FDA Grants Orphan Drug Designation *for the Treatment of Huntington's Disease*

Dear Huntington's Disease Advocacy Community,

We are proud to share that today Sage Therapeutics announced the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) to SAGE-718 for the treatment of Huntington's disease (HD). The ODD is an encouraging regulatory milestone in our development program for HD-related cognitive impairment. There are currently no approved treatments for cognitive impairment associated with HD and the ODD provides continued momentum in our efforts to help people suffering from this disease.

ODD is granted by the FDA Office of Orphan Products Development to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. SAGE-718 previously received Fast Track Designation from the FDA for HD and an ODD for the treatment of HD by the European Medicines Agency.

For complete information, please see the press release.

Clinical studies investigating the safety and efficacy of SAGE-718 across several disease areas are ongoing and we look forward to sharing future updates with stakeholders and the HD community.

SAGE-718 is an investigational drug and has not been approved by a health authority for any use.

Sage is grateful for the role played by study participants, family members, and caregivers in making this research possible. We applaud the Huntington's disease advocacy community for raising awareness of the burdens faced by those with cognitive impairment in HD and your ongoing efforts to give the community a voice in driving progress.

Please be in touch if you have any questions. We look forward to our continued conversation.

With gratitude,

Lesley White, MSW, LICSW
Director, Pipeline Patient Engagement & Advocacy
Sage Therapeutics, Inc.

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