Herantis Pharma announces initiation of Phase 2 study for Lymfactin® gene therapy in secondary lymphedema

Herantis Pharma Plc
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Herantis Pharma Plc ("Herantis") announced today the initiation of the Phase 2 clinical study AdeLE (Adenoviral gene therapy for the treatment of LE), which will evaluate the efficacy of Lymfactin® gene therapy in the treatment of secondary lymphedema (LE). The AdeLE study is a multicentre, randomized, double-blind, placebo-controlled study that intends to recruit 40 patients with breast cancer associated LE. The main goal is to analyse the therapeutic effect of Lymfactin® over placebo on improving the quality-of-life of patients, as well as reducing the swelling and other symptoms associated with the disease. Lymfactin is an adenovirus type 5-based gene therapy expressing human growth factor VEGF-C directly in the damaged tissue to promote the growth and repair of lymphatic vessels and restore the lymphatic network.

"The robust Phase 1 data, confirming safety and tolerability of Lymfactin®, favorably positioned us to quickly move into Phase 2 clinical evaluation, which is an important achievement for this program and the company," said **Pekka Simula**, Herantis' CEO. "Secondary lymphedema remains a disease with a noteworthy and underserved patient population and as a locally administered single dose therapy, Lymfactin® offers great potential to address this significant gap."

"At the moment there is no curative treatment for lymphedema. Lymfactin® stands out as a unique, easy-to-administer, and hopefully the first curative treatment option in a disease area where current therapies only relieve symptoms," added **Anne Saarikko**, MD, PhD, Principal Investigator of the study. "As such, we see the great potential of Lymfactin® and look forward to supporting the next step in terms of clinical development and further evaluation of this novel treatment."

The AdeLE study is now recruiting patients at Helsinki University Hospital, with Tampere and Turku University Hospitals (Finland) planned to join in June 2018. By the end of 2018, 2-3 additional hospitals in Sweden and Finland are planned to start enrolling patients.

About the AdeLE Study

AdeLE is a Phase 2 multi-center, randomized, double-blind, placebo-controlled study in patients with secondary lymphedema associated with the treatment of breast cancer. The study is planned to enrol 40 patients in Finland and Sweden and will assess the efficacy, safety and tolerability of a single dose of Lymfactin® compared to placebo in patients undergoing lymph node transfer surgery. Primary endpoints include volumetric measurements of the arm, quantitative lymphoscintigraphy, and quality-of-life assessment. To learn more, please visit http://herantis.com/lymfactin?lang=en.

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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 cure lymphedema, which is caused by damage to the lymphatic system. There are currently no approved medicines for the treatment of this disease.

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 damaged area and thus repairs the underlying cause of secondary lymphedema. Data from a Phase 1 clinical study in 15 patients with breast cancer associated LE suggest Lymfactin® is safe and well tolerated. The Phase 1 study continues with patient follow-up.

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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