NEWS RELEASE

Prilenia and Ferrer Provide Update on European Regulatory Process for Pridopidine in Huntington's Disease

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NAARDEN, Netherlands & WALTHAM, Mass. & BARCELONA, Spain--(BUSINESS WIRE)-- **Prilenia Therapeutics B.V.** and **Ferrer** today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended the refusal of the marketing authorization for pridopidine's marketing authorization application for Huntington's disease (HD).

We are disappointed, but undeterred in our commitment to bring what we believe is an effective therapy to patients and will explore all options collaboratively with regulators.

Prilenia and Ferrer are focused on bringing pridopidine to people living with HD and amyotrophic lateral sclerosis (ALS) worldwide as quickly as possible. Near-term plans are in place to initiate a potentially registrational global HD study, to provide confirmation of the previously observed pridopidine results, and a pivotal global Phase 3 ALS study, with recruitment for both expected to start as soon as possible.

About pridopidine

Pridopidine (45 mg twice daily) is a potent and selective, orally administered sigma-1 receptor (S1R) agonist which stimulates key neuroprotective mechanisms often impaired in neurodegenerative diseases such as HD and ALS[i].

Pridopidine's extensive development program involved approximately 1,600 people, demonstrating clinically meaningful and sustained benefits in disease progression, cognition, motor ability, and quality of life in patients, with a favorable safety and tolerability profile.

In addition to HD, pridopidine is in late-stage clinical development for ALS, with Prilenia and Ferrer planning to initiate a single, pivotal Phase 3 trial in ALS as early as possible, building on the findings in the population with early and rapid progressing disease from the Phase 2 HEALEY ALS Platform Trial.

Pridopidine has Orphan Drug designation in HD and ALS in the US and EU, and FDA Fast Track designation for the treatment of HD[ii].

Nurzigma® (pridopidine) is a registered trademark of Prilenia.

About Huntington's Disease

Huntington's disease (HD) is a rare, inherited, autosomal dominant, neurodegenerative disease that results in functional, motor, cognitive and behavioral symptoms. HD is caused by a mutation in the huntingtin gene[iii], and each child of a parent with HD has a 50 percent chance of developing the disease.[iv]

HD affects approximately 4.88 out of 100,000 people around the world with an additional 300,000 people at risk of developing HD[v,vi]. It is usually diagnosed between the ages of 30 and 50, 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 15 to 20 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 nothing impacting measures of overall progression.

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 children and adults with neurodegenerative disorders. Our mission is simple but urgent: to develop and provide sustainable access to transformative medicines for people affected by devastating neurodegenerative diseases.

On April 28, 2025, Prilenia entered into a collaboration and license agreement with Ferrer for the commercialization

and co-development of pridopidine in Europe and other select markets, retaining full commercialization and development rights to pridopidine in North America, Japan and Asia Pacific.

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

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

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 in adults and children. 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**

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[iv] Myers RH. Huntington's disease genetics. NeuroRx. 2004 Apr;1(2):255-62. doi: 10.1602/neurorx.1.2.255. PMID: 15717026; PMCID: PMC534940.)

[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**

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