24th April 2025

Dear Ataxia UK,

Following your request for information, I want to inform you that Biogen has withdrawn omaveloxolone from the National Institute for Health and Care Excellence (NICE) appraisal process. This follows the news of the medicine's approval by the Medicines and Healthcare products Regulatory Agency (MHRA) on 23rd April.

As you are aware, omaveloxolone was under evaluation by NICE as a treatment for Friedreich's ataxia (FA) in adults and adolescents aged 16 years and older with NICE, the body that oversees reimbursement in England and Wales. This appraisal was due to be the first for a potential medicine for FA in the UK, where less than 1 in 50,000 people are living with this rare condition.

Our decision to withdraw follows our discussions with NICE during which they indicated that they would not proceed to committee stage when the patient and clinical community would have had the opportunity to highlight the unmet need in FA and the potential of the treatment.

I am aware that this decision is disappointing for people living with or affected by FA. I want to assure you that we remain steadfast in our commitment to identify a solution that enables broad access to omaveloxolone across the UK. To do so we will need NICE, NHS England and the Government to come to the discussion with real intent to make progress.

Finally, I want to thank Ataxia UK and the FA community for the ongoing partnership toward bringing omaveloxolone to those who may benefit from it.

Yours sincerely,

Kylie Bromley BSc(Hons), PhD

General Manager and Managing Director, United Kingdom & Ireland

Biogen