Herantis Pharma announces submission of a Clinical Trial Application (CTA) for a Phase 1 study for HER-096

Herantis Pharma Plc, Press release, 19 December 2022 at 2:15 p.m. EET

The purpose of the Phase 1 study is to demonstrate safety, tolerability, and blood-brain barrier penetration of HER-096 in human.

Herantis Pharma Plc ("Herantis") developing disease-modifying therapies for Parkinson's disease, announced it submitted a Clinical Trial Application (CTA) today to the Finnish Medicines Agency Fimea, the national competent authority for regulating pharmaceuticals. The Phase 1 study, which includes assessment of safety, tolerability, and blood-brain barrier penetration in healthy volunteers, will be carried out in Finland.

"Filing of the CTA demonstrates the substantial progress we have made in advancing the HER-096 program during this year including conducting the GLP preclinical safety studies and GMP-manufacturing", said Antti Vuolanto, the CEO of Herantis Pharma. "The compelling preclinical data supports the potential of HER-096 to be a disease-modifying therapy for Parkinson's disease with a unique mechanism of action. Pending decision from Fimea, we look forward to the first HER-096 human dose in 1H 2023."

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 an innovative biotech 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 shares of Herantis are listed on the Nasdaq First North Growth Market Finland and Nasdaq First North Growth Market Sweden.
For more information, please visit www.herantis.com**.**

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.