September 3, 2024

Dear Huntington's Disease Community,

We are pleased to let you know that we've filed a European Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for pridopidine as a treatment for Huntington's disease (HD). An MAA is submitted to seek approval to market a medicine in European Union member countries. The MAA review process typically takes 12-14 months. If approved, pridopidine could be prescribed to first HD patients in Europe by the end of 2025.

In the meantime, Prilenia will continue having discussions with the U.S. Food and Drug Administration (FDA) and other regulatory agencies about a potential path forward for pridopidine as a treatment option for those living with HD in the United States, United Kingdom, Canada and other countries.

To learn more about this news and pridopidine, please read our press release here.

We will continue moving with urgency on behalf of the many families affected by HD. We thank you for your commitment and collaboration as we move one step closer to providing a potential treatment option to the HD community.

Sincerely,

Seth Rotberg

Seth Rotberg, Senior Manager of Patient Advocacy and Engagement
On behalf of the team at Prilenia

Pridopidine is an investigational drug that is not approved for the treatment of HD by health authorities.

Q&A

Who can I reach out to for help or if I have any questions?

- *For members of the larger HD community, please reach out to your local HD care center or patient advocacy organization.*
- *You can also reach out to info@prilenia.com.*

What is 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. Activation of the S1R by pridopidine enhances many cellular pathways that keep the brain cells functioning properly and prevent them from dying.*
- *It is an investigational drug, and its safety and efficacy have not been determined by regulatory authorities including FDA or CHMP.*

What is the European Medicines Agency (EMA)?

- *EMA is responsible for the scientific evaluation, supervision, and safety monitoring of medicines. EMA protects public and animal health in EU Member States, as well as the countries of the European Economic Area, by ensuring that all medicines available on the EU market are safe, effective and of high quality.*

What are Prilenia's plans for juvenile onset HD (JHD)?

- *As part of the regulatory process in Europe, companies need to agree on a pediatric investigation plan (PIP) to assess efficacy and safety in pediatric patients from 2-18 years of age. This is a legal requirement in the EU before submitting a Marketing Application. Prilenia has an agreed pediatric investigation plan with the European authorities. We will soon be able to communicate more about the design of the planned clinical development.*

What are the next steps for Prilenia in the United States and Canada?

- *In the US, Prilenia is still having discussions with the FDA to determine next steps.*
- *In Canada, we are planning interactions with the Canadian authorities.*
- *We will also consider submissions for approval in additional countries and regions following the regulatory review process in Europe.*

If the MAA is approved, what happens next?

- *The next step is that pridopidine will be discussed and evaluated at each country's local regulatory authority.*
- *If approved, the earliest pridopidine will be available in Germany is* by the end of 2025. *Other countries require a health technology assessment prior to pricing and*

reimbursement discussions. Those need to be completed prior to allow access to patients in each individual country.

Is there a difference between approval and access to the medicine?

- *Yes, once a medicine gets approved, there are still several steps to make sure patients can get access based on which country they reside in. These steps include a health technology assessment and obtaining reimbursement.*

Is there a way to receive access to pridopidine prior to it being approved?

- We are currently offering PROOF-HD study participants continued access to pridopidine through an expanded access/compassionate use program (EAP/CUP) while it remains an investigational product in clinical development.
- We also have programs in place for access to pridopidine outside of clinical trials. To learn more, please visit https://www.prilenia.com/expanded-access/