

Nordic Life Science Days, Stockholm 2015

Pekka Simula, CEO, 9 Sep 2015

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Herantis Pharma Plc

- Drug development company aiming to develop novel pharmaceutical products based on leading scientific research
- Focus in regenerative medicine developing growth factors in indications with significant unmet clinical needs

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- Expertise in early clinical development
 - Preclinical research
 - Early clinical research
 - Clinical Proof-of-Concept
- IPO in June 2014 raised approximately 20 MUSD
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Herantis portfolio (drug candidates)

Drug candidate	Indication	Preclin	Phase 1	Phase 2	Phase 3
CDNF neuro- protective factor	Parkinson's disease	Δ	*		
CDNF neuro- protective factor	Amyotrofic lateral sclerosis (ALS)**	Δ			
CDNF neuro- protective factor	Alzheiemer's disease	**			
Lymfactin®	Secondary Iymphedema	Δ	*		
Cis-UCA Eye Drops	Dry Eye	Δ	Δ	Δ	
Cis-UCA Emulsion Cream	Atopic dermatitis	Δ	Δ	Δ	

*This stage of clinical development in planning and scheduled **Next steps pending later decisions.



CDNF for Parkinson's disease (PD)

Based on preclinical data we believe that CDNF is one of the most promising new compounds for a <u>disease-modifying treatment</u> of Parkinson's disease.



- Parkinson's disease is an uncured progressive neurodegenerative disease
 - Estimated seven million patients worldwide
 - Available treatments only help motor symptoms of the disease
- CDNF aims to relieve <u>both</u> motor <u>and</u> non-motor symptoms <u>and</u> slow down disease progression
 - CDNF protects and restores dopaminergic neurons based on preclinical studies in several Parkinson models
 - Based on preclinical data, more potent in PD than GDNF, which is finishing its phase 2 in the UK and partnered to Pfizer
 - Herantis prepares its Clinical Trial Application for the First-in-Human study in 2015



CDNF First-in-Human study: Overview

- Phase 1(-2) placebo-controlled, randomized, blinded safety study in Finland and Sweden
 - 18 patients with Parkinson's disease
 - Intracranial administration of CDNF or placebo 4-weekly for 6 months, using a device resembling Deep Brain Stimulation

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- Extension protocol where all patients will receive CDNF
- Data expected in 2017

Figure: Illustration of a possible way to administer CDNF with a device resembling Deep Brain Stimulation, a routine treatment of Parkinson's Disease



Barua et al. *J. Neurosci. Methods.* 214: 223-232, 2013.

CDNF for ALS (Lou Gehrig's disease)

ALS is an aggressive motoneuron disease with no cure. In preclinical studies, a single CNDF injection has prolonged survival and reduced symptoms in a mouse model of ALS



- Estimated 140,000 diagnosed cases per year worldwide
- First symptom typically weakness of limb muscles
 - Disease progression causes difficulty in moving, speaking, swallowing, and eventually breathing, leading to death
 - Huge unmet clinical need: Average survival 3-5 years
- Preclinical studies are on-going to assess the benefits of multiple dosing of rhCDNF in a novel TDP43 ALS model
- Herantis' plan is to proceed to clinical development as soon as the preclinical efficacy can be confirmed



CDNF for Alzheimer's disease

Published preclinical data suggest Herantis' CDNF improves longterm memory in mouse model of Alzheimer's Disease (AD)

- CDNF is known to reduce ER (endoplasmic reticulum) stress, linked to AD
- Recent publication in Behavioural Brain Research suggests that in addition to reducing ER stress CDNF improves long-term memory in AD mouse model
 - CDNF even improved long-term memory in healthy mice, compared to vehicletreated animals

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- AD is the most common neurodegenerative disease and the cause in majority of cases of dementia
- Herantis is looking for partners to launch a development program in AD



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Lymfactin® for secondary lymphedema

Based on scientific studies Herantis believes that damage to lymphatic system leading to secondary lymphedema can be treated with Lymfactin[®]

- Secondary lymphedema is a chronic progressing disease with no approved medicines
 - Estimated 15,000 18,000 patients annually in the USA as a consequence of breast cancer therapies
 - Main symptom is a permanent swelling of affected limb, with significant impact on quality of life
- In preclinical models Lymfactin[®] has promoted new lymphatic growth in the damaged area
- Herantis targets to launch its Phase 1 clinical study in 2015
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Cis-UCA Eye Drops for dry eye

Based on clinical results we believe that Cis-UCA Eye Drops is the most well tolerated dry eye medicine under development, with efficacy shown in randomized study



- Dry eye syndrome is the most common cause of irritation in the eye
 - Estimated 45 million people in the USA and Europe suffer from dry eye syndrome
- Herantis' Phase 2 clinical study completed in 2015 in the USA
 - N=161, randomized, placebo-controlled
 - While primary endpoints were not reached secondary endpoints show statistically significant efficacy based on corneal staining
- Herantis continues result analysis and discussions with potential development partners



Herantis Pharma summary

- Ongoing clinical development: Two fully funded clinical studies in regenerative medicine
 - CDNF for a disease-modifying treatment of Parkinson's disease
 - Lymfactin® for the treatment of secondary lymphedema caused by breast cancer treatments
 - Partnering will be considered after completion of FIH studies
- Looking for development partners in selected areas
 - Cis-UCA Eye Drops for the treatment of Dry Eye, Phase 2 completed
 - Cis-UCA Emulsion Cream for the treatment of skin inflammations
 - Clinical development of CDNF in new indications: ALS and Alzheimer's Disease





Thank you

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