

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

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Herantis will initiate the Phase 1 study with the aim to demonstrate evidence of HER-096 safety and blood-brain penetration in humans.

Herantis Pharma Plc ("Herantis"), a company developing disease-modifying therapies for Parkinson's disease, is pleased to announce that the Finnish Medicines Agency, Fimea and the ethics committee have approved the Clinical Trial Application (CTA) submitted in December 2022. The Phase 1 study will be conducted in Finland.

"We are excited to commence HER-096 clinical development", said Antti Vuolanto, the CEO of Herantis Pharma. "The regulatory approval to start first HER-096 in-human study is an important milestone for Herantis on our path of developing a potentially disease-modifying treatment for Parkinson's disease. This progress is key for our strategy of pursuing partnering opportunities for HER-096."

About the HER-096 Phase 1 study:

The approved study is a randomized, double-blinded, placebo-controlled, safety, tolerability, and pharmacokinetic study of subcutaneous single ascending doses of HER-096 in healthy volunteer subjects.

About HER-096

HER-096 is a peptidomimetic molecule designed to retain the biological activity of the neuroprotective CDFN protein. HER-096 has demonstrated to have a multimodal mechanism of action mimicking CDFN 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.

For more information, please contact:

Julie Silber/Gabriela Urquilla

Tel: +46 (0)7 93 486 277/+46 (0)72-396 72 19

Email: ir@herantis.com

Certified Advisor: UB Securities Ltd, Finland: +358 9 25 380 225, Sweden: +358 40 5161400

Company website: www.herantis.com

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 CDFN protein. It combines the compelling mechanism of action of the CDFN protein with the convenience of subcutaneous administration. The shares of Herantis are listed on the Nasdaq First North Growth Market Finland.

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.