Herantis Pharma Plc: First healthy volunteers dosed in the part 2 of the HER-096 Phase 1a clinical study

Herantis Pharma Plc
Press release, 22 August 2023 at 10:30 a.m. EEST

Herantis Pharma Plc ("Herantis"), a clinical-stage biotechnology company developing disease modifying therapies for Parkinson's disease, announces that the dosing of the healthy volunteers in part 2 of the Phase 1a clinical study has been started based on decision from the Data and Safety Monitoring Board.

Top-line data of the Phase 1a clinical study is expected in Q4 2023.

About the HER-096 Phase 1a clinical study:

Phase 1a is a randomized, double-blinded, placebo-controlled, safety, tolerability, and pharmacokinetic study of subcutaneous single ascending doses of HER-096. In part 1 of the study, HER-096 or placebo was administered to young healthy volunteers and in the now started part 2 of the study, 12-16 elderly healthy volunteers, both males and females, will be administered with a single dose of HER-096 to evaluate the blood-brain-barrier penetration of HER-096. In total, the study aims to recruit around 60 healthy volunteer subjects.

The study takes place in Turku, Finland conducted by the contract research organization CRST.

Link to ClinicalTrials.gov for more information about the study:

https://www.clinicaltrials.gov/study/NCT05915247?term=herantis&rank=1

More information about participation into the study can be found on the website (only in Finnish):

https://osallistulaaketutkimukseen.fi/kliininen-laaketutkimus-50-75-vuotiaille-c739/

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 in 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.

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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 parent CDNF protein. It combines the compelling mechanism of action of the CDNF protein with the convenience of subcutaneous administration. The ongoing Phase 1a clinical study will assess safety, tolerability, and blood-brain barrier penetration of subcutaneously administered HER-096.

Top-line data is expected in Q4-2023. The shares of Herantis are listed on the Nasdaq First North Growth Market Finland.

Company website: www.herantis.com

Forward-looking statements

This press 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.