

Herantis Pharma Announces xCDNF Preclinical Candidate Selection

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Herantis Pharma Plc (“Herantis or the Company”), focusing on disease modifying therapies for debilitating neurodegenerative diseases, announced today that the Company has nominated HER-096 as the preclinical xCDNF candidate to take forward into further preclinical development for the treatment of Parkinson’s Disease (PD) and other neurodegenerative diseases.

HER-096 was selected based on clear and compelling preclinical data including that it:

- Effectively penetrates the Blood-Brain-Barrier (BBB)
- Potently protects neurons and restores their functional phenotype
- Significantly reduces aggregation of the toxic protein alpha-synuclein and the associated neuroinflammation
- Restores proteostasis

In 2018, Herantis began conducting lead optimization of several xCDNF molecular candidates to maximize their plasma half-life, BBB penetrance and potency for targeting PD. Neurodegenerative disorders such as PD are characterised by increased levels of cellular stress and the breakdown of proteostasis, which is the normal mechanism that directs the synthesis and folding of proteins, and also the removal of misfolded proteins. HER-096 has the potential to be a disease-modifying therapy, designed to be given via subcutaneous injection with no requirement for surgery.

As a result the Herantis pipeline now comprises two promising Parkinsons assets: CDNF (Cerebral Dopamine Neurotrophic Factor), a clinical stage biological, and HER-096 a preclinical stage compound. The two assets will continue to be developed as separate projects in tandem.

“Our nomination of HER-096 as the preclinical candidate is a key milestone as there are very few brain-penetrating compounds with disease-modifying potential out there. This has been an important R&D program for Herantis as it not only has strengthened our pipeline but also has improved our understanding of the mechanistic basis of CDNF action, generating important synergies between the two programs,” Dr. Henri Huttunen, Chief Scientific Officer and Founder.

“It is exciting to have achieved this diligent milestone, and move forward with our xCDNF nominated candidate for the treatment of PD and other neurodegenerative disorders. This decision reflects our primary goal to bring a well-tolerated and effective disease-modifying treatment to patients,” said Dr. Craig Cook, M.D., Chief Executive Officer of Herantis. “Many steps have been taken towards this important milestone which is the culmination of an extensive, collaborative and unprecedented R&D program and I would like to thank our network of excellent partners and the team at Herantis for making this happen.”

About CDNF & HER-096

CDNF is a powerful protein that occurs naturally in the body whose normal role is to protect neurons via its ability to protect and restore a key biological system/process called Proteostasis, which becomes dysfunctional in PD. Herantis is looking to harness this natural potential as a potent treatment for illnesses like Parkinson's Disease. CDNF acts upon three key elements of proteostasis: synthesis, folding, and degradation, and can thereby reduce cellular stress and prevent formation of protein aggregates. However, CDNF cannot readily penetrate an intact blood-brain-barrier (BBB). HER-096 is a synthetic peptidomimetic version of CDNF, designed to be given via subcutaneous injection with no requirement for surgery. xCDNF has been engineered with the dual aims of crossing the notoriously impermeable BBB, while retaining the potency of the parent molecule to protect neurons, both critical elements for successful Parkinsons treatment.

Target Market

Comprehensively, the total available market for neurodegenerative diseases was estimated to be worth €29.2Bn in 2018 and is projected to reach €54Bn by 2026 (CAGR = 7.2%). PD represents a serviceable market of €3.8Bn, growing to €5.0Bn by 2024. PD is the second most common form of neurodegeneration, affecting 7 to 10 million people worldwide, with over 60,000 new diagnoses in the US each year. Based on the market shares of incumbent therapeutics for PD, the overall market opportunity for Herantis CDNF assets is independently estimated to be approximately €8Bn.

For more information, please contact:

Julie Silber/Gabriela Urquilla

Tel: +46 (0)7 93 486 277/+46 (0)72-396 72 19

Email: ir@herantis.com

Certified Advisor: UB Securities Ltd, Finland: +358 9 25 380 225, Sweden: +358 40 5161400

Company website: www.herantis.com

About Herantis Pharma Plc

Herantis focuses on disease modifying therapies for debilitating neurodegenerative diseases by restoring the neuronal protective mechanism of proteostasis, a key system in neurodegenerative disease. Proteostasis regulates proteins within the body and influences the fate of every protein from synthesis to degradation. Its failure results in a vicious cycle of pathological accumulation of protein aggregates, neuroinflammation and various forms of cellular stress that is widely implicated with the development of many neurodegenerative diseases including Parkinson's Disease, Alzheimer's and other diseases. CDNF is a protein that occurs naturally in the body whose normal role is to protect neurons by balancing and supporting proteostasis, thereby preventing and counteracting disease generating mechanisms. Herantis is taking this natural ability and harnessing it as a treatment for neurodegenerative disease. CDNF – a biological protein – is Herantis' lead program and a clinical stage asset; and HER-096 – a synthetic peptidomimetic version of CDNF – is Herantis' follow-on program. Both CDNF and HER-096 have, via their multimodal mechanism of action, the potential to improve neuronal survival and function, and to stop the progression of Parkinson's and other neurodegenerative disease and have a significant therapeutic impact on the lives of patients.

The shares of Herantis are listed on the Nasdaq First North Growth Market Finland and Nasdaq First North Growth Market Sweden. For more information, please visit <https://www.herantis.com>