



Press Release

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Santhera and Juvantia to Collaborate on Development of Phase II Product for Dyskinesia in Parkinson's Disease

Strategic Agreement with a Call Option for Acquisition of Juvantia Strengthens Santhera's Clinical Pipeline

Liestal, Switzerland; Turku, Finland – Santhera Pharmaceuticals, a Swiss specialty pharmaceutical company with a focus on neuromuscular diseases, and Juvantia Pharma, a Finnish biotechnology company, announced today that they have entered into a strategic collaboration to advance the development of Juvantia's fipamezole (JP-1730) for the treatment of Dyskinesia in Parkinson's Disease (DPD) patients. A Phase IIa clinical trial in the US has already shown proof-of-concept for fipamezole and a fast track registration status has been granted by the FDA.

The collaboration is aimed at advancing fipamezole through a larger-scale Phase IIb clinical trial next year to confirm the encouraging results seen in the earlier Phase IIa clinical trial. Santhera will be responsible for conducting and funding development work and has a call option to secure all rights to the product via the acquisition of all Juvantia shares at a later point in time. No further financial terms of the agreement were disclosed.

Dr. Juha-Matti Savola, former CEO and President of Juvantia, has joined Santhera as Director Clinical Development and will be responsible for the fipamezole development program at Santhera's facilities in Liestal, Switzerland.

"This agreement with Juvantia is an excellent strategic fit for Santhera," said Dr. Klaus Schollmeier, Santhera's CEO. "Fipamezole targets a movement disorder where there is a high unmet medical need given that there is currently no treatment available on the market. With our option to acquire all rights to fipamezole, we are in a position to add another late-stage clinical development product to our pipeline once we have seen the outcome of the Phase IIb clinical trial. This agreement covering fipamezole further supports our vision of becoming a leading specialty pharmaceutical company focused on neuromuscular diseases," Dr. Schollmeier added.

Fipamezole, an alpha-2 adrenergic receptor antagonist, offers a novel and unique mode of action to treat dyskinesia (involuntary movements) in Parkinson's Disease (PD). In a Phase IIa clinical trial, carried out in collaboration with the US National Institutes of Health (NIH), fipamezole was able to reduce levodopa-induced dyskinesias and prolong levodopa's duration of action. Levodopa is currently the standard therapy for PD and can result in patients developing dyskinesia after several years of its use. The Phase IIa results have established proof-of-concept for fipamezole. Today, at least 200,000 PD patients in Europe and the US suffer from severe DPD. The market has been estimated to reach at least EUR 500 million, according to market analysts.

Keijo Väkiparta, Chairman of Juvantia, said: "This collaboration represents an excellent opportunity for Juvantia to drive the further development of this important product. Santhera has commitment and extensive experience in devising and managing clinical trials, built on their deep understanding of the therapeutic field of neuromuscular disorders."

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About Dyskinesia in Parkinson's Disease

Parkinson's disease (PD) is the second most common neurodegenerative disease, whose symptoms include uncontrollable tremor of the extremities, rigidity of muscles and jerky movements, stooped posture, expressionless face and difficulty in any function requiring a high degree of motor coordination, such as walking, writing, and talking. Current standard medical treatment for Parkinson's disease is based on levodopa. Over time, as the disease progresses, the beneficial effects of these therapies diminish and further symptoms, such as movement disorders, increase in frequency and severity. As a result, patients often require extended periods of hospitalization or placement in a full-time nursing environment. In advanced disease stages, movement disorders, known as dyskinesias, include chaotic movements of limbs, face, tongue and the body. These complications derive principally from long-term levodopa use. It is estimated that approximately 20% of all PD patients develop troublesome DPD within 5 years of initiating levodopa treatment.

About Santhera

Santhera Pharmaceuticals is a Swiss specialty pharmaceutical company focusing on the discovery, development and marketing of small molecule pharmaceutical products for the treatment of neuromuscular diseases. Santhera's vision is to become the leading specialty pharmaceutical company offering therapies for a number of indications in this area of high unmet medical need which includes many orphan indications with no current therapy. Santhera has a proven track record in discovering and developing drug candidates that address severe neuromuscular disorders in orphan and ultra-orphan diseases. The Company's lead product SNT-MC17 (INN: idebenone) is in a European Phase III clinical trial for the treatment of Friedreich's Ataxia, a rare but devastating disease which is ultimately fatal. Santhera has orphan drug designations for this indication in both the US and EU. Santhera is also conducting a Phase II clinical trial in Duchenne Muscular Dystrophy with SNT-MC17. The drug pipeline comprises another three preclinical programs in diabetes (out-licensed to Biovitrum), cachexia/anorexia, and Duchenne Muscular Dystrophy.

Santhera was formed in 2004 through a business combination of MyoContract AG and Graffinity Pharmaceuticals AG. The Company is based in Liestal, Switzerland. Santhera has attracted investment from leading global industry investors including NGN Capital, Merlin Biosciences Limited, 3i Group plc, Varuma AG, Oxford Bioscience Partners, the Novartis Venture Fund, Heidelberg Innovation, GIMV, Carnegie Asset Management, TechnoStart, Clariden Biotechnology Fund, the Swiss Foundation for Research on Muscle Diseases, The Dow Chemical Company, Altana Innovationsfonds, tbg, and private investors.

For further information on Santhera, please visit www.santhera.com.

For further information please contact:

Santhera Pharmaceuticals

Klaus Schollmeier, CEO

phone: +41 (0) 61 906 89 52
klaus.schollmeier@santhera.com

Thomas Staffelbach, VP Public & Investor Relations

phone: +41 (0) 61 906 89 47
thomas.staffelbach@santhera.com

Media contact for Santhera: Citigate Dewe Rogerson

David Dible

phone: +44 (0) 207 638 9571
david.dible@citigatedr.co.uk

Chris Gardner

phone: +44 (0) 207 638 9571
chris.gardner@citigatedr.co.uk

Juventia Pharma

Keijo Väkiparta

phone: +358 400 455 571
keijo.vakiparta@biofund.fi