Press Release

Herantis Pharma Announces Favorable 24-Month Follow-Up Review from Phase I Lymfactin® Trial in Breast Cancer Associated Lymphedema

Key Highlights:

- Safety and tolerability maintained through to 24 months
- Clinically meaningful improvements after 12 months, maintained out to 24 months
- Top-line data for follow on Phase II study expected in Q1 2021 after 12 months blinded follow-up

Herantis Pharma Plc
Company release, 17 November 2020 at 9:00 a.m. Eastern European Time

Herantis Pharma Plc ("Herantis"), an innovative drug development company pioneering new disease modifying and regenerative biologic and gene therapies, today announced its novel gene therapy candidate Lymfactin®, a Vascular Endothelial Growth Factor C (VEGF-C) expressing adenoviral vector for the treatment of secondary Lymphedema, continues to be safe and well tolerated at 24 months in all patients with no severe adverse events.

The treatment is focused on lymphedema which can occur after breast cancer surgery (Breast Cancer Related Lymphedema or "BCRL") when lymph nodes are removed from the axilla (armpit) to prevent spread of the cancer. Removal of these lymph nodes combined with radiotherapy, destroys the lymphatic drainage of the arm. This results in the accumulation of fluids and lymph in the affected arm causing it to become swollen, heavy, and painful which severely impairs the quality of life for patients suffering from lymphedema.

Lymfactin® VEGF-C gene therapy was administered locally into the lymph node transplant during the lymph node transfer surgery as a single-dose medical treatment, aiming to promote and establish reconstitution of a functional lymphatic system.

About the Phase I Safety Study:

Commencing in 2017, this phase I safety study with Lymfactin® was an open label, multi-center, uncontrolled first-in-human trial assessing 15 patients across three university hospitals in Finland: Helsinki, Tampere, Turku. Lymfactin® was administered as a single dose by *ex-vivo* perinodal injection combined with lymph node transplantation surgery. The patients were divided into two dose cohorts, one with a lower dosage of Lymfactin® and the other with a higher dosage. There was no control group in the study, hence no conclusions can be drawn on efficacy observations.

The company previously announced results from the 12-month read-out in April 2019 (link to press release), which concluded that the treatment continued to be safe and well-tolerated in

all patients with no severe adverse events or dose limiting toxicities observed. This favorable safety profile has maintained and continued to be seen through the 24 months follow-up.

Although not an efficacy study, observations of clinical benefit that were observed at 12 months have been maintained, and even improved, out to the 24 month time period as well. These observations included a clinically meaningful decrease in the affected arm volume of approximately half of the patients at 12 and 24 months, as well as clinically meaningful improvement in the lymphatic flow of some patients as measured by lymphoscintigraphy at these time points. In-line with these improvement trends, most patients have similarly reported improvements in their quality of life through the LyQLI questionnaire (Lymphedema Quality of Life Inventory) at 12 months as well as 24 months post-treatment.

“Breast cancer associated lymphedema is a chronic disease that severely compromises quality of life of patients. Lymfactin® gene therapy is a highly promising investigational product that has the potential to transform the treatment of this debilitating disease,” commented Anne Saarikko, Phase I Principal Investigator, Helsinki University Hospital.

“We are very pleased with the continuing safety profile of Lymfactin® out to 2 years. Also, although we cannot draw conclusions on efficacy of Lymfactin® due to the nature of the study, we are nevertheless encouraged by the potential efficacy observations of the treatment, ” said Craig Cook, CEO of Herantis Pharma. “We look forward to the readout in Q1 of 2021 of the ongoing Phase II AdeLE study, a multi-center, randomized, double-blind, placebo-controlled study of Lymfactin®. We continue to be excited about the potential Lymfactin® holds to make a real difference for patients suffering from lymphedema, and where current therapies are very limited.”

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About Herantis Pharma Plc
Herantis Pharma Plc is an innovative clinical stage biotech company with a diverse pipeline of pioneering investigational therapeutics looking to modify the course of debilitating nervous system and lymphatic diseases, and break the boundaries of standard therapeutic approaches. Leveraging deep scientific brilliance in protein dysregulation for neurodegenerative diseases, and growth stimulation in lymphatic diseases, Herantis is advancing a rich pipeline of regenerative biological and gene therapies for high impact diseases. These 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. Herantis is pursuing disease modifying treatments that slow, stop, or even reverse the course of diseases, and bring much needed innovation to these underserved diseases. The shares of Herantis are listed on the Nasdaq First North Growth Market Finland and Nasdaq First North Growth Market Sweden.