Herantis Pharma Announces 12-Month Follow-Up Review from Phase 1 Lymfactin® Trial in Breast Cancer-Associated Lymphedema

Herantis Pharma Plc
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Herantis Pharma Plc ("Herantis") announced today the topline results from the 12-month follow-up review of the Phase 1 Lymfactin® trial in breast cancer-associated lymphedema. The study's data monitoring committee (DMC) concluded that the treatment continues to be safe and well-tolerated in all patients with no severe adverse events. Lymfactin®, the novel gene therapy of Herantis that aims to repair the damaged lymphatic system in breast-cancer associated lymphedema patients, is currently in a multi-center Phase 2 clinical study AdeLE in Sweden and Finland.

"We are encouraged by the additional confirmation of the safety and tolerability of Lymfactin® from the 12-month review. These data remain in line with what we have seen in our first interim analysis. This is a promising step for lymphedema patients who currently only have limited symptomatic treatment options, none of which render long-lasting therapeutic effects," commented Pekka Simula, CEO of Herantis Pharma. "Following the positive safety data, we look forward to a more in-depth investigation of the benefits of Lymfactin® in the ongoing Phase 2 AdeLE study, for which we expect initial results by the end of 2020."

"Breast cancer-associated lymphedema is a highly debilitating disease that severely impacts quality-of-life of patients that have already experienced a significant impact on their day-to-day health," added Anne Saarikko, MD, PhD, Principal Investigator of the study and Associate Professor at the Hospital District of Helsinki and Uusimaa. "Addressing this unmet medical need is an important endeavor to which we are excited to contribute. Lymfactin® has a very interesting product profile addressing the underlying root cause by restoring the functionality of lymphatic vasculature, which will be critical to evaluate going forward."

The Phase 1 study enrolled a total of 15 patients from three university hospitals in Finland: Helsinki, Tampere and Turku. Lymfactin® was administered in a single dose following lymph node surgery. Safety and tolerability were assessed at baseline, 6-months and 12-months post-treatment. Based on the promising interim results announced in April 2018, Herantis has initiated the placebo-controlled Phase 2 AdeLE trial in June 2018. More information on Lymfactin® and both trials can be found on the Lymfactin website or on www.clinicaltrials.gov.

Further information:

Herantis Pharma Plc, Pekka Simula, CEO, telephone: +358 40 7300 445
Company web site: www.herantis.com
Certified Advisor: UB Securities Ltd, telephone: +358 9 25 380 225

About breast cancer associated lymphedema

Approximately 20% of breast cancer patients who undergo axillary lymph node dissection develop secondary lymphedema, a chronic, progressive, disabling, and disfiguring disease that severely affects the quality of life. Symptoms include a chronic swelling of an upper limb, thickening and hardening of skin, loss of mobility and flexibility, pain, and susceptibility to secondary infections. Secondary lymphedema is currently treated with compression garments, special massage, and

exercises. While these therapies may relief the symptoms in some patients, they do not address the underlying cause of lymphedema, which results from damage to the lymphatic system. There are currently no approved medicines for the treatment of secondary lymphedema.

About Lymfactin®

Lymfactin® is world's first and only clinical stage gene therapy that repairs damages of the lymphatic system. It expresses the human growth factor VEGF-C, which is natural and specific for the development of lymphatic vessels. Based on preclinical studies, Lymfactin® triggers the growth of new functional lymphatic vasculature in the injured area and thus repairs the underlying cause of secondary lymphedema. The efficacy of Lymfactin® is currently studied in the Phase 2 clinical study AdeLE in Finland and Sweden. Based on cumulated data from a Phase 1 clinical study in 15 patients with breast cancer associated LE, Lymfactin® is safe and well tolerated.

Lymfactin®, patented by Herantis, is based on the internationally renowned scientific research of academy professor **Kari Alitalo** and his research group, a national centre of excellence at the University of Helsinki. See an introductory video on Lymfactin®: http://herantis.com/media/videos/

About drug development in general

Drug development projects can usually be divided in two stages: The preclinical stage, and the clinical stage involving human subjects. The clinical stage can be further broken in three formal phases. Phase 1 clinical studies assess the safety of a drug candidate in human subjects. In Phase 2, the optimal dosing and possible efficacy in the treatment of a particular disease is studied. Phase 3 studies finally aim to establish a statistical proof of safety and efficacy of the drug candidate in typically hundreds or thousands of patients for market approval. Drug development can take 10-15 years from the first preclinical studies to market approval.

About Herantis Pharma Plc

Herantis Pharma Plc is an innovative drug development company focused on regenerative medicine and unmet clinical needs. Our clinical stage assets CDNF and Lymfactin® are based on globally leading scientific research in their fields. They both aim at breakthrough in the treatment of severe diseases: CDNF in neurodegenerative diseases such as Parkinson's disease; and Lymfactin® in breast cancer associated lymphedema with potential also in other lymphedemas. The shares of Herantis are listed on the First North Finland marketplace run by Nasdaq Helsinki stock exchange.

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