compelling mechanism of action of CDNF with the convenience of subcutaneous administration. A Phase 1a clinical trial has demonstrated a good safety and tolerability profile, and efficient blood-brain barrier penetration of subcutaneously administered HER-096 in humans. The shares of Herantis are listed on the Nasdaq First North Growth Market Finland.

Company website: www.herantis.com

About HER-096
HER-096 is a peptidomimetic molecule designed to retain the biological activity of the neuroprotective CDNF protein. HER-096 has demonstrated to have a multimodal mechanism of action mimicking CDNF and to improve functional recovery of damaged neurons in preclinical models. Importantly, HER-096 has been shown to readily penetrate the blood-brain barrier both in clinical and preclinical studies allowing convenient subcutaneous dosing. Thanks to its multimodal mechanism of action, Herantis' HER-096 has the potential to stop the progression of Parkinson's disease and significantly improve patients' quality of life.

Forward-looking statements
This company release includes forward-looking statements which are not historical facts but statements regarding future expectations instead. These forward-looking statements include without limitation, those regarding Herantis' future financial position and results of operations, the Company's strategy, objectives, future developments in the markets in which the Company participates or is seeking to participate or anticipated regulatory changes in the markets in which the Company operates or intends to operate. In some cases, forward-looking statements can be identified by terminology such as "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "guidance," "intend," "may," "plan," "potential," "predict," "projected," "should" or "will" or the negative of such terms or other comparable terminology.

By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance and are based on numerous assumptions. The Company's actual results of operations, including the Company's financial condition and liquidity and the development of the industry in which the Company operates, may differ materially from (and be more negative than) those made in, or suggested by, the forward-looking statements contained in this company release. Factors, including risks and uncertainties that could cause these differences include, but are not limited to risks associated with implementation of Herantis' strategy, risks and uncertainties associated with the development and/or approval of Herantis' drug candidates, ongoing and future clinical trials and expected trial results, the ability to commercialize drug candidates, technology changes and new products in Herantis' potential market and industry, Herantis' freedom to operate in respect of the products it develops (which freedom may be limited, e.g., by competitors' patents), the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions, and legislative, regulatory and political factors.

In addition, even if Herantis' historical results of operations, including the Company's financial condition and liquidity and the development of the industry in which the Company operates, are consistent with the forward-looking statements contained in this company release, those results or developments may not be indicative of results or developments in subsequent periods.

Attachments

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