15th January 2021

RE: Letter in support of campaign to approve Omaveloxolone

Ataxia UK is the leading patient organisation supporting those affected with ataxia in the UK. The charity was established over fifty years ago as the Friedreich's ataxia group, and has a membership consisting of people with a range of ataxias including Friedreich's ataxia (FA). Ataxia UK provides support and information to families, and importantly actively engages in research activities by funding projects, facilitating and promoting research to find treatments for this group of rare conditions.

As one of the sites for the MOXIe study was in the UK (at the London Ataxia Centre accredited by Ataxia UK) we have been supporting the dissemination of information about the study to our community and assisted in the recruitment process. There has been much interest in the UK in this trial at the various stages, and in particular, when the topline results were first announced just over a year ago.

We are submitting this letter to give a voice to FA patients and carers in the UK and we are aware that the FDA and the sponsor recognise the importance of this input. FA is a progressive condition with no current approved treatment and consequently the availability of interventions that have the ability to slow progression is urgent. Patients and caregivers provide important insight on the level of risk and uncertainty that they are willing to take, as they live with the condition daily.

Ataxia UK agrees with the Friedreich's Ataxia Research Alliance that Omaveloxolone has the potential to benefit Friedreich's ataxia patients as demonstrated by clinical trials to date, and that these trials could be considered sufficient to allow the drug to be used by neurologists for their patients. Although the MOXIe trial did not include a very large number of participants, it is important to consider the rarity of the condition. We would support the continued data collection in order to determine the long-term effects of the drug in patients, whilst not stopping patients from access to a drug that has shown efficacy in the trials to date. We therefore support the efforts of the Friedreich's Ataxia Research Alliance and the global FA Community Call to Action requesting Reata to submit a New Drug Application (NDA) on an urgent basis and FDA to exercise the flexibility granted by law and contained in FDA guidance in considering approval of an NDA for Omaveloxolone in FA based on the existing evidence from clinical trials.

The FDA's decision has important implications for decisions to be made in the future by regulators outside the US and we are keen for the decision for approval of this drug be also extended to the UK, Europe etc. in due course.

We thank you for your consideration of this important issue.

Yours sincerely,

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Head of Research

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CEO

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