## HERANTIS PHARMA

Our mission is to develop disease-modifying therapies to stop or reverse the progression of neurodegenerative diseases to address the unmet medical need

**MAY 2024** 





### **Herantis in Brief**



Herantis Pharma plc was founded in Helsinki, Finland in 2008; Listed at Nasdaq First North Helsinki



**Developing disease-modifying treatment** to address the unmet clinical need in Parkinson's disease and other neurodegenerative diseases



Lead asset **HER-096** is a small engineered peptide molecule with a **unique mechanism of action** and **subcutaneous injection** as an **easy route of administration** 



Phase 1a clinical trial readout in October 2023: Good safety profile, blood-brain barrier (BBB) penetration demonstrated



Ambition: engage with a partner before Phase 2

### The unmet clinical need in Parkinson's disease

#### PARKINSON'S DISEASE (PD)

- Degeneration of dopaminergic nerve cells in mid brain results in loss of dopamine that cause severe motor and non-motor symptoms
- At the time of diagnosis, approximately half of the dopaminergic activity is lost

# CURRENT TREATMENTS CANNOT STOP THE PROGRESSION OF PD

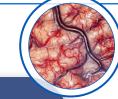
 For 50 years, the mainstay of Parkinson's treatment has been levodopa, which helps to restore dopamine levels in the brain

# BLOOD-BRAIN BARRIER (BBB) PROTECTS THE BRAIN

- Most pharmaceuticals cannot pass the BBB
- Efficient BBB penetration is important reach the target tissue within the brain







# UNMET NEED: DISEASE-MODIFYING TREATMENTS

#### **HERANTIS' HER-096**

- Efficient BBB-penetration
- HER-096 Slows down or stops the progression of Parkinson's disease





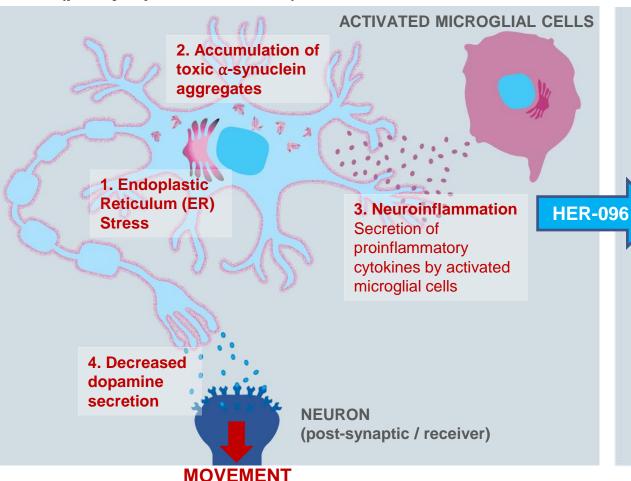
#### **OVER \$10B MARKET**

- 8-10 million patients globally
- Current market \$5B
- Market estimated to grow to \$11B by 2029 driven by disease-modifying treatments (source: GlobalData)

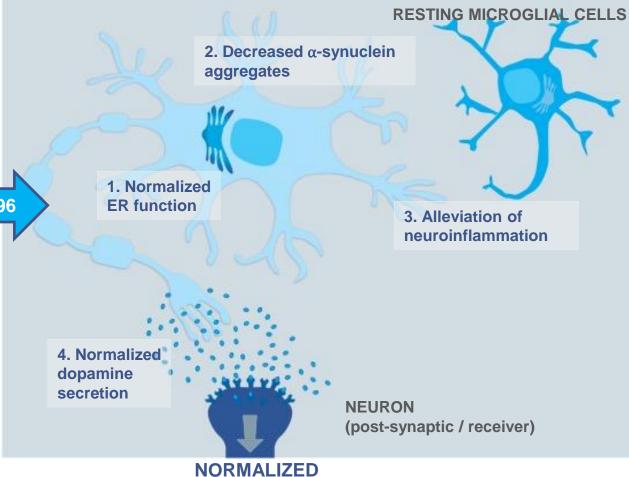


### HER-096 restores the normal function of the dopaminergic neurons

## DEGENERATING DOPAMINERGIC NEURON (pre-synaptic / transmittor)



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**DISORDER** 

**MOTOR FUNCTION** 

### Preclinical HER-096 Improves Motor Function in Mouse PD Model (α-Synuclein Fibril Model)



CLICK THE BELOW LINK TO SEE THE VIDEO:

https://youtu.be/L3W mkhP2Opw

### **Status of HER-096 Program**

#### Clinical

- ➤ Phase 1a completed in 2023 (single ascending dose in healthy volunteers) → data support moving forward with subcutaneous HER-096 dosing
- > Phase 1b in PD patients planned to be started in 2H 2024 (4 weeks treatment for safety and tolerability, biomarkers)

#### Preclinical

- $\triangleright$  Strong preclinical efficacy data demonstrating the MoA ( $\alpha$ -synuclein fibril model)
- > 28-day daily dosing GLP toxicology study completed
- > 6-month toxicology study planned to start in late 2024

#### Manufacturing

- > HER-096 bulk manufactured by solid phase peptide synthesis (SPPS) by Bachem AG (Switzerland), current scale 1000 grams, straightforward further scale-up
- Phase 1b GMP manufacturing ongoing
- > Formulation development work on-going to decrease the volume of injection for Phase 2

#### IPR

➤ Composition of matter patent filed in Dec 2019 (WO2021123050A1)



### **Recent Business highlights**

- HER-096 Phase 1a clinical trial met all primary and secondary endpoints
  - Favorable safety and tolerability profile
  - Fast uptake of HER-096
  - Significant HER-096 concentration in the cerebrospinal fluid (CSF) after a single subcutaneous injection
- Funding/financing
  - ➤€2.5 million grant funding from the EIC Accelerator program over the next two years secured in April 2023.
  - Direct equity investment term sheet from EIC Fund of up to €15 million signed in July 2023. EIC to participate with maximum of 1/3 of the future share issues.
  - ➤ Successfully completion of a directed share issue raising gross €4.5 million in December 2023.



### Seeking a partner for HER-096 to co-develop future potential

Significant opportunities in further development in Parkinson's and in other neurodegenerative diseases

HER-096 global patenting
Straightforward

manufacturing

evidence of disease modifying effect

**Preclinical** 

HER-096 is delivered to the human brain after subcutaneous administration

Preclinical and clinical expertise with the same mechanism of action with CDNF protein





### **Summary**



# What we want to achieve with HER-096?

To develop a treatment to slow or stop the progression of Parkinson's disease with symptomatic relief



# **Evidence of subcutaneous** HER-096

- HER-096 is delivered in the central nervous system in humans in therapeutic concentrations
- Good safety and tolerability profile in humans
- Strong preclinical efficacy data in aged mouse model of Parkinson's disease (α-synuclein model)
- Clinical and preclinical experience and evidence with CDNF protein in Parkinson's disease that has the same MoA as HER-096



#### **Next steps**

- Phase 1b to start in 2024 (safety, tolerability of multiple subcutaneous dosings in PD patients)
- Prepare for Phase 2 readiness
- Explore HER-096 in other indications



**Strategy** 

Find a development partner for HER-096



# Thank you!

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