NEWS RELEASE

Prilenia's Pridopidine for Huntington's Disease Accepted for European Marketing Authorisation Review

2024-09-03

Pridopidine's Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) is the first submission for approval for an investigational new treatment for adults with Huntington's disease (HD) with potential to impact disease progression

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This MAA filing, if approved, means that pridopidine could be available to HD patients as early as H2 2025

NAARDEN, Netherlands & WALTHAM, Mass.--(BUSINESS WIRE)-- **Prilenia Therapeutics B.V.** , a clinical stage biotechnology company focused on the urgent mission to develop novel therapeutics to slow the progression of neurodegenerative diseases and neurodevelopmental disorders, announces the acceptance of its European Marketing Authorisation Application (MAA) for pridopidine (45 mg orally twice daily) for the treatment of adults with Huntington's disease (HD) by the European Medicines Agency (EMA).

Pridopidine is a highly selective and potent sigma-1 receptor (S1R) agonist with an established safety profile. If approved, pridopidine could be the first treatment for Huntington's disease with the ability to impact progression. The MAA is based on the totality of evidence for safety and efficacy from pridopidine's extensive development program.

"HD is a genetic, rare, fatal neurodegenerative disease that remains without any approved therapeutic options capable of impacting the progression of the disease. All we have to give patients right now is a small handful of options that may offer some degree of symptom control for HD-related chorea and behavioral complications," said Dr. Ralf Reilmann, Board Certified Neurologist and Founding Director of the George-Huntington-Institute in Muenster, Germany . "Patients deserve better than to slowly and inexorably decline from this devastating disease, and this could be the biggest advance in therapy in years. Pridopidine could, for the first time, provide an option that may slow down decline in several functionally relevant disease domains and thus potentially offer patients and their families an extension to the quality time they have together. Since its safety profile appears favorable and it is taken orally, pridopidine can be easily made available to patients . "

"We have studied pridopidine extensively and have a clear understanding of its efficacy and safety. Pridopidine has delivered consistent efficacy benefits across multiple key measures of HD and has demonstrated a placebo-like safety profile in a large safety database," said Dr. Michael R. Hayden, CEO of Prilenia . "We have submitted a compelling suite of evidence and pridopidine presents the opportunity for a much-needed paradigm shift in HD therapy."

"People with HD are acutely aware of their need for new and better treatment options, especially those that can slow down decline," said Astri Arnesen, President of the European Huntington's Association . "Complex and rare diseases, like HD, are highly challenging and require forward-thinking, and we applaud the progress regulators are making in trying to support the urgent needs of people with HD. If we can come out of the other end of this process with a new therapeutic approach, offering the potential to slow down disease progression, we will have taken a huge step forward for the whole community."

MAA review typically takes 12-14 months but can take longer. In parallel, Prilenia continues its dialogue with the FDA on a potential path forward for pridopidine in the U.S. The Company will consider regulatory submissions for additional countries and regions following the regulatory review process in Europe.

About Pridopidine

Pridopidine (45 mg twice daily) is an oral, highly selective and potent investigational S1R agonist that has exhibited a safety and tolerability profile similar to placebo in clinical studies to date. The current safety dataset includes

approximately 1,700 patients who have been on pridopidine for up to seven years. The S1R protein is highly expressed in the brain and spinal cord, regulating several key processes that are commonly impaired in HD and other neurodegenerative diseases. Activation of the S1R by pridopidine stimulates multiple cellular protective pathways, including enhancing autophagy, axonal transport, mitochondrial energy production and respiration, and restores calcium homeostasis. These effects are essential to neuronal function and survival, and lead to neuroprotective effects.

Prilenia holds Orphan Drug designation for pridopidine in HD and ALS in the U.S. and EU. In addition, pridopidine has received Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of HD.

About Huntington's disease

Huntington's disease (HD) is a rare inherited (genetic) neurodegenerative disorder caused by a mutation in the huntingtin gene. Each child of a parent with HD has a 50 percent chance of developing the disease. HD causes neurons in the brain to degenerate and lose their ability to communicate with each other, resulting in functional, motor, cognitive and behavioral symptoms. HD affects about 100,000 people around the world with an additional 300,000 people at risk of developing HD. It is usually diagnosed between the ages of 30 and 50, although HD can also occur at any age, including in children and young adults (known as juvenile onset HD or JHD). The disease progresses slowly over 15 to 20 years, with patients slowly losing their ability to work, communicate, manage day to day life and take care of themselves. Currently, there is no treatment to address the progression of HD.

About Prilenia

Prilenia is a clinical stage biotechnology company founded in 2018 focused on the urgent mission to develop novel therapeutics to slow the progression of neurodegenerative diseases and neurodevelopmental disorders. The initial focus of the company has been on HD and ALS.

Prilenia is backed by a group of respected investors including: Forbion, Morningside, Sands Capital, SV Health Investors, Sectoral Asset Management, Talisman, Amplitude Ventures and the ALS Investment Fund. The Company is based in the Netherlands, Israel and Massachusetts in the U.S.

For more information, visit **www.prilenia.com** and follow us on **LinkedIn** or **X (Twitter)** .

For a copy of this release, visit Prilenia's website at **www.prilenia.com** .

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Source: Prilenia Therapeutics B.V.