Herantis Pharma Announces Expansion of its Phase 2 Study AdeLE in Breast Cancer Associated Lymphedema with Two Centers in Sweden

Herantis Pharma Plc
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Herantis Pharma Plc ("Herantis") announced today the expansion of its Phase 2 AdeLE clinical trial in Sweden to include the Karolinska University Hospital in Stockholm, and the Uppsala University Hospital. The AdeLE study will also continue to recruit patients at three university hospitals in Finland.

"As two of the largest and most renown clinical centers in Sweden, it is very positive for our AdeLE trial to have initiated at the Karolinska and Uppsala University Hospital," said Pekka Simula, CEO of Herantis Pharma. "We anticipate these centers to contribute to enrolment and our strategy to rapidly move the study forward."

The AdeLE study is designed to evaluate the efficacy of Lymfactin® gene therapy in the treatment of secondary lymphedema (LE). Lymphedema describes a chronic, progressive swelling of the affected tissues due to dysfunction of the lymphatic system. It is a disabling and disfiguring disease, which severely affects the patients' quality of life. There are currently no approved therapies to address the underlying syndrome that causes lymphedema. More information on secondary lymphedema, Lymfactin®, and the AdeLE study can be found on the Herantis company website http://herantis.com/pipeline/lymfactin-for-lymphedema/.

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 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 enroll 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.

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 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. 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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