Herantis Pharma Announces R&D Update

Herantis Pharma Plc
Company release, insider information, 1 November 2020 at 10:00 p.m. Eastern European Time

Herantis Pharma Plc ("Herantis"), an innovative drug development company aiming to revolutionize standard therapeutic approaches with leading biologic and gene therapy, today announced an update on its Research & Development pipeline. Management will host a webcast on the R&D Update at 2:00 p.m. CET on Monday 2nd November 2020.

Updates on the CDNF Program:
The company has recently reported 6- and 12-month data of an EU funded Phase I/II clinical study with Cerebral Dopaminergic Neurotrophic factor (CDNF) in patients with Parkinson's Disease (PD). Being a first-in-human study with CDNF, the primary endpoint was safety and tolerability, which was successfully achieved for CDNF treatment. The advanced stage of the patients recruited into the study, as required by regulators and ethics committees, precluded any efficacy conclusions due to already significant loss of dopaminergic cells in this patient group. The exploratory secondary endpoints did however suggest no worsening of the patients' Parkinson's Disease where typically annual deterioration would have been expected, with additional promising biological signals observed in a few patients. CDNF is one of the few clinical stage assets in development targeting Parkinson's Disease with potential for disease modification.

In the study, CDNF was administered directly into the brain via an investigational, surgically implanted device appropriate for a small, exploratory study of limited duration. This invasive route of administration requiring surgery, however, significantly limits the available patient population for further clinical development. It also risks approvability of the therapy as a drug-device combination, subsequent commercialization, and potentially delays partnerability of CDNF. The aim of Herantis is to develop a treatment that can benefit patients with all stages of Parkinson's Disease and not be constrained to late stage patients. If CDNF-treatment is started as early as possible after onset of disease, patients can be expected to optimally benefit from the biological disease modifying and regenerative effects of CDNF treatment.

Thus, Herantis has decided to evaluate the best path forward with its clinical stage asset CDNF, using alternative administration methods. Instead of committing significant resources towards a Phase II study involving an implanted surgical device the company has, at this stage, resolved to pursue more patient-friendly modes of delivery that do not require the need for a surgical device. In this way, Herantis will build on the current research data and knowledge attained from the Phase I/II study and purpose the drug for alternative available administration options such as via subcutaneous injection or intranasal application. This will facilitate the CDNF clinical development program, allow Herantis to explore additional indications and increase the attractiveness of its CDNF-asset to partners.

“Following a review of and learnings from the CDNF program to date and building on the recently completed Phase I/II data, we believe this new direction for CDNF is optimal moving forward. It would allow patients suffering from Parkinson’s Disease to be treated early with CDNF, and it would also maximize and expedite our chances of success with partners, regulators, and commercialization of both our Parkinson’s Disease assets – CDNF and xCDNF - to earlier inflection points. This aligns closely with our objective of establishing new frontiers of care in debilitating neurodegenerative diseases,” commented *Craig Cook, CEO*. “We are focused on ensuring that our resources are targeting the strengths of our assets while at the same time mitigating risks and creating value for all our stakeholders.”

Updates on the xCDNF Program:
The company continues to progress on track for final xCDNF lead selection early in 2021. This program focuses on treatment of Parkinson’s Disease and other neurodegenerative diseases, without the need for a surgically implanted medical device, using patented, chemically synthesized small but potent biologically active fragments of the parent CDNF molecule. Preclinical data, following simple parenteral dosing, e.g., with subcutaneous injection, indicate that these fragments can reach the key areas of the brain in therapeutic concentrations.

“We are very encouraged by the potential of this program as we continue through the research phase. Additionally, we have obtained invaluable insight from the recently completed CDNF Phase I/II study that is directly relevant to this program and its future successful development. Both CDNF and xCDNF, with their proteostatic mechanism of action, provide a compelling portfolio of assets for the spectrum of neurodegenerative diseases therapies sought by patients as well as the pharmaceutical industry,” stated *Henri Huttunen, Herantis CSO.*

Updates on the VEGF-C Lymfactin® Program:
A fully funded Phase II study in Lymphedema remains on schedule with the next data readout expected in Q1 2021. In addition, a 24-month follow-up data readout is expected soon for the already completed Phase I study, which at 12 months confirmed Lymfactin® was safe and well tolerated by patients with promising improvements observed in signs and symptoms of disease. Lymfactin® is a novel growth factor gene therapy that aims to regenerate and potentially cure the lymphatic system where it has been damaged by cancer treatments including both surgery and radiotherapy, such as that for Breast Cancer Associated Lymphedema (BCAL), the initial indication being studied in the current Phase II.

“Lymfactin is an intriguing program in gene therapy, which is a clear focus area for the biotech and pharmaceutical industry at present. This program is furthermore unique in that it is targeted to be the first medical therapy in the treatment of BCAL. We are excited at the prospect of this program for oncology related applications, as well as beyond for other lymphatic related diseases,” added *Antti Vuolanto, Herantis COO*.

R&D Update webcast: Monday 2nd November 2020 at 2:00 p.m. CET

To join: https://attendee.gotowebinar.com/register/1293647308971278091

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About Herantis Pharma Plc
Herantis Pharma Plc is an innovative drug development company looking to break the boundaries of standard therapeutic approaches. Our regenerative medicine drug candidates include i. CDNF biological therapy that acts on the proteostatic mechanisms of disease for the treatment of Parkinson's disease and other neurodegenerative diseases, and ii. Lymfactin® VEGF-C gene therapy for restoring lymphatic structure and function for the treatment of oncology related secondary Lymphedema and other lymphatic based diseases. The Herantis programs are potentially disease modifying that treat the cause as well as symptoms of disease, and bring the innovation necessary to provide further treatment options in underserved diseases. The shares of Herantis are listed on the Nasdaq First North Growth Market Finland and Nasdaq First North Growth Market Sweden.

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.