



NEWS RELEASE

Prilenia and Ferrer Announce Authorization for EU Initiation of Confirmatory PRECISE-HD Study of Pridopidine in Huntington's Disease

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Recruitment is expected to start this month, rolling out to upwards of 31 sites across nine EU countries, and joining the ongoing enrollment in the US and UK, with Canada set to follow

Prilenia and Ferrer will share new data analyses and clinical trial updates at the European Huntington's Disease Network (EHDN) Clinical Research Congress

NAARDEN, Netherlands & WALTHAM, Mass. & BARCELONA, Spain--(BUSINESS WIRE)-- **Prilenia Therapeutics B.V.** and **Ferrerⁱ** today announced that the confirmatory Phase 3 PRECISE-HD study of investigational pridopidine in Huntington's disease (HD) has received authorization to begin in participating EU Member States (clinicaltrialsregister.eu **2026-526093-16-00**, clinicaltrials.gov **NCT07609108**). Recruitment in the EU is expected to commence this month, joining currently recruiting sites in the US and UK, with Canada to follow.

Designed to evaluate the efficacy and safety of pridopidine (administered as an oral capsule twice a day), and to generate data for regulatory evaluation, the global, approximately 400-participant, randomized, double-blind, placebo-controlled PRECISE-HD study will assess the clinical effect of the investigational treatment on disease progression, functional capacity, motor function, cognition, speech and quality of life.

"The initiation of PRECISE-HD in Europe marks a milestone for the Huntington's disease research community. This

confirmatory Phase 3 study has been designed to build on learnings from previous research and to rigorously evaluate the efficacy and safety of pridopidine in people living with HD. As investigators, we look forward to working with participating centers and the HD community to generate robust evidence that can help us better understand the potential role of the study treatment in HD,” said **Dr. Ralf Reilmann, Principal Investigator and member of the PRECISE-HD Steering Committee.**

“For people living with Huntington’s disease and their families, every step toward a better understanding of the disease and potential treatment options matters. We welcome the involvement of European centers in PRECISE-HD and the continued focus on outcomes that reflect the realities and priorities of people living with HD and their families,” said **Astri Arnesen, President of the European Huntington Association.**

EHDN 2026 Clinical Research Congress

Prilenia and Ferrer will participate at the European Huntington's Disease Network (EHDN) Clinical Research Congress 2026, taking place October 22–24, 2026, in Kraków, Poland, with Prilenia’s Chief Executive Officer, Dr. Michael R. Hayden, giving an oral presentation on clinical trial design and determination of clinical meaningfulness, in addition to four poster presentations, describing clinically meaningful change in early manifest HD, placebo response in the PROOF-HD clinical trial, and the designs of the PREVAiLS and PRECISE-HD studies of pridopidine in ALS and HD respectively.

[This press release is intended for informational purposes only. Pridopidine is an investigational medicine and is not approved for commercial use by any regulatory authority. Its safety and efficacy have not been established. Information contained herein does not constitute medical advice. Patients should consult their healthcare provider for guidance regarding diagnosis or treatment options. Local regulations may vary; this release is not intended to promote or advertise any product.]

About HD

Huntington’s disease (HD) is a rare, inherited, autosomal dominant, neurodegenerative disease that results in functional, motor, cognitive and behavioral symptoms, and ultimately leads to death. HD is caused by a mutation in the huntingtin (HTT) geneⁱⁱ, and each child of a parent with HD has a 50 percent chance of developing the diseaseⁱⁱⁱ.

Across the world an estimated 100,000 people have HD^{iv}, with an additional 300,000 people at risk of developing HD^{v,vi}. It is usually diagnosed between the ages of 35 and 55^{vii,viii}, although HD can occur at any age, including in children and young adults (known as juvenile onset HD or JHD). The disease progresses slowly over 10 to 30^{ix} years, with patients slowly losing their ability to work, communicate, manage day-to-day life and take care of themselves. This increasing disability leads to full reliance on a caregiver and, ultimately, death.

The only currently available treatments for HD focus on symptomatic relief and palliative care, with no approved therapies shown to impact measures of overall disease progression.

About pridopidine

Pridopidine is an investigational highly selective, oral sigma-1 receptor (S1R) agonist. S1R has been shown to play a role in stimulating multiple neuroprotective pathways impaired in neurodegenerative diseases, such as Huntington's disease (HD) and amyotrophic lateral sclerosis (ALS)^x.

In clinical studies to date, pridopidine (taken as an oral capsule twice a day) has shown a generally favorable safety and tolerability profile, with data from more than 1,600 people (mostly from HD studies), some of whom have received active treatment for up to seven years^{xi}.

Pridopidine is currently in late-stage clinical development for HD and ALS. It has Orphan Drug Designation in HD and ALS in the US and EU, and FDA Fast Track designation in the US for the treatment of HD. These designations do not imply that pridopidine has been approved or that safety and efficacy have been established.

About the PRECISE-HD Study

PRECISE-HD (Pridopidine Phase 3 Study to Establish Clinical Impact and Safety in Huntington's Disease) is a confirmatory, global, 400-participant, randomized, double-blind, placebo-controlled study designed to further evaluate the efficacy and safety of pridopidine, an investigational medicinal product, in people living with Huntington's disease (HD), from early to mid-stage disease (TFC 7-13).

Focused on generating data to further support regulatory evaluation, the study will assess the clinical effect of pridopidine on disease progression, functional capacity, motor function, cognition, speech and quality of life. It incorporates learnings from prior research, advice and input from the HD patient and research community, and regulatory authorities.

PRECISE-HD comprises two consecutive stages: a 52-week placebo-controlled stage, with participants randomized to receive either pridopidine or placebo on a 1:1 basis, followed by a 104-week open-label extension stage in which all eligible participants will receive pridopidine. The primary endpoint is the change from baseline to Week 52 in the combined Unified Huntington's Disease Rating Scale (cUHDRS) score.

PRECISE-HD will be undertaken at up to 75 sites globally, including sites in the United States, European Union, United Kingdom and Canada. Further details are available at clinicaltrials.gov (**NCT07609108**) and

clinicaltrialsregister.eu (2026-526093-16-00).

About Prilenia

Prilenia is a private biopharmaceutical company driven by an unwavering commitment to scientific excellence and accelerating progress for people affected by Huntington's disease (HD), amyotrophic lateral sclerosis (ALS) and other neurodegenerative disorders. Our mission is simple but urgent: to develop and provide sustainable access to transformative medicines for people affected by devastating neurodegenerative diseases.

Prilenia is incorporated in the Netherlands and backed by leading life sciences investors.

Prilenia and Ferrer are partners in co-development and commercialisation of pridopidine.

For more information, please visit www.prilenia.com, and connect with us on [LinkedIn](#), [X](#) or [Instagram](#).

About Ferrer

At Ferrer, we use business to fight for social justice. We have long been a company that wants to do things differently; instead of maximizing shareholder returns, we reinvest much of our profit in initiatives that give back to society. Back where it belongs. We go beyond compliance and are guided by the highest standards of sustainability, ethics and integrity. As such, since 2022, we are a B Corp.

Founded in Barcelona in 1959, Ferrer offers transformative solutions for life-threatening diseases in more than one hundred countries. In line with our purpose, we have an increasing focus on pulmonary vascular and interstitial lung diseases and rare neurological disorders. Our 1,800-strong team is driven by a clear conviction: our business is not an end in itself, but a way to change lives.

We are Ferrer. Ferrer for good. www.ferrer.com

ⁱ In April 2025, Prilenia and Ferrer signed a commercialization and co-development agreement for pridopidine. <https://news.prilenia.com/press-releases/press-release-details/2025/Prilenia-Enters-into-a-Collaboration-and-License-Agreement-with-Ferrer-for-the-Commercialization-and-Co-Development-of-Pridopidine-in-Europe-and-Other-Select-Markets/default.aspx>

ⁱⁱ Eddings CR, Arbez N, Akimov S, Geva M, Hayden MR, Ross CA. Pridopidine protects neurons from mutant-huntingtin toxicity via the sigma-1 receptor. *Neurobiol Dis.* 2019 Sep;129:118-129. doi: 10.1016/j.nbd.2019.05.009. Epub 2019 May 17. PMID: 31108174; PMCID: PMC6996243.

ⁱⁱⁱ Myers RH. Huntington's disease genetics. *NeuroRx.* 2004 Apr;1(2):255-62. doi: 10.1602/neurorx.1.2.255. PMID:

15717026; PMCID: PMC534940.)

^{iv} Pringsheim T, Wiltshire K, Day L, Dykeman J, Steeves T, Jette N. The incidence and prevalence of Huntington's disease: a systematic review and meta-analysis. *Mov Disord*. 2012 Aug;27(9):1083-91. doi: 10.1002/mds.25075. Epub 2012 Jun 12. PMID: 22692795.

^v Medina et al., Prevalence and Incidence of Huntington's Disease: An Updated Systematic Review and Meta-Analysis. *Mov Disord*. 2022 Dec;37(12):2327-2335.

^{vi} Jiang, A., Handley, R. R., Lehnert, K., & Snell, R. G. (2023). From Pathogenesis to Therapeutics: A Review of 150 Years of Huntington's Disease Research. *International Journal of Molecular Sciences*, 24(16), 13021.

<https://doi.org/10.3390/ijms241613021>

^{vii} EHDN. About Huntington's Disease. April 2024. Available at: **<https://ehdn.org/about-hd/>** (accessed April 2025).

^{viii} Petracca M, et al. Clinical and genetic characteristics of late-onset Huntington's disease in a large European cohort. *Eur J Neurol*. 2022;29:1940–51.

^{ix} Mayo Clinic. Huntington's disease. Available at: **<https://www.mayoclinic.org/diseases-conditions/huntingtons-disease/symptoms-causes/syc-20356117>**

^x Lachance V, Bélanger S-M, Hay C, Le Corvec V, Banouvang V, Lapalme M, Tarmoun K, Beaucaire G, Lussier MP, Kourrich S. Overview of Sigma-1R Subcellular Specific Biological Functions and Role in Neuroprotection.

International Journal of Molecular Sciences. 2023; 24(3):1971. **<https://doi.org/10.3390/ijms24031971>**

^{xi} Goldberg YP, Navon-Perry L, Cruz-Herranz A, Chen K, Hecker-Barth G, Spiegel K, Cohen Y, Niethammer M, Tan AM, Schuring H, Geva M, Hayden MR. The Safety Profile of Pridopidine, a Novel Sigma-1 Receptor Agonist for the Treatment of Huntington's Disease. *CNS Drugs*. 2025 May;39(5):485-498. doi: 10.1007/s40263-025-01171-x. Epub 2025 Mar 7. PMID: 40055280; PMCID: PMC11982116.

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