Henk Schuring joins Prilenia as Chief Regulatory and Commercialization Officer

[Naarden, NL, 10 September 2020] - Prilenia Therapeutics B.V., a clinical stage biotech company focused on developing novel treatments for neurodegenerative and neurodevelopmental disorders, announces the appointment of Henk Schuring as Chief Regulatory and Commercialization Officer.

At this newly established position, Henk will play a critical role in defining the regulatory pathway for marketing authorization, and will support the Company's strategy as it advances toward commercialization. The Company has recently completed its Series A funding of $62.5M which is financing two late-stage clinical trials, one in ALS and one in HD.

Henk is a strategic regulatory and market access expert with more than 25 years of experience in global orphan drug development and commercialization. He joins Prilenia after 21 years at Sanofi Genzyme, where he managed the Rare Nephrological Diseases business and the Rare Neurological Diseases business. Prior to moving to commercial roles, Henk championed regulatory affairs (RA) for Genzyme in multiple roles, including Head of RA Strategy in EMEA & JAPAC. During his time at Genzyme, Henk played a crucial role in the development and commercialization of various products with first approvals amongst others in the areas of Multiple Sclerosis, Pompe Disease and Fabry disease. Henk has a PharmD degree from the University of Groningen in Netherlands.

Henk Schuring, Chief Regulatory and Commercialization Officer at Prilenia, said: *"Joining Prilenia is a unique opportunity to contribute to scientific advancements in HD and ALS therapy. The Company's lead asset, Pridopidine, shows great potential in treating these chronic progressive and life-threatening diseases which have such significant unmet medical need. I am excited to help guide the further development and future commercialization of Pridopidine which has the potential to improve the lives of patients and their families."*

"We are delighted to welcome Henk to the team, who is joining at a crucial time ahead of the initiation of our late-stage clinical trials." **Michael R. Hayden, CEO of Prilenia**, **commented:** *"Henk's unique combination of experience in regulatory and commercialization will accelerate our strategy, the regulatory submission process and future potential launch of Pridopidine. This is an exciting time for the Company and we are thrilled to have someone of Henk's caliber and experience join the team."*

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About Prilenia (www.prilenia.com)

Prilenia is a clinical stage biotech startup founded in 2018 with the purpose of improving the lives of patients and their families by developing treatments for neurodegenerative and neurodevelopmental disorders. Prilenia raised $ 82.5 million thus far and is backed by a group of well-respected investors:

Talisman, Forbion, Morningside and Sectoral. The Company is based in Naarden, the Netherlands, Herzliya, Israel and Boston, MA in the U.S.

About Pridopidine

Prilenia's lead asset is Pridopidine, a first-in-class drug candidate with an established safety profile and therapeutic potential in several neurodegenerative diseases affecting adults and children. The highly selective S1R agonist was acquired from Teva in 2018.

Pridopidine for Huntington Disease

HD is a fatal, inherited, neurodegenerative disorder. Every offspring of an HD patient has a 50% chance of inheriting the gene. Usually starting at around 40 years of age, HD patients suffer from movement disorder, progressive functional and cognitive decline, psychiatric disturbances and behavioral symptoms. Following diagnosis, functional, motor and cognitive functions decline steadily, ultimately leading to immobility, dementia and premature death.

Pridopidine has demonstrated maintenance of functional capacity in HD patients, as measured by Total Functional Capacity (TFC), in a clinical trial. This effect was most prominent in early stage HD patients (HD1 and HD2), who showed functional benefit from pridopidine 45 mg, taken twice a day.

There is extensive preclinical evidence that further supports pridopidine's potential beneficial effect in HD. The therapeutic effect has been shown to be mediated exquisitely by the sigma-1 receptor (S1R).

Prilenia has an orphan drug designation for pridopidine for the treatment of HD in both the US and Europe and is planning to start a global phase 3 in HD in Q4 2020.

Pridopidine for ALS

ALS is the most prevalent adult-onset progressive motor neuron disease, affecting approximately 30,000 people in the U.S. and an estimated 500,000 people worldwide. ALS causes the progressive degeneration of motor neurons, resulting in progressive muscle weakness and atrophy. There are currently two FDA therapies approved specifically for treating ALS: riluzole and edaravone.

Compelling preclinical data supports the potential use of pridopidine as a therapeutic for ALS. In ALS $SOD1^{G93A}$ motor neurons (MNs), pridopidine exerts neuroprotective effects via activation of the S1R. Specifically, pridopidine improves BDNF (brain-derived neurotrophic factor) and GDNF (glial cell line-derived neurotrophic factor) axonal transport, restores synaptic activity and neuro-muscular junction (NMJ) function, and increases neuronal survival. *In vivo*, pridopidine treatment of $SOD1^{G93A}$ mice reduces toxic protein aggregates and ameliorates muscle fiber wasting.

Previous clinical data also suggest that S1R is a promising target for ALS therapy, indicating that S1R activation may enhance bulbar and speech function in ALS patients. The sigma 1 receptor has been genetically validated for ALS, as patients with mutations in this gene develop ALS.

Pridopidine has been chosen to participate in the first ALS platform trial by the Healey Center for ALS at Massachusetts General Hospital. The Pridopidine regimen is planned to start within the platform trial in Q4 2020.

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